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Category : Drug Industry

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Issue Areas/Comments

GENERAL

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Comments attached in PDF file.

CMS-1501-P-545-Attach-1.PDF



September 15, 2005

Submitted Electronically: <http://www.cms.hhs.gov/regulations/ecomments>

Administrator Mark McClellan
 Centers for Medicare and Medicaid Services
 Department of Health and Human Services
 Hubert H. Humphrey Building
 ROOM 445-G
 200 Independence Avenue, S.W.
 Washington, DC 20201

ATTN: FILE CODE CMS-1501-P

**Re: Medicare Program; Proposed Changes to the Hospital Outpatient
 Prospective Payment System and Calendar Year 2006 Payment Rates;
 Proposed Rule**

Dear Administrator McClellan:

Bracco Diagnostics Inc. (Bracco) offers a full line of diagnostic imaging products including contrast agents, drugs, and radiopharmaceuticals. Bracco provides a select line of quality radiopharmaceuticals that assist in the diagnosis and treatment of disease for Medicare beneficiaries. Bracco's featured product line for nuclear medicine departments includes: Choletec®, the undisputed market leader in hepatobiliary imaging; Iodotope® diagnostic and therapeutic capsules for thyroid diseases, offered in potencies up to 130 mCi with low volatility and the smallest capsule commercially available; MDP-Bracco, an exceptional bone imaging agent; Rubratope®, the only nuclear medicine test available for the diagnosis of pernicious anemia; and CardioGen-82® the only generator-based Positron Emission Tomography (PET) Agent. Our comments and recommendations will focus on three of our products, CardioGen-82®, Choletec® and Rubratope®.

We are writing in response to the Proposed 2006 Hospital Outpatient Prospective Payment System (HOPPS) rule published in the July 25, 2005 (70 Fed. Reg. 42673). Our comments for the 2006 NPRM will focus on two sections as identified by CMS in the proposed rule: **Non-Pass Thoughts for Radiopharmaceuticals** and **Relative Weights - Packaging**.





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I. Non-Pass-Through - Radiopharmaceuticals

CMS Proposes Payment Policy Change For Radiopharmaceuticals

For 2006, CMS proposes significant changes in payment policies for radiopharmaceuticals. CMS intends to implement "a temporary 1-year policy for CY2006 to pay for radiopharmaceutical agents that are separately payable in CY 2006 based on the hospital's charge for each radiopharmaceutical agent adjusted to cost."

Bracco agrees with the implementation in CY2006 of this one-year temporary policy, with the understanding that the CMS intends to use the hospital general cost to charge ratio (CCR) and not a department specific CCR to make this adjustment. We understand medical professional societies and other nuclear medicine stakeholders will conduct studies and analyze this and other radiopharmaceutical payment policy options for 2007. Therefore, we will hold comments on options for the 2007 until this information is available. We do encourage CMS to consider outside data and the unique aspects of diagnostic, therapeutic and PET radiopharmaceuticals when establishing future radiopharmaceutical payment policies.

II. Relative Weights

Myocardial PET Procedures

Bracco is pleased regarding the 2004 CMS claims data and the proposed 2006 national rate \$1,019.50, which support higher payments for Myocardial PET for 2006. Bracco along with other professional societies spent significant time and resources to educate hospitals regarding proper codes and the importance of charges in assisting to establish future payment for Myocardial PET imaging with CardioGen®. We remain cautiously optimistic and believe this educational process has resulted in better claims and cost data to CMS and moving forward. We are hopeful this education process has assisted the hospitals and CMS and we are committed as a company to continue to provide this support in the future.

In 2004 and 2005, Bracco and others commented that HOPPS rates for Myocardial PET were inappropriately low, (2004 \$772.08 and 2005 \$735.77). Additionally, the APC panel agreed and recommended the following at the February 2005 meeting;

The Panel recommends that CMS delete all cardiac PET G codes and use appropriate CPT codes for cardiac PET services (effectively eliminating APC 285) and that CPT codes 78459, 78491, and 78492 be moved to new technology APC 1513.





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Bracco supports payment for myocardial PET procedures at \$1,019.50 or similar for 2006 in APC 0285. We support this with the understanding that should the updated CMS claims data significantly reduce the final published rate in 2006, CMS should consider moving these three myocardial PET procedures into the same new technology PET as Oncology PET procedures, in order to maintain the proposed 2006 rate and appropriate payments for myocardial PET procedures.

Hepatobiliary Agents – Inconsistent Status Indicator Changes within Classes of Radiopharmaceuticals

In this proposed 2006 rule, CMS has changed the status indicator for one radiopharmaceutical in a class of radiopharmaceuticals used for hepatobiliary agents (A9510) from a status indicator "N" to "H" while keeping another similar product bundled. ***We disagree with this type of inequity within the same class of drug.*** We are attaching the Society of Nuclear Medicine procedure guidelines for these procedures, for your information. The SNM guideline identifies two potential radiopharmaceuticals that are used for hepatobiliary imaging, Tc-99m Disofenin and Tc-99m Mebrofenin.

The HCPCS codes, descriptions and CMS mean, median costs are located in table 1 below. We first call your attention to the descriptions of these two HCPCS codes; one product is described *per vial*, while the other is *per mCi*. Both of these products are administered *per dose* and multiple doses can be obtained from that single vial. We believe the confusing HCPCS descriptions are contributing to the inaccurate cost data to CMS and inadvertently triggering a separately paid status indicator for the per vial description (disofenin, Hepatolite®) and a bundled status indicator for the per mCi description (mebrofenin, Choletec®).

We understand the CMS HCPCS committee may change these descriptions for both HCPCS codes, to "per dose" effective 2006. ***We agree with this potential change in HCPCS descriptions and believe this change to per dose will more accurately reflective both products actual administrations to patients and better reflect the actual costs to hospitals.***

In the mean time, CMS should recognize the products are used in similar procedures and CMS should not implement a change in status indicator (with over and under represented hospital costs due to inaccurate HCPCS descriptions) which would clearly inappropriately advantage one radiopharmaceutical over another. Choletec®, is the undisputed market leader, with 90% share in hepatobiliary imaging. We believe CMS does not intend to set payment policy to potentially drive utilization toward one separately paid radiopharmaceutical due to inaccurate data and away from a "bundled" market leader and preferred radiopharmaceutical, Choletec®.





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Similar to the CMS decision regarding the antiemetic drug policy, CMS should not implement policies which will clearly shift medical practice. CMS should implement policy that maintains availability of the preferred or appropriate product to Medicare patients. **Therefore, we strongly recommend that CMS assign the same status indicator to both HCPCS code A9510 and A9513, as they are in the same class of drugs.**

Table 1 Radiopharmaceutical Hepatobiliary Agents

HCPCS	Description	CMS Volume Units/days	CMS Mean Unit Cost‡	CMS Median Unit Cost‡	Payment Status 2005	Proposed Payment Status 2006
A9510	<i>Technetium Tc-99m Disofenin, <u>per vial</u></i> Trade Name: Hepatolite®	8455/8402 = 1.006	\$50.71	\$36.70	N	<u>H</u>
A9513	<i>Technetium Tc-99m Mebrofenin, <u>per millicurie</u></i> Trade Name: Choletec®	76053/30754 = 2.473	\$16.70	\$7.47	N	<u>N</u>

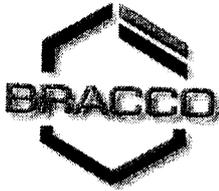
‡ Median Costs for Drugs, Biologicals and Radiopharmaceuticals located at <http://www.cms.hhs.gov/providers/hopps/2006p/1501p.asp>

Nuclear Medicine Schilling Tests

We would like to bring to the CMS attention some payment issues for nuclear medicine schillings tests. These payment issues are arising due to inconsistent availability of components of the three different schillings tests. We would like to start by reviewing the potential components and HCPCS codes available for these nuclear medicine procedures followed by reviewing the CMS claims data. Below in table 2 we list the potential radiopharmaceuticals used with the three schillings test procedure CPT codes listed in table 3. Please note that C1079 is permanently off the market to the best of our knowledge, providers may be using this code in error. CMS proposes to change the status indicator for all three of these radiopharmaceuticals from status "K" separately paid to status "N" bundled.

We believe the change in status resulted from the small number of claims and thus poor data. As far back as 2003 the Rubratope® kit, containing (1) Co-57 cobaltous chloride capsule, (1) cyanocobalamin Co-57 0.5 mCi and oral B-12 intrinsic factor was not available due to the backorder of several of its' components. At present, some components are now available. However, the second part of the test requiring intrinsic factor remains unavailable. We continue to work to make intrinsic factor available for our customers. At present, we can offer no





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projection date as to the availability of intrinsic factor in the future. Currently, providers can order some of the components of a Rubratope® kit as mentioned above and perform a vitamin B-12 absorption study without intrinsic factor CPT 78270. We believe we are the only manufacturer of this type of product in the US.

Table 2 Radiopharmaceutical used with Schillings Tests

HCPCS	Description	CMS Volume‡	Payment Status 2005	Payment Status P 2006
C1079	Supply of Radiopharmaceutical Diagnostic Imaging Agent, Cyanocobalamin Co 57/58, per 0.5 mCi <i>(Product was manufactured by Nycomed Amersham and we believe it is permanently off the market since 2004 or even earlier.)</i>	104/105	K	N
C9013	Supply of Co 57 cobaltous chloride, radiopharmaceutical diagnostic imaging agent	2/2	K	N
Q3012	Supply of Oral Radiopharmaceutical Diagnostic Imaging Agent, Cyanocobalamin Cobalt Co57, per 0.5 mCi	88/88	K	N

Table 3 Schillings Test Nuclear Medicine Procedure Codes

HCPCS	Description	CMS "single frequency"	CMS Mean Unit Cost‡	CMS Median Unit Cost‡	Payment 2005	Proposed 2006
78270	<i>Vitamin B-12 absorption study (eg, Schilling test); without intrinsic factor</i>	33	\$190.03	\$209.30	\$101.46	\$88.87 -12.41%
78271	<i>Vitamin B-12 absorption study (eg, Schilling test); with intrinsic factor</i>	8	\$192.59	\$242.15	\$101.46	\$88.87 -12.41%
78272	<i>Vitamin B-12 absorption studies combined, with and without intrinsic factor</i>	5	\$285.59	\$336.79	\$101.46	\$88.87- 12.41%

‡ Median Costs for Drugs, Biologicals and Radiopharmaceuticals located at <http://www.cms.hhs.gov/providers/hopps/2006p/1501p.asp>





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Bracco is concerned regarding the changing of status indicators from K to N along with a reduced APC procedure rate for the procedures that providers will not offer Medicare patients this important test for pernicious anemia when it is fully available. **We encourage CMS to consider these availability and utilization issues. CMS should consider a freeze of the status indicators to a K status or as other radiopharmaceuticals may transition to H to allow HCPCS codes C9013 and Q3012 to continue to be paid separately in 2006.**

Additionally, we understand that the three procedure CPT codes 78270, 78271 and 78272 are in an APC with other clinically similar procedures. However the higher cost procedures CPT 78271 and 78272 currently have and may continue to have low volume due to the availability of the products and therefore inadvertently pull down the APC category rate due to lack of volume. **We ask CMS to consider a freeze or buffer in 2006 for APC 0389 for these procedures so as not to limit the potential availability of these procedures in the future to Medicare patients.**

Bracco appreciates the opportunity to comment on this proposed rule to CMS. If you have any further questions, please contact me at 609-514-2268.

Respectfully submitted,

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Cc: Kenneth Simon, MD
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Society of Nuclear Medicine Procedure Guideline for Hepatobiliary Scintigraphy

version 3.0, approved June 23, 2001

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I. Purpose

The purpose of this procedure guideline is to assist nuclear medicine practitioners in recommending, performing, interpreting, and reporting the results of hepatobiliary scintigraphy.

II. Background Information and Definitions

Hepatobiliary scintigraphy is a radionuclide diagnostic imaging study that evaluates hepatocellular function and patency of the biliary system by tracing the production and flow of bile from the liver through the biliary system into the small intestine. Sequential images of the liver, biliary tree and gut are obtained. Computer acquisition and analysis as well as pharmacological interventions are frequently employed.

III. Common Indications

- A. Functional assessment of the hepatobiliary system
- B. Integrity of the hepatobiliary tree

These broad categories include, for example:

- Evaluation of suspected acute cholecystitis
- Evaluation of suspected chronic biliary tract disorders
- Evaluation of common bile duct obstruction
- Detection of bile extravasation
- Evaluation of congenital abnormalities of the biliary tree

IV. Procedure

A. Patient Preparation

To permit gallbladder visualization, the patient must have fasted for a minimum of two, and preferably four hours prior to administration of the radiopharmaceutical. If the patient has fasted for longer than 24 hr or is on total parenteral nu-

trition, the gallbladder may not fill with tracer. In these cases the patient may be pretreated with sincalide, see IV.F.1 below.

B. Information Pertinent to Performing the Procedure

The physician should review all available pertinent clinical/laboratory/radiographic information about the patient prior to the study. Additional information specifically related to hepatobiliary scintigraphy includes:

1. History of previous surgeries, especially biliary and gastrointestinal.
2. Time of most recent meal.
3. Current medications, including the time of their most recent administration (with particular attention to opioid compounds).
4. Results of bilirubin and liver enzyme levels.
5. Results of gallbladder or abdominal ultrasound.

C. Precautions

The test should be performed fasting to avoid a false-positive result. Interference by opioids can be minimized by delaying the study for 4 hours after the last dose. In some cases the effect can be reversed with Narcan. Additional details are listed in IV.A. ("Patient Preparation") and IV.K. ("Sources of Error").

D. Radiopharmaceutical

Tc-99m labeled disofenin (DISIDA, 2,6-diisopropylacetanilido iminodiacetic acid) or mebrofenin (BRIDA, bromo-2, 4,6-trimethylacetanilido iminodiacetic acid) is administered intravenously in activities of 50–200 MBq (1.5–5 mCi) for adults; higher dosages may be needed in hyperbilirubinemia, 100–370 MBq (3–10 mCi). Mebrofenin may be selected instead of disofenin in moderate to severe hyperbilirubinemia due to its somewhat higher hepatic extraction. For infants and children the administered activity is 2–7 MBq/kg (0.05–0.2 mCi/kg) with a minimum of 15–20 MBq (0.4–0.5 mCi).

Radiation Dosimetry for Adults

Radiopharmaceuticals	Administered Activity MBq (mCi)	Organ Receiving the Largest Radiation Dose* mGy/MBq (rad/mCi)	Effective Dose* mSv/MBq (rem/mCi)
Tc-99m Disofenin Tc-99m Mebrofenin	50 – 200 i.v. (1.5 – 5.0)	0.11 Gallbladder Wall (0.41)	0.024 (0.089)

* ICRP 53, page 203, normal liver function

E. Image Acquisition

A large field of view gamma camera equipped with a low energy all-purpose or high-resolution collimator is usually used. For a smaller field of view gamma camera a diverging collimator may be needed. Whenever possible, continuous computer acquisition (usually in the anterior view) should be performed (1 frame/min for 30–60 min). Imaging should start at injection and continue serially for 60 min or until activity is seen in both the gallbladder (which confirms patency of the cystic duct) and the small bowel (which confirms patency of the common bile duct). Additional views (e.g., right lateral, left or right anterior oblique) may be obtained as needed to clarify anatomy.

The digital data can be reformatted to 5–15 min images for filming. Cinematic display of the data may reveal additional information not readily apparent on the film.

When acute cholecystitis is suspected and the gallbladder is not seen within 40–60 min, 3–4 hr-delayed images should be obtained, or morphine augmentation (see IV.F.2.) may be employed in

lieu of delayed imaging. Delayed imaging at 18–24 hr may be necessary in some cases (e.g., severely ill patient, severe hepatocellular dysfunction, suspected common bile duct obstruction, suspected biliary atresia).

If the patient is being studied for a biliary leak, 2–4 hr delayed imaging and patient-positioning maneuvers (e.g., decubitus views) may be helpful. Any drainage bags should be included in the field of view if the biliary origin of a leak or fistula is in question.

F. Interventions

A variety of pharmacologic or physiologic interventions may enhance the diagnostic value of the examination. Appropriate precautions should be taken to promptly detect and treat any adverse reactions caused by these interventions.

1. Sincalide pretreatment: Sincalide, a synthetic C-terminal octapeptide of cholecystokinin (CCK), in doses of 0.01–0.02 µg/kg, may be given intravenously, 30–60 min prior to the hepatobiliary tracer injection to minimize the potential for a false-positive study (e.g., in patients who have fasted longer than 24 hr, are

Radiation Dosimetry for Children (5 year old)

Radiopharmaceuticals	Administered Activity MBq (mCi)	Organ Receiving the Largest Radiation Dose* mGy/MBq (rad/mCi)	Effective Dose* mSv/MBq (rem/mCi)
Tc-99m Disofenin Tc-99m Mebrofenin	50 – 200 i.v. (1.5 – 5.0)	0.11 Gallbladder Wall (0.41)	0.024 (0.089)

* ICRP 53, page 203, normal liver function

on parenteral hyperalimentation, or have a severe intercurrent illness). Sincalide should be administered slowly (over a 3–5 min duration) to prevent biliary spasm and abdominal cramps. A slower infusion (30–45 min) may also be used (see IV.F.3.).

2. Morphine Sulfate: When acute cholecystitis is suspected and the gallbladder is not seen by 40–60 min, morphine sulfate, 0.04–0.1 mg/kg, may be administered intravenously over 2–3 min. If the cystic duct is patent, flow of bile into the gallbladder will be facilitated by morphine-induced temporary spasm of the sphincter of Oddi. The intrahepatic biliary tree and common bile duct (CBD) must contain radioactive bile, and tracer activity should be present in the small bowel at the time of morphine injection. A second injection of radiopharmaceutical (booster dose of approximately 1 mCi) may be necessary prior to morphine if the remaining liver/biliary tree activity appears insufficient to permit gallbladder filling. Shielding the bowel activity with lead may also be helpful. Imaging is usually continued for another 30 min following morphine administration but may be extended if desired. Contraindications to the use of morphine include respiratory depression in non-ventilated patients (absolute), morphine allergy (absolute) and acute pancreatitis (relative).
3. Sincalide stimulation: Gallbladder contractility may be evaluated by determining the gallbladder ejection fraction (GBEF) response to sincalide. The study involves an intravenous injection over a minimum of 3 min or a 30–45 min infusion of 0.01–0.02 µg/kg sincalide after the gallbladder is maximally filled with radiopharmaceutical (usually 60 min after the injection) and there is minimal activity in the liver. Computer acquisition (1–2 frames/min) then continues for 30 min. Various protocols can be employed. When performing and interpreting this procedure, the physician must adhere to a specific technique (i.e., total dose of sincalide, dose rate and duration of infusion) and normal values validated for that technique.
4. Fatty meal stimulation: Gallbladder ejection fraction measurement using a fatty meal challenge instead of sincalide has also been described. If visual assessment of gallbladder emptying is sufficient, a fatty snack may be used.
5. Phenobarbital: In jaundiced infants in whom biliary atresia is suspected, pretreatment with phenobarbital, 5 mg/kg/day, may be given

orally in two divided doses daily for a minimum of 3–5 days prior to the hepatobiliary imaging study to enhance the biliary excretion of the radiotracer and increase the specificity of the test. Mebrofenin may be preferred over Disofenin in suspected biliary atresia.

G. Processing

1. Gallbladder ejection fraction (GBEF): Using the immediate pre-sincalide and the post-sincalide data, regions of interest (ROI) are drawn around the gallbladder (taking into account patient motion) and adjacent liver (background) using any standard nuclear medicine software package. The liver background ROI is selected taking care to exclude ductal activity. GBEF is calculated from the gallbladder time-activity curve as:

$$\text{GBEF (\%)} = \frac{(\text{net GB cts}_{\text{max}}) - (\text{net GB cts}_{\text{min}})}{\text{Net GB cts}_{\text{max}}} \times 100$$

2. Hepatocellular function may be assessed by deconvolution analysis from ROI over the liver and heart (hepatic extraction fraction) or by analysis of a heart ROI for tracer clearance from the blood pool.

H. Interpretation Criteria

1. Normal: A normal hepatobiliary scan is characterized by immediate demonstration of hepatic parenchyma, followed sequentially by activity in the intra- and extrahepatic biliary ductal system, gallbladder and upper small bowel. All these structures should be seen within one hour. Gallbladder filling implies a patent cystic duct and excludes acute cholecystitis with a high degree of certainty.
2. Acute cholecystitis: The hallmark of acute cholecystitis (acalculous as well as calculous) is persistent gallbladder non-visualization 30 min post morphine or on the 3–4 hr delayed image. A pericholecystic hepatic band of increased activity (rim sign) is often associated with severe phlegmonous/gangrenous acute cholecystitis, a surgical emergency.
3. Chronic cholecystitis and clinical settings associated with physiologic failure of the gallbladder to fill with radiotracer (e.g., prolonged fasting for >24–48 hr, severely ill or post-operative hospitalized patients) may result in gallbladder non-filling within the first hour, but may be separated from acute cholecystitis using low dose intravenous morphine (see above) or delayed imaging. In chronic cholecystitis the gallbladder will usually be seen within 30 min of morphine administra-

- tion or on 3-4 hr delayed images, while true cystic duct obstruction (acute cholecystitis) will result in persistent gallbladder non-visualization. Appearance of the gallbladder after the bowel has a significant correlation with chronic cholecystitis. In severely ill patients and in those on total parenteral nutrition, frequently the gallbladder will not be seen even after morphine despite a patent cystic duct, and a larger dose of morphine (0.1 mg/kg) may be necessary to decrease the false positive rate of the study.
4. Reduced gallbladder ejection fraction in response to sincalide occurs in calculous and acalculous biliary diseases (i.e., chronic acalculous cholecystitis, cystic duct syndrome, sphincter of Oddi spasm). It may also be associated with various non-biliary diseases and conditions, as well as caused by a variety of medications (e.g., morphine, atropine, calcium channel blockers, octreotide, progesterone, indomethacin, theophylline, benzodiazepines, histamine-2 receptor antagonists).
 5. Common bile duct obstruction: Delayed biliary-to-bowel transit beyond 60 min raises the suspicion for partial common bile duct (CBD) obstruction, although this may be seen as a normal variant in up to 20% of individuals. With high grade CBD obstruction, there is usually prompt liver uptake but no secretion of the radiotracer into biliary ducts. With prolonged obstruction, concomitant hepatic dysfunction may be seen. With partial biliary obstruction, radiotracer fills the biliary system but clears poorly proximal to the obstruction by 60 min or on delayed images at 2-4 hours or with Sincalide. Clearance into the bowel may or may not be seen. Severe hepatocellular dysfunction may also demonstrate delayed biliary-to-bowel transit.
 6. Biliary leak: A bile leak is present when tracer is found in a location other than the liver, gallbladder, bile ducts, bowel or urine. This may be seen more easily using a cinematic display or decubitus positioning (see above).
 7. Biliary atresia: Biliary atresia can be excluded scintigraphically by demonstrating transit of radiotracer into the bowel. Failure of tracer to enter the gut is consistent with biliary atresia, but can also be caused by hepatocellular disease or immature intrahepatic transport mechanisms. Renal or urinary excretion of the tracer (especially in diaper) may be confused with bowel activity and is a potential source of erroneous interpretation.
 8. Duodenogastric bile reflux: During a hepatobiliary scan, activity may reflux from the duodenum into the stomach. If the bile reflux is marked and occurs in a symptomatic patient, it may be abnormal, since it is highly correlated with bile gastritis, a cause of epigastric discomfort.
 9. Post-cholecystectomy sphincter of Oddi dysfunction: Sphincter of Oddi dysfunction has the appearance of partial common bile duct obstruction. Pretreatment with sincalide or morphine may improve the sensitivity for its detection. Various visual, quantitative and semiquantitative scintigraphic parameters of bile clearance have been used in conjunction with image analysis. (e.g., a scoring system, hepatic hilum-to-duodenum transit time, % biliary emptying post-morphine provocation, etc.).
- I. Reporting

Aside from patient demographics, the report should include the following information:

 1. Indication for the study (e.g., suspected acute cholecystitis, suspected common bile duct obstruction, suspected bile leak, etc.).
 2. Procedure
 - a. Radiopharmaceutical and dose administered
 - b. Other medications given and their dosage (e.g., pre-treatment with sincalide, morphine, post-treatment with sincalide)
 - c. Duration of imaging, special or delayed views obtained
 3. Findings

Include the appearance of the liver, the presence and time of tracer appearance in the gallbladder, small bowel, any unusual activity (e.g., bile leak, enterogastric reflux, etc.), any quantitative data generated (e.g., GBEF)
 4. Study limitations, patient reactions to drugs administered
 5. Comparison/correlative imaging data
 6. Impression

This should be concise, as precise as possible, should address the clinical question, provide a differential diagnosis and make recommendations if appropriate.
 7. Any urgent or unexpected findings should be directly communicated to the referring physician and this should be documented.
 - J. Quality Control

None
 - K. Sources of Error
 1. The causes of a *false-positive* study (gallbladder non-visualization in the absence of acute

cholecystitis) include:

- a. Insufficient fasting (<2–4 hr)
 - b. Prolonged fasting (>24–48 hr), especially total parenteral nutrition (despite Sincalide pre-treatment and Morphine augmentation)
 - c. Severe hepatocellular disease
 - d. High grade common bile duct obstruction
 - e. Severe intercurrent illness (despite sincalide pre-treatment and morphine augmentation)
 - f. Pancreatitis (rare)
 - g. Rapid biliary-to-bowel transit (insufficient tracer activity remaining in the liver for delayed imaging)
 - h. Severe chronic cholecystitis
 - i. Previous cholecystectomy
2. The causes of a *false-negative* study (gallbladder visualization in the presence of acute cholecystitis) are rare, but include:
- a. Bowel loop simulating gallbladder (drinking 100–200 ml water may remove the radiopharmaceutical from the duodenum and allow differentiation of gall bladder from bowel).
 - b. Acute acalculous cholecystitis
 - c. The presence of the “dilated cystic duct” sign simulating gallbladder. If this sign is present, morphine should not be given.
 - d. Bile leak due to gallbladder perforation
 - e. Congenital anomalies simulating gallbladder
 - f. Activity in the kidneys simulating gallbladder or small bowel (may be clarified by a lateral image).

V. Issues Requiring Further Clarification

None

VI. Concise Bibliography

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VIII. Disclaimer

The Society of Nuclear Medicine has written and approved guidelines to promote the cost-effective use of high quality nuclear medicine procedures. These generic recommendations cannot be applied to all patients in all practice settings. The guidelines should not be deemed inclusive of all proper procedures or exclusive of other procedures reasonably directed to obtaining the same results. The

spectrum of patients seen in a specialized practice setting may be quite different than the spectrum of patients seen in a more general practice setting. The appropriateness of a procedure will depend in part on the prevalence of disease in the patient population. In addition, the resources available to care for patients may vary greatly from one medical facility to another. For these reasons, guidelines cannot be rigidly applied.

Advances in medicine occur at a rapid rate. The date of a guideline should always be considered in determining its current applicability.

Submitter : Ms. Marilyn Litka-Klein
Organization : Michigan Health & Hospital Association
Category : Health Care Provider/Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Please see the MHA's attached comment letter. Thanks.

CMS-1501-P-546-Attach-1.DOC



MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Advocating for hospitals and the patients they serve.

September 16, 2005

Attachment #546

Centers for Medicare & Medicaid Services
Department for Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1501-P — Medicare Program; Changes to the Outpatient Prospective Payment System and 2006 Rates; Proposed Rule, July 25, 2005 *Federal Register*

Dear Dr. McClellan:

On behalf of its 145 member hospitals, the Michigan Health & Hospital Association welcomes this opportunity to comment to the Centers for Medicare & Medicaid Services regarding the proposed rule to update the Medicare Outpatient Prospective Payment System for calendar year 2006, as published in the July 25, 2005 *Federal Register*.

The adequacy of Medicare payments to cover the cost of services provided is crucial for ensuring the future viability of Michigan's nonprofit hospitals. Based on the latest data available, **59 percent** of Michigan hospitals experienced a negative margin on all Medicare services. This represents a 17 percent increase in the number of hospitals that lose money providing services to Medicare beneficiaries when compared to two years earlier. In addition, the latest data indicates an average margin for Medicare outpatient services of negative 12 percent for Michigan hospitals, or \$137 million, which is very alarming since many hospitals predominantly service outpatients in today's environment, with little inpatient volume. This is also very concerning particularly since Michigan's population is aging and the number of Medicare beneficiaries is projected to increase significantly over the next decade. By 2020, the number of Michigan residents who are 65 and older is expected to comprise 16.6 percent of the state's population.

When all payors are aggregated, Michigan hospitals experienced a negative 3.3 percent patient margin, with **97 hospitals**, or **67 percent**, losing money on patient care services. The proposed changes will further threaten the future viability of hospitals and access to healthcare services for Medicare beneficiaries and other residents of the state of Michigan. **We strongly urge the CMS to incorporate revisions to prevent a further decline in Medicare payment levels.**


SPENCER JOHNSON, PRESIDENT

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HOSPITAL MARKET BASKET INCREASE

(Federal Register pages 42694-42695)

The hospital update is based on a “marketbasket” factor that is intended to reflect the average change in the price of goods and services hospitals purchase to furnish patient care. These price changes must be projected forward to estimate increases for the subsequent year so that an appropriate marketbasket update can be determined in advance of payment. The payment system is prospective, and the update is not retroactively reconciled to reflect actual price increases for the year. Therefore, a reliable projection methodology is vital to ensure equitable payments.

For the hospital inpatient PPS, the FY 2006 inpatient proposed rule included a 3.2 percent update, with the actual increase in the final rule set at 3.7 percent, based upon a change in methodology. **The MHA requests that the CMS revise the marketbasket update included in the final OPPS rule to include a 3.7 percent marketbasket update, consistent with the inpatient final rule.**

COST OUTLIER PAYMENT THRESHOLDS

(Federal Register pages 42701- 42702)

The CMS provides outlier payments for individual services or procedures with extraordinarily high costs compared to the payment rates of the APC group. For the 2005 OPPS, outlier payments are made for services with costs that exceed 1.75 times the APC payment rate and the APC rate plus a \$1,175 fixed-dollar threshold. This dual test was intended to eliminate outlier payments for low-cost services and provide higher outlier payments for more expensive procedures.

Since implementation of the OPPS in August 2000, the CMS has set aside a targeted outlier payment pool of 2.0 percent of total OPPS payments. In the proposed rule, the CMS cited the Medicare Payment Advisory Commission’s (MedPAC) March 2004 report, which suggests Congress should eliminate the outlier policy under the OPPS. The CMS states that, although elimination of outlier payments would require a statutory change, many of the reasons cited by MedPAC justify a reduction in the size of the outlier payment pool.

For 2006, the CMS is proposing to set a projected target for aggregate outlier payments at 1.0 percent of aggregate total payments under the OPPS. In order to ensure that estimated 2006 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under OPPS, the CMS is proposing that the outlier threshold be modified so that outlier payments are made when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a \$1,575 fixed dollar threshold, which is \$400 more than the current threshold. The CMS will continue to pay 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate when the cost of a hospital outpatient service exceeds these thresholds. The proposed change to reduce the outlier pool by 1 percent will be implemented in a budget-neutral manner by increasing the APC conversion factor by 1 percent.

The MHA is concerned about the re-distributional impact of this change, which we believe is inappropriate. In the inpatient final rule, the CMS indicated its charge estimate was too high, and lowered the threshold considerably in the final rule. If the CMS is using the same charge estimates for purposes of the OPPS proposed rule, then the agency should make a similar adjustment to the methodology used to calculate the threshold in the OPPS final rule. In addition, for the past four years, the CMS set aside two percent of total estimated OPPS payments to fund hospital outlier payments. For 2006, the CMS is proposing to set aside only one percent for outlier payments. However, the agency does not publicly release data regarding how much of the established outlier pool was actually spent in prior years in the *Federal Register* or on its website. Due to the significant changes to outlier policies proposed for 2006, the MHA is concerned that Medicare may not actually spend the entire one percent pool. Therefore, **the MHA strongly recommends that in the final rule, the CMS publish data regarding actual outlier payments made in 2004 and prior years, and to report this data in the future.** We also seek further clarification from the CMS regarding how the \$1,575 fixed dollar threshold was calculated. In addition, we **urge the CMS to maintain the outlier threshold at the current level and to maintain the total outlier pool at the current 2.0 of aggregate OPPS payments.**

MULTIPLE DIAGNOSTIC IMAGING PROCEDURES

(Federal Register pages 42748 - 42751)

Currently, hospitals receive a full APC payment for each diagnostic imaging procedure on a claim, regardless of how many procedures are performed using a single imaging modality and whether or not contiguous areas of the body are studied during the same encounter.

For 2006, the CMS is proposing to pay 100 percent for the diagnostic imaging procedure with the highest APC payment rate, and pay only 50-percent for each additional imaging procedure when all the procedures are performed during a single patient encounter and all are within an identified “family” of procedures that are commonly billed on the same day. The CMS identified 11 “families” of imaging procedures by imaging modality and by contiguous body area. The agency is proposing to apply the multiple imaging procedure reduction to individual services described by codes within one Family, not across Families. For example, no reduction would apply to an MRI of the brain (CPT code 70552) in code Family 5, when performed in the same session as an MRI of the spinal canal and contents (CPT code 72142) in code Family 6. The CMS is proposing to make full payment for the procedure with the highest APC payment rate, and payment at 50 percent of the applicable APC payment rate for each additional procedure, when performed in the same session. In developing this policy, the CMS did not examine hospital cost data but relied on Medicare physician fee schedule practice expense data for determining the discount level.

We are very concerned about the impact of this proposal. We agree that the cost of obtaining an additional image, within the same “family” during the same encounter, is somewhat lower than the cost of the initial image. A corresponding reduction in payment might be appropriate under a payment system that uses discrete procedural costing, such as RBRVS. We would argue however, that it is inappropriate to apply these reductions under OPPS. Since the OPPS utilizes aggregate departmental costs for determining the APC payment level, payments already reflect the lower costs of additional images. To apply a further reduction would result in

aggregate payments for this category of services being substantially below aggregate costs. The MHA believes this is contrary to the statute.

The oversight in the proposal stems from the fact that hospitals do not generally reduce their charges for additional images. Within a given “family” the charges are generally a uniform per image charge. Because the charge is the same for both the initial and additional images, the costs allocated to each is the same, reflecting the weighted average costs of doing single and multiple images. When the APC amount for a given family was calculated, even though only single procedure claims were used, the cost to charge ratio (CCR) converts the claim to this weighted average cost, as opposed to the true cost for the initial image.

As an example, let’s assume a CT department does 2,000 “family 2” scans, resulting in a total cost of \$410,000. With a unit charge of \$500 per test, total charges would equate to \$1,000,000 resulting in an overall CCR for the department of 41 percent ($\$410,000/\$1,000,000$). The mean cost per test would be \$205 using this CCR of 41 percent ($\$500 \times .41$). This is the amount that the CMS would use to calculate the base APC payment amount. On claims for two images, the total charges would be \$1,000 and the calculated mean cost would be \$410 ($\$1,000 \times .41$), or twice the cost of one test. At an APC payment rate of \$193, this represents \$386,000 in payments, and a loss of \$24,000 compared to cost.

We can model the proposed impact of the multiple image reduction on a hospital for “family 2 CT scans” using average cost data from the CMS median cost file (the \$205 cost noted above) and using the ratio of multiple to single image claims for “family 2 CT scans” as reported by the CMS in the proposed rule (1.1 million of 2.7 million claims or 41 percent were for multiple images). Using that ratio, a CT department doing 2,000 images would, on average, have about 1,350 encounters/claims. About 800 of the encounters would be for single images. The remaining 550 encounters would involve two or three images for a total of 2,000 images. Using the CMS proposal for 50 percent payment for the second claim, this represents payment of \$314,000, with the same cost of \$410,000, or a loss of \$96.

The problem again lies in the fact that aggregate costs are spread evenly to single and multiple image services by virtue of the hospital charge policies. Total costs do not change, since these reflect a hospital’s actual costs. Total charges would decrease if hospitals reduced their percent charges for multiple procedures. However, the cost-to-charge ratio would increase. This would increase the mean cost for the initial image by 19 percent. Since this is an issue that is universal for hospitals, and the data reflects actual national mean costs and multiple image volumes, it would result in a corresponding increase in the APC payment amount for the initial image. This increase would maintain an aggregate payment to cost ratio that would be consistent with the other APCs.

We strongly recommend that the CMS either continue to pay additional images at the full APC amount or that an adjustment be applied to the median cost data. We believe to implement this proposal would violate section 1833(t)(2)(C) of the BBA 1997, since it would result in aggregate payments well below average hospital costs. It would also make the impacted APCs big losers for hospitals, potentially limiting access for Medicare beneficiaries.

The MHA opposes moving forward with this policy without solid justification, and more substantial, hospital-based data to support the policy. We note that the APC Advisory panel came to the same conclusion. Additional concerns include:

- how this policy would be applied; use of the Medicare physician fee schedule practice expense data for determining the level of the discount;
- the policy lacks detail and justification for the 50 percent discount;
- how the CMS would define the “same session”. In some circumstances a patient may have a procedure performed earlier in the day and subsequently on the same day have another procedure that may fall within the same family and incorrectly be subject to the discount.
- how the CMS would ensure that this change is budget neutral.

PHARMACY OVERHEAD & DRUG HANDLING – PAYMENT RATE ADJUSTMENT
(Federal Register pages 42728 – 42731)

The MMA required MedPAC to submit a report to the HHS Secretary on adjusting the APC rates for specified covered outpatient drugs, taking into account overhead and related expenses, such as pharmacy services and handling costs. The provision required a recommendation as to whether payment adjustment should be made, and as to the methodology for adjusting payment, if an adjustment is recommended. MedPAC concluded that the handling costs for drugs, biologicals, and radiopharmaceuticals delivered in the hospital outpatient setting are significant, as medications administered in outpatient departments generally require greater pharmacy preparation time than those provided in the inpatient setting.

For 2006, the CMS did not propose to create separate handling categories for radiopharmaceutical agents. However, for drugs and biologicals, the CMS proposes to establish three distinct HCPCS C-codes and corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals and instruct hospitals to charge the appropriate pharmacy overhead C-code for overhead costs associated with administration of each separately payable drug and biological based on the code description that best reflects the service required by the hospital in preparing the pharmaceutical product for administering to a patient. Since the CMS does not have separate hospital charge data for pharmacy overhead, for 2006, they propose to pay for these costs based on two percent of the Average Sales Price (ASP). This would result in overall drug payments, including the drug itself and the associated handling payment, of ASP + 8 percent which is a rate that the CMS states is equivalent, on average, to the mean cost for drugs derived from hospital claims data.

The MHA agrees with the MedPAC finding that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. In addition, we believe that the proposed adjustment of the ASP + 2 percent adjustment for drug handling would be inadequate, particularly for certain ASP + drugs that have very high handling costs due to special equipment or procedures related to the drug's toxicity or special compounding or preparation requirements. For 2006, we recommend that the CMS freeze payment rates for drugs whose payment rates are declining significantly from 2005. In the future, the CMS should work with hospital and pharmacy stakeholders to develop an approach to

establish differential add-on payments for drug handling costs to account for a wide variety of drug handling categories.

The MHA is strongly opposed to the CMS' proposal to require hospitals to establish separate charges for pharmacy overhead for separately payable drugs and biologicals and to utilize the three proposed C-codes for charging these overhead costs. This would be extremely burdensome for hospitals to implement. There are many complex issues and administratively burdensome aspects to adopting the CMS proposal for charging drug handling through the use of these new C-codes. These issues include:

- Hospitals will have to evaluate the normal mark-up formula for all pharmacy items and pull out the handling costs for some, but not all, of these drugs and biologicals. That is, hospitals would have to identify and strip out the handling charges for separately payable drugs under Medicare, while the drug handling charges for packaged drugs would remain incorporated within the overall charge for the drug.
- For each separately payable drug, hospitals will need to assign the handling charge to one of the CMS' proposed new drug handling C-codes. These codes are only recognized by and acceptable to Medicare, but not other payers. Hospitals will therefore have to modify their billing systems to separate out the drug handling from the drug charge for Medicare claims but bill them as a single line item for other payers. This may be impossible for hospitals to implement as they have uniform charging policies for all payors. In addition, drug pricing is generated via a pharmacy charging system that is often outside the hospital's normal charging system and may not be able to accommodate the CMS proposed C-codes.
- There is confusion regarding how the handling C-codes would apply when a hospital pharmacy mixes multiple doses of a drug for a patient.
- Many hospitals use the same charge master for inpatient and outpatient services. If the handling charge must be separated out of the drug charge for the outpatient setting, there are questions regarding how the CMS will expect providers to report drug charges in the inpatient setting versus the outpatient setting.

The MHA strongly opposes this expansion of the drug handling C-coding proposal to packaged drugs. This would exponentially increase the coding and administrative burden on hospitals due to the sheer number of drugs that would require special charging practices for Medicare purposes. In addition, we strongly recommend that the CMS does not implement the proposed drug handling C-codes in 2006, but we suggest that the CMS work with stakeholder groups to collect further data and develop alternative and simplified solutions for ensuring that hospitals are appropriately paid for their pharmacy overhead and drug handling costs and the CMS obtains the information that it desires. If the CMS decides to proceed with implementing this burdensome drug-handling C-codes policy, then the MHA strongly suggests that the CMS provide a grace period of no less than 90 days after implementation of the 2006 OPPTS, or until April 1, 2006, to allow hospitals to make necessary system changes, educate pharmacy staff, finance staff and coders on the required use of the drug handling "C" codes.

DEVICE DEPENDENT APCs
(Federal Register page 42716)

We urge the CMS to reevaluate the methodology used to calculate median costs for device dependent APCs. Utilizing the hospitals overall cost-to-charge ratios results in payments less than cost for very expensive impacts. Generally, hospitals incorporate a lower mark-up on high-cost devices than other lower costs supplies. We are particularly concerned about the proposed rates for cardiac defibrillator implants. The average supply cost for the defibrillator, without leads, (APC 107) is \$24,700 and the FY 2005 APC payment is \$17,963. The FY 2006 proposed rule reduces the payment to \$15,362. With leads, the cost increases to \$29,400. The 2005 APC payment is \$24,121, reduced to \$20,629 in 2006. When the non-supply costs are included, the loss for a defibrillator with leads will be almost \$12,000 per case under the 2006 proposed rates.

While the MHA supports the APC Panel recommendation to convert defibrillator claims to single procedure claims, we believe the payment rate must be increased to cover the cost of the device. Otherwise, hospitals will incur a significant loss on every Medicare procedure performed. In order to more accurately determine the APC payment rate, we suggest that the CMS obtain cost information from selected suppliers or contact hospitals with the highest volume.

INPATIENT ONLY PROCEDURES LISTING
(Federal Register pages 42745 – 42746)

The CMS proposes to remove 25 codes from the “inpatient only” listing—a listing that identifies services for which Medicare does not provide payment if they are performed in an outpatient setting and assigns them to clinically appropriate APCs.

The MHA continues to urge that the CMS entirely eliminate the “inpatient only” list, which undermines clinical decision making. Physicians, not hospitals, determine where procedures can be safely performed, as well as whether a patient’s medical condition warrants an inpatient admission. If a physician determines that a service can be safely performed in an outpatient setting, under current rules, the hospital is penalized if that procedure is on the “inpatient only” listing. If the “inpatient only” list is not eliminated for 2006, the CMS should consider establishing an appeals process to address circumstances in which payment for a service provided on an outpatient basis is denied because it is on the “inpatient only” list. This would allow the provider an opportunity to submit documentation to appeal the denial, such as physician’s intent, patient’s clinical condition, and the circumstances that allowed the patient to safely be sent home without an inpatient admission.

INDIRECT MEDICAL EDUCATION ADJUSTMENT

The MHA strongly believes an indirect medical education (IME) adjustment is need to account for the higher costs incurred by teaching hospitals. The financial performance of teaching hospitals under the OPSS has lagged far below other hospitals, as borne out by the CMS’ impact analysis. At the inception of OPSS major teaching hospitals had lower payment-to-cost ratios than other hospitals and the gap has widened each year. From 2000 to 2006, based on

annual CMS impact analysis, the cumulative increase in major teaching hospital payment rates has been 18 percent, compared to 32 percent for minor teaching hospitals and 30 percent for non-teaching hospitals.

In direct response to a comment in the interim final rule published Nov. 13, 2000 (65 FR 67818) addressing the OPPS impact on teaching hospitals, the CMS stated:

“We will perform further comprehensive analyses of cost and payment differences between different classes of hospitals as soon as there is a sufficient amount of claims data submitted under the prospective payment systems. We will use data from the initial years of the PPS to conduct regression and simulation analyses... These analyses will be used to consider and possibly propose adjustments in the system, particularly beginning in 2004 when the transitional corridor provision expires.”

With the adoption of an IME adjustment in the inpatient rehabilitation facility PPS for FY 2006, every Medicare PPS except the OPPS has an IME adjustment. We believe that the same factors that support an IME adjustment in the inpatient systems exists in the hospital outpatient environment as well:

- Significant and demonstrable cost differences for the major teaching hospital class.
- More complex patient populations whose complexity is not adequately measured by the payment groups.
- Inherent inefficiencies associated with graduate medical education, as residents spend a great deal of their training in outpatient and ancillary areas.

We recall that when the CMS analyzed the impact of teaching programs prior to the implementation of the OPPS, the findings were less persuasive than they have been in the inpatient settings. One issue may have been that the CMS attempted to apply a resident-to-bed ratio to outpatient services. There should be more effective ways to relate the size of a hospital's teaching program to the volume of outpatient services provided, such as an outpatient equivalent-discharge statistic. We recommend that the CMS evaluate different ways to construct a teaching variable that is relevant to the outpatient setting and produces a statistically valid adjustment.

The MHA urges the CMS to address the inequities faced by teaching hospitals, and develop an IME adjustment as soon as possible.

APC RELATIVE WEIGHTS

(Federal Register pages 42680 – 42692)

While the MHA continues to support the use of the most recent claims and cost report data and the inclusion of multi-procedure claims, we request that the CMS provide a public use file that would indicate the impact of each individual proposed methodology change. This would allow health care providers to review the file and determine the specific impact on their own operations while also providing a stronger, more solid basis for helpful comments to the CMS.

PARTIAL HOSPITALIZATION
(*Federal Register pages 42692 – 42694*)

The MHA is concerned that the 15 percent reduction in the per diem payment rate for partial hospitalization services that the CMS proposed for 2006 could have serious negative consequences on the financial viability of partial hospitalization services in hospitals and health care systems which could endanger Medicare beneficiary access to these vital services. This is particularly concerning since these services are already vulnerable, with many programs closing or drastically limiting the number of patients accepted during recent years.

While we recognize the CMS's proposal was made in order to avoid an even more significant reduction in the payment rate for these services, we do not believe that hospitals that offer partial hospitalization services should be penalized for the instability in data reporting that stems from community mental health center (CMHC) based services. Instead, the MHA recommends that in the final rule for 2006, the CMS freeze payment rates for partial hospitalization services at the 2005 levels. This approach will provide for payment stability for these services while protecting beneficiary access and allowing the CMS adequate time to address the instability in the CMHC data.

BLOOD & BLOOD PRODUCTS
(*Federal Register pages 42740 – 42742*)

The CMS proposes to continue making separate payments for blood and blood products through individual APCs for each product. The agency also proposes to establish payment rates for blood and blood products based on their 2004 claims data, utilizing an actual or simulated hospital blood-specific cost-to-charge ratio to convert charges to costs for blood and blood products. For blood and blood products whose 2006 simulated medians would experience a decrease of more than 10 percent in comparison to their 2005 payment medians, the CMS is proposing to limit the decrease in medians to 10 percent.

While this approach results in modest payment increases for many blood and blood product APCs, the payment rate for leukocyte-reduced red blood cells (APC 0954), the most commonly transfused blood product, and rates for certain other blood and blood product APCs will continue to decline under this methodology. According to data from the American Association of Blood Banks, the proposed rate for several of these blood products is significantly below hospitals' actual acquisition cost for blood, most notably for leukocyte-reduced red blood cells, and, with the introduction of additional blood safety measures, it is likely that the cost of these products will continue to increase, making the proposed Medicare payment rate even more inadequate.

To ensure continued beneficiary access to all blood and blood products, the MHA recommends that CMS set 2006 rates at *the greater of*: (1) the simulated medians calculated using the 2004 claims data; or (2) the 2005 APC payment medians for these products.

EVALUATION & MANAGEMENT SERVICES (*Federal Register* page 42740)

The CMS is developing and testing new evaluation and management codes and guidelines and will give a minimum notice of between 6 and 12 months prior to implementation. Adopting a new scheme for assigned levels/codes will be an enormous undertaking for hospitals. **The MHA urges that the CMS provide at least 12 months prior to implementation to prepare for the changes and train staff. Also, for a change of this magnitude, it is important that the CMS ensure that there is adequate opportunity to review and comment on the new guidelines prior to them being finalized.**

OBSERVATION SERVICES (*Federal Register* pages 42742 – 42745)

Currently, Medicare provides a separate observation care payment for patients with congestive heart failure (CHF), chest pain, and asthma. In order to reduce administrative burden on hospitals when attempting to differentiate between packaged and separately payable observation services, the CMS proposes to discontinue current HCPCS codes for observation services (G0244, G0263, and G0264) and instead create two new HCPCS codes to be used by hospitals to report all observation services: GXXXX (Hospital observation services, per hour) and GYYYY (Direct admission of patient for hospital observation care). The CMS would shift determination of whether or not observation services are separately payable under APC 0339 from the hospital billing department to the outpatient PPS claims processing logic contained in the Outpatient Code Editor (OCE) system.

The MHA supports the concept of allowing the OCE logic to determine whether services are separately payable as this will result in a simpler and less burdensome process for ensuring payment for the provision of covered outpatient observation services. The existing G codes for observation services, with their long, complex descriptors that encompassed all variables required for claim processing into a single code, create a significant administrative burden for hospital coders and billers. We are pleased that CMS has found a method to reduce the burden by simplifying the G codes required for observation services and making changes to the OCE logic.

However, we believe that the OCE logic could be used even more efficiently by making the HCPCS code GYYYY (Direct admission of patient for hospital observation care) unnecessary. If the hospital bills the GXXXX code and the claim *does not* include a 45X (emergency department) or 516 (urgent care center) revenue code, then OCE logic should determine that this was a direct admission to observation care. If the hospital bills the GXXXX code with a 45X or 516 revenue code, then it is clear that the patient came in through ED or urgent care center. Once such logic is programmed into the OCE, it would be up to the system to determine whether the observation is a result of a direct admission or not and pay accordingly.

The MHA seeks clarification regarding the reference to inpatient status in the statement on page 42743 in the proposed rule that states “That is, hospitals would bill GXXXX when observation services are provided to any patient admitted to ‘observation

status,' regardless of the patient's status as an *inpatient* [emphasis added] or outpatient."

We are concerned about this statement because if a patient is admitted as an inpatient, the hospital would not report HCPCS codes, but instead would be using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes since ICD-9-CM is the Health Insurance Portability and Accountability Act code set standard for reporting procedures for hospital inpatient reporting.

PAYMENT FOR INTERRUPTED PROCEDURES

(Federal Register pages 42751 – 42753)

The CMS proposes to decrease payment from 100 percent to 50 percent for interrupted procedures coded with modifiers 52 (discontinued procedure, no anesthesia provided) or 74 (procedure discontinued after administration of anesthesia). However, no analysis was conducted to support the reduction.

These modifiers cannot be used for elective cancellations; therefore, the procedures generally have been interrupted due to clinical reasons. In the event that a procedure is interrupted because a patient is having medical problems, costs may actually increase, not decrease, as the team addresses the patient's needs. Detailed claims analysis is needed to determine whether these additional costs could be covered through additional billed services or not. In any event, much of the hospital's costs have already been incurred at this point. For example, the operating room will have been occupied during the start of the procedure and must still be prepared for the next patient. Similarly, sterile supplies will have been opened and will either be disposed of or be reprocessed at additional cost.

The MHA believes that before the CMS establishes reductions in payments for procedures billed using these modifiers, there must be evidence supporting the need for payment reductions and the level of reductions that would be applied.

PHYSICIAN OVERSIGHT OF NON-PHYSICIAN PRACTITIONERS

(Federal Register pages 42753 – 42754)

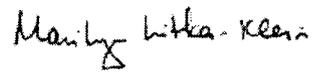
The MHA supports the CMS's proposal to defer to State law regarding the need for physicians to review and sign the medical records for outpatients cared for by non-physician practitioners in critical access hospitals (CAHs). However, we also recommend that the CMS extend the application of this policy to physician review of inpatient records for patients cared for by non-physician practitioners. If state law permits these practitioners to practice independently, the CMS should not require physician oversight in either the outpatient or inpatient setting. We agree that State laws providing independent practice authority generate sufficient control and oversight of these non-physician practitioners and we do not believe that quality of care is reduced by non-physician practitioners.

The MHA also supports the additional flexibility the CMS adds under this proposed policy for those states that do not allow for independent practice of non-physician practitioners – in particular permitting the facility to establish policy regarding the sample size of outpatient records to be reviewed and signed, consistent with current standards of practice.

Sept. 16, 2005, Page 12 of 12
MHA Comments – Medicare 2006 OPPS Proposed Rule

Thank you for your review and consideration of these comments. If you have any questions, please contact me at (517)703-8603 or via email at mklein@mha.org.

Sincerely,

A handwritten signature in cursive script that reads "Marilyn Litka-Klein".

Marilyn Litka-Klein
Senior Director, Health Policy

Submitter : Dr. Richard Goldberg
Organization : Rhode Island Hospital
Category : Physician

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

September 16, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Response on Proposed Changes to
the Hospital Outpatient PPS-CMS-1501-P.

Our agency, Rhode Island Hospital, is an acute care Hospital facility in Providence, Rhode Island. We serve approximately 2,500 patients on an annual basis.

We are requesting the proposed 15% cut for Partial Hospitalization Services be stopped. The proposed rate is not sufficient to cover the costs needed to provide our intensive programs. We strongly support the position of the Association of Ambulatory Behavioral Healthcare in all areas of their proposed considerations.

Please consider not cutting the Partial Hospitalization Program cost so drastically when most medical costs are actually increasing by 3.5% annually. These programs need to be supported by reasonable reimbursement rates that sufficiently cover the costs of providing services to such a needy population.

Thank you for your consideration.

Sincerely,

Richard J. Goldberg, M.D., M.S.
Psychiatrist-in-Chief:
Rhode Island Hospital / The Miriam Hospital
Professor
Departments of Psychiatry and Medicine
Brown Medical School
Email: RJGOLDBERG@lifespan.org
Telephone: (401) 444-5291

Submitter : Dr. Patrick Wheat
Organization : Woodcrest Healthcare, Inc.
Category : Physician

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Our agency, Woodcrest Healthcare, Inc., is a freestanding community mental health center in Louisiana. We serve approximately 400 patients on an annual basis. We employ approximately 12 employees and contract workers in our community. We provide intensive psychiatric programs that are much needed by the patients in our community. I am the medical director and psychiatrist for this facility and feel our services are invaluable to those we serve. We enable individuals to become productive members of society and prevent repeated admissions for inpatient psychiatric care.

We are requesting that the proposed 15% cut for our program be stopped. The proposed payment rate is inadequate to cover the cost of our intensive program. This cut in our funding will result in the closure of our program. Twelve people will be without work and 400 patients without services.

We have a 100% compliance rating and have never been denied payment for any services for any reason by CMS. We are independent from any hospital affiliation and do not share or spread costs with other departments.

Our Community Mental Health Center services rural areas and is not funded by the state as a Medicaid service.

In light of the tragedy Hurricane Katrina wrought on our state, it is unthinkable that such valuable mental health services be in jeopardy of loosing funding. Our facility is currently active through volunteer work in the shelters and accepting patients displaced by the hurricane. At the very least, please consider leaving the rate at the 2005 level pending further review so we may continue to provide services to those in need.

We cannot abandon those in need in the time they need us the most.

Sincerely- Dr. Patrick Wheat MD

Submitter : Dr. Timothy Bateman
Organization : American Society of Nuclear Cardiology
Category : Health Care Professional or Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-549-Attach-1.TXT

CMS-1501-P-549-Attach-2.TXT

September 16, 2005

Administrator Mark McClellan, M.D., PhD
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, ROOM 445- G
200 Independence Avenue, S.W.
Washington, D.C. 20201
File Code: CMS-1501-P

Re: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and Calendar Year 2006 Payment Rates: Proposed Rule

Dear Dr. McClellan:

The American Society of Nuclear Cardiology (ASNC) is pleased to submit these comments in response to the Proposed 2006 Hospital Outpatient Prospective Payment System (HOPPS) rule published in the July 25, 2005 Federal Register. ASNC is a greater than 5,000 member professional medical society which provides a variety of continuing medical education programs related to nuclear cardiology, develops standards and guidelines for training and practice, promotes accreditation and certification in this sub-specialty field, and is the principal advocacy voice for nuclear cardiology.

The Society would first like to thank the Centers for Medicare & Medicaid Services (CMS) for their thoughtful consideration of our HOPPS comments over the past few years - in particular the agency's actions over the past year regarding Adenosine and cardiovascular positron emission tomography diagnostic procedures. We believe that the consensus changes that have occurred through dialogue have played a vital role in supporting quality and maintaining access to the powerful clinical tools of nuclear cardiology. We appreciate the opportunity to submit these new comments as we all work on better refining the maturing HOPPS process.

The primary issues that ASNC will discuss in these comments involve CMS' proposed changes for radiopharmaceutical payment policy and the agency's classification of Dipyrindamole as a bundled service.

Proposed Changes in Payment Policy for Radiopharmaceuticals For next year's hospital outpatient payment system, CMS is proposing to implement "a temporary 1-year policy for CY2006 to pay for radiopharmaceutical agents that are separately payable in CY 2006 based on the hospital's charge for each radiopharmaceutical agent adjusted to cost." ASNC believes that implementation of this one-year temporary policy is reasonable - provided that CMS intends to use the hospital general cost to charge ratio (CCR) and not a department specific CCR to make this adjustment. While ASNC supports the use of the hospital general CCR for 2006 for the determination of most radiopharmaceuticals, we have real concern over use of this policy for highly expensive radiopharmaceuticals (those greater than \$500 in acquisition costs per patent study) due to likely cost compression. ASNC believes that CMS should freeze the CY 2005 payment rates for these radiopharmaceuticals and use that time to gather external data to better verify true invoice acquisition costs and handling fees.

On the issue of radiopharmaceutical handling costs, we are troubled that CMS believes that "hospitals' different purchasing and preparation and handling practices for radiopharmaceuticals would be reflected in their charges, which would be converted to costs using hospital specific cost-to-charge ratios". The agency should not assume that hospitals are automatically incorporating these costs - especially in light of recent data from the Government Accountability Office (GAO) that show CMS median costs for a number of radiopharmaceuticals being less than GAO's findings on hospital purchase prices, which specifically excluded handling fees. In addition, differing payment policies and lack of clear instructions in the different settings (physician offices vs. hospital outpatient) contribute to the uncertainty of where, if anywhere, radiopharmaceutical handling costs are reported by hospitals. CMS needs to explicitly define where handling costs should reside and

then give clear direction to providers.

In terms of the government's efforts to "capture radiopharmaceutical handling costs," through CMS defining specific categories, ASNC believes that the following ones could be utilized:

I: Single Photon Emitting Diagnostic Radiopharmaceutical for a nuclear medicine procedure

A: supplied as a unit dose

B: compounded on-site

II: Radiopharmaceutical for a Therapeutic nuclear medicine procedure

A: supplied as a unit dose

B: compounded on-site

III: Positron Emitting Diagnostic Radiopharmaceutical for a nuclear medicine procedure

A: supplied as a unit dose

B: compounded on-site

IV: Add-on Handling Costs associated with a Radiopharmaceutical compounded off-site, not included in acquisition costs or handling costs in categories

I-III (use in addition to I-III above).

Appropriate Classification of Dipyridamole (J1245) Currently, nuclear cardiology procedures utilize three major pharmacological stress agents: Adenosine (J0152 & C9223), Dipyridamole (J1245) and Dobutamine (J1250). While Dobutamine is a low cost stress agent that is used under very specific clinical indications, Adenosine or Dipyridamole is administered to the vast majority of cardiovascular patients undergoing pharmacological stress. To date, both Adenosine and Dipyridamole are classified with a K status indicator and are therefore paid for separately outside of the procedure APC.

ASNC is concerned over the agency's decision to bundle Dipyridamole into the procedure in 2006, when the reported median cost is just under fifty dollars (\$48.85). While we understand that a threshold (\$50) was set for bundling certain items into the procedure APC, CMS should be receptive to making exceptions in cases where arbitrary payment policy may limit access and create perverse incentives to change medical practices based on factors other than individual clinical patient care. ASNC recommends that CMS maintain a status indicator of K for J1245 Dipyridamole so that patients are able to receive the stress agent that is most clinically effective for them.

Finally, ASNC would like to express its concern over CMS' proposed policy for multiple diagnostic imaging procedures performed on contiguous body parts. While there is some validity to CMS' argument that some resource costs are not incurred twice, we believe that more time should be allowed to study this issue to ascertain whether or not the agency's proposed 50 percent reduction is appropriate.

The Society thanks CMS for the opportunity to submit these comments. Should you have any questions, please contact me or Christopher Gallagher, Director of Health Policy, at 301-493-2310 or via email at [HYPERLINK "mailto:gallagher@asnc.org"](mailto:gallagher@asnc.org)

Sincerely,

Timothy Bateman, MD, FACC
Chair, ASNC
Government Relations Committee

Submitter : Dr. George Thibault
Organization : Partners Healthcare and Partners Radiology
Category : Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-550-Attach-1.DOC

Electronic:

September 16, 2005

Mark McClellan M.D., Ph. D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**Re: CMS-1501-P; Medicare Program, Changes to the Hospital Outpatient
Prospective Payment Systems and Calendar Year 2006 Rates**

Dear Dr. McClellan:

Partners Radiology is pleased to comment on the Proposed Rule for Medicare Prospective Payment System for Hospital Outpatient Services, 42 CFR Part 419 and 485, et al., July 25, 2005 Federal Register, on behalf of the radiology departments in the following member institutions:

<u>Institution</u>	<u>Provider Number</u>
Brigham & Women's Hospital	220110
Faulkner Hospital	220119
Massachusetts General Hospital	220071
North Shore Medical Center	220035
Newton-Wellesley Hospital	220101

Mark McClellan MD, PhD, Administrator, CMS
Comments to 2006 Medicare OPPS Proposed Rule

Introduction

Partners Radiology is a part of Partners Healthcare System, Inc. and represents radiology departments residing in our member hospitals. Partners Healthcare System is the largest healthcare organization in Massachusetts, and in fiscal year 2005, we estimate that we will provide radiology services to 30,000 Medicare beneficiaries.

Multiple Diagnostic Imaging Procedures

We strongly oppose the proposed policy to discount multiple imaging procedures provided within the same family outlined in the rule. As mentioned in the comment letters from Partners Healthcare, Inc. and Massachusetts Hospital Association, the payment methodology of the physician payment system should not be applied to hospital payment methodology. The efficiencies achieved by providing multiple procedures are already reflected in hospitals' cost reports, thus effectively reducing the ratio of cost to charge used in CMS' payment calculation. In other words, current Medicare outpatient payments to imaging procedures already reflect the savings due to efficiencies of multiple procedures.

This policy, if implemented, will reduce payment to radiology departments across our member hospitals by 15%, or 2.5 million dollars, and may affect our ability to provide quality service and care to our patient population. While we agree with the APC Panel's recommendation to delay the implementation of this policy until further study, we also believe that the study will confirm that the current cost-based rate setting methodology already accounts for any cost efficiencies derived by providing multiple procedures. Therefore, we believe that any discounting on current payment methodology would be inappropriate and that CMS should withdraw the proposed policy.

On behalf of all radiology departments of Partners Radiology, I thank you for the opportunity to comment on this proposed rule.

Sincerely,

George E. Thibault, MD
Vice President, Clinical Affairs
Partners Healthcare System

G. Scott Gazelle MD. MPH. PhD
Director
Partners Radiology

**Mark McClellan MD, PhD, Administrator, CMS
Comments to 2006 Medicare OPPS Proposed Rule**

Submitter : Dr. Gary Stein
Organization : American Society of Health-System Pharmacists
Category : Health Care Professional or Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1501-P-551-Attach-1.DOC

September 16, 2005



American Society of
Health-System Pharmacists*

7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-652-8278
www.ashp.org

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-1850

**Re: CMS-1501-P: Medicare Program; Proposed Changes to the Hospital
Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates**

To Whom It May Concern:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS's) July, 2005, proposed rule that would revise the Medicare hospital outpatient prospective payment system (HOPPS), particularly the proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system and the proposed payment policies for overhead costs of drugs, biologicals, and radiopharmaceuticals. ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems.

Section V (B) – NonPass-Throughs

ASHP believes that the changes to drug reimbursement proposed by CMS will have a substantial detrimental effect on the ability of hospital outpatient departments to provide the level of patient care needed by Medicare beneficiaries. In fact, many ambulatory clinics will be forced to terminate their services.

ASHP recognizes that CMS is mandated by Section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to base its 2006 payment rate for HOPPS drugs on Average Sales Price (ASP). However, our members tell us that ASP does not adequately reflect a hospital's average acquisition cost. ASHP urges CMS to gather data on the adequacy of ASP reimbursement over the next year and report to Congress if the agency finds that ASP is not an appropriate reimbursement formula.

The MMA mandated the Medicare Payment Advisory Commission (MedPAC) to prepare "a report on adjustment of payment for ambulatory payment classifications for specified

Centers for Medicare & Medicaid Services
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Page 2

covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs.” MedPAC’s report, submitted to Congress in June 2005, noted that these expenses were “not insignificant” and that they “made up 26 percent to 28 percent of pharmacy departments’ direct costs.”

Inexplicably, CMS’s proposed rule does not mention the percentage of pharmacy costs noted by MedPAC. Instead, CMS proposes to pay only “an additional 2 percent of the ASP scaled for budget neutrality to cover the handling costs of these drugs.”

This reimbursement formula is inadequate to cover handling costs of drugs reimbursed under the HOPPS. It appears to our members that CMS is merely attempting to pay as little as possible for needed services. Small hospitals, particularly, may be forced to limit or eliminate the treatment of patients in outpatient settings. The ramifications of instituting this formula will be disastrous. The care settings and safeguards of providing services will change – to the detriment of patients who will not receive treatment by their providers of choice. Reimbursement concerns should never dictate where patients receive their therapy. Inadequate reimbursement to hospital outpatient departments will impact the quality, safety, and level of their services.

ASHP supports the proposal being made by the Association of Community Cancer Centers (ACCC) that CMS consider an allowance of 8% to cover pharmacy handling and overhead expenses in addition to ASP + 6% to cover the drug acquisition cost. CMS must realize, however, that although the finalized reimbursement rates may have the greatest effect on the oncology/hematology outpatient clinics, the additional 8% to cover drug handling costs must be applied to all drugs reimbursed under the HOPPS. Although more adequate than the 2% add-on recommended in the proposed rule, an 8% add-on is significantly less than the 26-28% or more of pharmacy costs found in the MedPAC study and surveys conducted by ACCC and others.

The 8% add-on that ASHP supports should not be considered by CMS to be a permanent solution. The proposed rule states that the agency intends to collect hospital charge data for overhead costs for two years and consider new reimbursement rates for these costs for payment in 2008. ASHP believes that if CMS raises the handling cost reimbursement to the requested 8% of ASP, the agency must still conduct its data analysis to determine if even this rate is adequate.

Another concern that our members have is the inadequate reimbursement under the ASP system for intravenous immune globulin (IVIG). Previously, IVIG was reimbursed in

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Page 3

hospital outpatient departments at 83% of the average wholesale price (AWP). The decision to reimburse IVIG at the ASP rate will result in patients losing access to this therapy in most, if not all, sites of care because products cannot be purchased at reimbursable rates.

Reimbursement for IVIG in physician offices was changed from the AWP rate to the ASP rate in 2005. Testimony at the May 2005 meeting of the HHS Advisory Committee on Blood Safety and Availability, noted that this change in reimbursement rates for IVIG has had a significant impact on both availability of the product and patients' continuity of care. Lowered reimbursement rates have made some providers reluctant to treat patients. Medicare patients not able to receive their IVIG infusions at their physicians' offices have been shifted to hospitals or hospital outpatient departments. Patients who have not been successfully transferred to hospitals are on waiting lists or denied access to this therapy. Similar situations will occur when IVIG reimbursement in hospital outpatient departments is shifted to ASP.

ASHP suggests that CMS retain reimbursement for IVIG at the current reimbursement formula of 83% of AWP for 2 years, during which time CMS, consulting with Congress, manufacturers, distributors, providers, and patient groups, should conduct a study to determine best payment methodology for IVIG with the goal of ensuring access to IVIG and continuity of care in all practice settings.

ASHP appreciates the opportunity to present comments on this important patient care issue. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at gstein@ashp.org

Sincerely,



Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

Submitter : Ms. Cherrill Farnsworth
Organization : NCQDIS
Category : Other Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-552-Attach-1.DOC

September 14, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates [CMS-1501-P]

The National Coalition for Quality Diagnostic Imaging Services (NCQDIS) respectfully submits these comments in response to the proposed rule on the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates as issued by the Centers for Medicare and Medicaid Services ("CMS") in the Federal Register on July 25, 2005.

NCQDIS is comprised of more than 2,400 outpatient imaging centers and departments in the United States. The coalition promotes "best industry practices," strategies for healthcare cost savings and advocates for public and private sector standards for quality and safety in diagnostic imaging services. Advances in diagnostic imaging have led to great strides in patient care: from reducing the need for invasive surgical procedures to early detection of life-threatening diseases. NCQDIS and its members are at the forefront of medical technology, providing physicians and patients with the most state-of-the-art innovations, techniques and procedures available in diagnostic imaging.

We applaud CMS for its commitment to providing Medicare beneficiaries with quality health care; however, we are very concerned that CMS has failed to include improvements to quality for diagnostic imaging services in its proposed rule. We are concerned that CMS has focused on only one aspect of diagnostic imaging services provided to Medicare beneficiaries—specifically, cutting payments for imaging services provided to contiguous body parts. CMS has not addressed the broader quality and utilization issues, which have a more compelling impact on quality of care provided to Medicare beneficiaries and on preserving scarce Medicare trust fund dollars. NCQDIS urges CMS to evaluate these important issues before implementing any policy changes for diagnostic imaging services. NCQDIS respectfully recommends that CMS delay implementation of these proposed payment changes, until CMS fully evaluates all of the quality and utilization issues in diagnostic imaging. NCQDIS submits that CMS should only implement its proposed coding edits/payment changes if these changes are part of a broader, comprehensive reform package that adequately addresses quality of care concerns and the overutilization of diagnostic imaging services within the Medicare program.

Multiple Diagnostic Imaging Procedures

Under the current Outpatient Prospective Payment System (OPPS), hospitals receive full payments for multiple diagnostic imaging procedures conducted in a single day regardless of whether contiguous areas of the body are studied in the same session. CMS has proposed a 50%

reduction in (1) the technical component and (2) the OPPS payment for some second and subsequent imaging procedures performed in the same session.

CMS noted in the proposed rule that codes within particular families of services are often provided during the same session to obtain the clinical information necessary to diagnose and treat a patient. While each procedure by itself utilizes a certain amount of hospital resources, some of those resource costs are not incurred twice when the procedures are performed in the same session. Therefore, the multiple imaging procedure reduction will apply only when more than one service within a family are performed in the same session. CMS proposes to make the full payment for the procedure with the highest APC rate and payment at 50% of the applicable APC rate for every additional procedure performed that session.

NCQDIS supports coding edits only as part of a broader package of reforms to promote appropriate utilization of diagnostic imaging services. In its March 2005 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) recommended that the Secretary improve Medicare's coding edits that detect unbundled and mutually exclusive services and reduce the technical component payment for multiple diagnostic imaging services performed on contiguous body parts on the same day. MedPAC also made several additional recommendations, in addition to updating coding systems, that were designed to further improve the quality of diagnostic imaging services and improve utilization of these procedures. NCQDIS believes that coding edits/payment changes should only be implemented, if CMS also implements the other MedPAC recommendations:

1. The Secretary should use Medicare claims data to measure fee-for-service physicians resource use and share results with physicians confidentially to educate them about how they compare with aggregated peer performance. The Congress should direct the Secretary to perform this function.
2. The Congress should direct the Secretary to set standards for all providers who bill Medicare for performing diagnostic imaging services. The Secretary should select private organizations to administer the standards.
3. The Congress should direct the Secretary to set standards for physicians who bill Medicare for interpreting diagnostic imaging studies. The Secretary should select private organizations to administer the standards.
4. The Secretary should expand the definition of physician ownership in the Ethics in Patient Referrals Act to include interest in an entity that derives a substantial proportion of its revenue from a provider of designated health services.

NCQDIS agrees that additional steps must be taken to ensure that Medicare beneficiaries have access to the best quality care provided by the best-trained specialists. Reducing reimbursements for scans of contiguous body parts does not address these broader issues of quality and utilization of diagnostic imaging services in Medicare—these problems will still exist even if CMS implements its proposed cuts to payments for contiguous body parts.

The proposed changes to coding/payment should only be considered if other reforms are also implemented. Imaging equipment and facilities operated by providers not specifically trained to provide complex diagnostic imaging services are often sub-optimal with regard to equipment quality, technicians operating the equipment, the quality of images produced, and ultimately interpretation of these diagnostic images. Appropriate training is a particularly important, as an unbiased interpretation of an image by a physician trained to interpret all areas of the body is the best way to prevent misdiagnosis. In addition, the use of aging equipment and images taken by improperly trained technicians inevitably produces a low-quality image that even the best-trained physician will have trouble interpreting.

NCQDIS recommends implementation of a comprehensive reform package that will improve the quality of patient care and protect Medicare trust fund dollars. Implementation of the coding edit system alone does not address the issues of quality and overutilization – Medicare has cut costs for certain services, yet potential quality problems and overutilization still exist. NCQDIS addresses these issues through broad-based reform, paralleling those implemented under the Mammography Quality Standards Act (MQSA), that will do the following:

#1) Redefine Medicare Coverage for Complex Diagnostic Imaging: Institute education and quality standards requirements for Medicare coverage and payment of complex diagnostic imaging services, including MRI, CT, and PET. Current coverage and payment requirements would continue for cardiac ultrasound procedures, plain X-rays, and other non-complex services.

#2) Implement Quality Standards: Require all providers of diagnostic imaging services to meet safety and quality standards, including:

- Education standards
- Standards for staff qualifications and quality monitoring procedures
- Quality standards for radiographic and other images
- Quality standards for facilities, particularly maintenance, safety and routine inspection of equipment to limit use of aging equipment
- Quality procedures and record keeping for non-radiologists analogous to radiologists

#3) Update Coding Systems: Require CMS update billing systems to more accurately reflect changes in technology

In Phase II of NCQDIS' reform proposal, CMS would expand quality standards to additional diagnostic imaging services through a demonstration program after quality standards for complex diagnostic imaging services have been successfully put in place.

Conclusion

Medicare patients deserve to receive care from health care providers that are adequately trained to perform imaging services and use well-maintained imaging equipment that meets defined quality standards. The proposed changes in the rule regarding contiguous body parts are only one potential method of managing Medicare resources, and should only be implemented within

CMS -1501-P
Wednesday, September 14, 2005
NCQDIS

the context of larger reform efforts that address diagnostic imaging quality and utilization concerns.

NCQDIS appreciates this opportunity to submit comments to CMS regarding its Proposed Rule on the Hospital Outpatient Prospective Payment System, and we look forward to working with CMS as on this and other issues affecting diagnostic imaging services. If you have any questions about these comments, please feel free to contact me at 281-447-7000.

Sincerely,

A handwritten signature in cursive script, reading "Cherrill Farnsworth".

Cherrill Farnsworth
Chairperson, NCQDIS

Submitter : Mr. Michael O'Neil
Organization : Four Winds Saratoga
Category : Psychiatric Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1501-P-553-Attach-1.DOC

September 16, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Response on Proposed Changes to the Hospital Outpatient
PPS-CMS-1501-P.

Four Winds Saratoga is a freestanding private psychiatric hospital and is a long standing provider of Partial Hospitalization services. This program provides an essential service to the upstate New York Region. During the year 2004, we served 497 clients. For 2005 we are expecting to have served over 500 clients. The continued existence of this program will be threatened if our facility must absorb the amount of revenue reduction currently proposed.

We are requesting that the proposed 15% cut for Partial Hospitalization Services be reconsidered. The proposed rate is not sufficient to cover the costs needed to provide our intensive programs. We strongly support the position of the Association of Ambulatory Behavioral Healthcare in all areas of their proposed considerations.

Please consider not cutting the Partial Hospitalization Program reimbursement rate so drastically when most medical costs are actually increasing by 3.5% annually. These programs need to be supported by reasonable reimbursement rates that sufficiently cover the costs of providing services to such an at risk population.

Thank you for your consideration.

Sincerely,

Michael F. O'Neil, M.S.P.S.
Administrator

Submitter : Ms. Erin Mass

Date: 09/16/2005

Organization : The Nebraska Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-554-Attach-1.DOC

substantial drop in the cost as a percentage of Medicare revenue to 18%. While we are willing to absorb some loss, the potential \$720,000 at stake is excessive. The reduction in reimbursement would make it impractical for us to acquire this technology.

We also question the proposed APC under which this technology will be grouped. Based on the sizeable decrease in reimbursement it seems as though APC 430 may not be suitable. The possibility exists that the claims data used in CMS's analysis may be invalid or APC 430 is not clinically appropriate. Although EEG's are used for similar purposes, these procedures and their results are vastly different. These potential concerns should be considered and evaluated before making a final determination.

In summary, The Nebraska Medical Center disagrees with the proposal to move CPT codes 95965, 95966 and 95967 out of New Technology to APC 430.

Outlier Payments

CMS has proposed to set the CY 2006 target for outlier payments at 1.0%. Additionally, an increase in the fixed dollar threshold has been proposed to help CMS achieve the 1.0% target. The Nebraska Medical Center suggests CMS consider utilizing an 80% payment versus the current 50%. This would mirror the inpatient payment methodology for outliers and improve the adequacy of payments under OPSS.

I would like to take this opportunity to thank CMS for allowing The Nebraska Medical Center to comment on these very important issues. If you should have any additional questions or need additional information, please feel free to contact me at (402) 559-5289 or EMass@nebraskamed.com.

Sincerely,

Erin Mass
Reimbursement Manager
The Nebraska Medical Center

Submitter : Mr. Steve Harwell
Organization : Healthcare Association of New York State
Category : Health Care Provider/Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Attached please find HANYS' comments.

CMS-1501-P-555-Attach-1.DOC



Healthcare Association
of New York State

September 16, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1500-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1501-P, Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and Calendar Year 2006 Rates; Proposed Rule

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Dear Dr. McClellan:

The Healthcare Association of New York State (HANYs), on behalf of our more than 550 hospitals, nursing homes, home health agencies, and other health care providers, welcomes the opportunity to comment on the proposed rule related to the Medicare Outpatient Prospective Payment System (OPPS).

OUTLIER PAYMENTS

Outlier payments are made for individual services or procedures with extraordinarily high costs compared to the payment rates for their Ambulatory Payment Classification (APC) group. For the 2005 OPPS, the Centers for Medicare and Medicaid Services (CMS) revised the outlier policy to include a fixed dollar threshold. The addition of the fixed dollar threshold created a dual test intended to eliminate outlier payments for low-cost services and provide higher outlier payments for more expensive procedures. For 2006, CMS proposes to significantly increase the fixed dollar threshold and to reduce the target for aggregate outlier payments from 2% of total OPPS payments in 2005 to 1%.

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In 2005, CMS made a significant change to the outlier policy by adding the fixed dollar threshold. HANYs supports the continued need for adequate outlier payments in all prospective payment systems, and we supported the 2005 policy change that better targets OPPS outlier payments to unusually high cost services. However, we are concerned that CMS is proposing to reduce outlier payments in 2006 before there has been even one year of experience with the fixed dollar threshold and without the data necessary to analyze the effects of the 2005 policy change. HANYs urges CMS to continue the 2% target for outlier payments until there are data available to analyze actual outlier payment experience under the fixed threshold policy.

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In addition, CMS has not released information on actual outlier payments in prior years. Without knowing if the current outlier policy is generating outlier payments that are reasonable compared to the target, it is impossible to assess any proposed change in the threshold. We urge CMS to provide information on actual outlier payments when proposing any future change in the threshold or any revisions to the outlier policy.

Mark McClellan, M.D., Ph.D.
September 16, 2005
Page 2

MULTIPLE DIAGNOSTIC IMAGING PROCEDURES

CMS has proposed to reduce OPPS payments for multiple diagnostic imaging procedures by 50% for some second and subsequent imaging procedures performed in the same session. HANYS and the American Hospital Association (AHA) oppose this provision.

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CMS based this proposal on the physician fee schedule methodology and data rather than hospital cost report data. CMS states that the data used are similar to the payments for multiple imaging procedures performed in the hospital outpatient department. HANYS disagrees that the physician fee schedule is an adequate proxy to use for determining outpatient hospital payments.

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In addition, OPPS rates include costs for doing single and multiple images within a given "family," therefore, adjusting the rate by 50% will underpay single image procedures that are performed. A given "family" APC amount is calculated using a single procedure claim, however, the cost-to-charge ratio (CCR) then converts the claim to the weighted average cost, as opposed to the true cost for a single image procedure. HANYS and AHA are concerned with the methodology CMS chose to use for this provision and the implications it will have on hospitals providing outpatient services for multiple imaging services.

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In the proposed rule, CMS did not provide a detailed analysis to support this decision and HANYS urges CMS not to implement this provision without better justification and hospital-based data to support it.

RURAL HOSPITAL ADJUSTMENT

Hold-harmless payments for small rural hospitals are due to expire on December 31, 2005. CMS was required as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to conduct a study to determine if the cost of providing outpatient care in rural hospitals exceeded that of urban hospitals. CMS' analysis showed that rural Sole Community Hospitals (SCH) demonstrated significantly higher cost per unit than urban hospitals. Therefore, in the proposed rule, CMS is providing an adjustment of 6.6% for SCHs. CMS stated that its analysis showed that other rural hospitals did show some levels of higher cost per unit, however, CMS did not believe it was significant enough to justify an adjustment for other rural hospitals.

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The Medicare Payment Advisory Commission's (MedPAC) 2005 report to Congress said, "MedPAC research indicates that low-volume hospitals have relatively high costs per case because they cannot take advantage of economies of scale to the extent that higher-volume hospitals can (MedPAC 2001). Most low-volume hospitals are rural, and many are isolated." As a result, MedPAC recommended that the hold-harmless payments for rural SCHs and other rural hospitals with 100 or fewer beds be extended through calendar year 2006 under OPPS.

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CMS has indicated that other rural hospitals do not have costs that justify an adjustment to the rate based on the results of the regression analysis in the proposed rule. HANYS is concerned that CMS has not provided sufficient documentation in Table 6 to make this conclusion. In addition, Table 6 does not show results for rural hospitals with 100 or fewer beds. Based on the MedPAC analysis, there is good reason to expect that costs for these facilities would be significantly higher.

Mark McClellan, M.D., Ph.D.
September 16, 2005
Page 3

HANYS supports the 6.6% adjustment for rural SCHs; however, we urge CMS to provide more details on the analysis for rural hospitals other than SCHs including separate results for rural hospitals with 100 or fewer beds. In addition, CMS should provide an adjustment in 2006 for these facilities if justified by the analysis.

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INTERRUPTED PROCEDURES

CMS has proposed to decrease payment by 50% for interrupted procedures coded with modifier 52 (discontinued procedure, no anesthesia provided) and possibly reducing modifier 74 (procedure discontinued after administration of anesthesia) payments as well. HANYS is concerned that CMS has not provided any analysis to support this reduction.

The APC Panel recommended that modifier 52 and 74 continue to be paid at 100% of the APC payment. HANYS supports that recommendation. Interrupted procedures require patient preparation time, operating room use, and recovery room care, which all have costs associated with them. In addition, these procedures are often interrupted due to clinical reasons rather than elective cancellations. CMS has failed to provide an adequate reduction in payment for these interrupted procedures. Therefore, we urge CMS to develop an analysis that shows these additional costs that may be incurred and how they would be covered.

HANYS and AHA believe that CMS should provide an analysis to support this provision before instituting any payment reductions for modifiers 52 or 74.

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CONVERSION FACTOR

HANYS joins AHA in assuming that CMS will follow the practice it has used in previous years of utilizing the same marketbasket update published in the final inpatient PPS final rule for the OPSS.

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In our comments to CMS regarding the Inpatient PPS proposed rule, HANYS noted that recent year marketbasket projections have been consistently and materially lower than the actual increase in costs and urged CMS to review the methodology that was used to determine the projected marketbasket. In the final Inpatient PPS rule for FFY 2006, CMS revised the methodology used for projection and thereby increased the projected marketbasket by 0.5%. HANYS assumes that this change will be incorporated in the final outpatient rule.

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NON PASS-THROUGHS—SPECIFIED COVERED OUTPATIENT DRUGS

The MMA established a class of drugs called "specified covered outpatient drugs." For calendar years (CYs) 2004 and 2005, the MMA required that payment for these drugs be based on a reference average wholesale price (AWP), increasing rates for these drugs. For 2006, the MMA requires that payment for specified covered outpatient drugs be equal to the average acquisition cost. CMS analyzed three different data sources to determine "average" acquisition cost: Government Accountability Office, mean purchase price survey data, fourth quarter Average Sale Price (ASP) data, and mean costs from CY 2004 claims data. CMS is proposing to pay ASP+6% for separately payable drugs and biologicals in CY 2006, stating that this is its best estimate of average acquisition costs.

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Mark McClellan, M.D., Ph.D.
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As published in the proposed rule, CMS estimates that the expiration of additional payments for drugs provided in CY 2005 will reduce overall OPSS payments by 2.3%. Although the reduction to overall payments is 2.3%, a number of specified covered outpatient drugs are decreasing at a rate of between 40% and 90% from 2005 to 2006. This reduction has the greatest negative impact on the 2006 OPSS and the proposed rule provides no cushion for the transition of payment based on CMS' estimate of average acquisition cost. HANYS joins AHA in its concern that drastic decreases in payment rates could affect patient access. Therefore, we urge CMS to freeze payment rates for specified covered outpatient drugs whose payment rate decreases compared to 2005 or apply some type of limit to the decrease as has been done in other instances throughout the OPSS including for payment rates for blood and device-dependent APCs.

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NON PASS-THROUGHS—ADDITIONAL PAYMENT FOR DRUGS AND BIOLOGICALS TO ACCOUNT FOR PHARMACY OVERHEAD COSTS

The MMA required that MedPAC submit a report to the Health and Human Services (HHS) Secretary on adjusting the APC rates for outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Based on MedPAC's recommendations, CMS is proposing to pay for separately payable drug and biological overhead costs based on a 2% adjustment to the rate.

HANYS agrees with MedPAC findings that pharmacy overhead costs for drugs and biologicals are significant and we support the 2% adjustment for handling costs in 2006. However, HANYS urges CMS to continue to analyze and refine payment for pharmacy overhead costs in the future to ensure that the 2% adjustment provides adequate payment for these services.

CMS further proposes to establish three distinct C-codes for drug handling categories, and instructs hospitals to report charges for overhead costs associated with each administration of each separately payable drug and biological based on the code description that best reflects the service the hospital provides to prepare the product for administration to a patient. CMS would then collect hospital charges for these C-codes for two years and consider basing payment for the corresponding drug handling APCs on the charges reduced to costs in CY 2008, similar to the payment methodology for other procedural APCs.

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HANYS urges CMS to withdraw the proposed requirement for reporting these charges. The establishment and reporting of pharmacy overhead charges will place an extensive administrative burden on providers. In addition, MedPAC notes in its report that "CMS has no control over the level of sophistication that hospitals would use to develop charges for handling costs." According to MedPAC, the advantage to the proposed use of C-codes is that it automatically provides CMS with information about hospital handling costs that could be used to establish rates. However, MedPAC cautions that charge data for pharmacy overhead costs could be low in quality and might not reflect the real handling costs. We believe that this caution is well founded. It would be difficult for hospitals to accurately define and determine the costs for pharmacy overhead. As a result, the charges that are assigned to the overhead C-codes would bear little relationship to actual costs for many hospitals.

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In its recommendation to CMS, MedPAC offered three options for collecting data on pharmacy overhead costs. HANYS urges CMS to review the other options offered by MedPAC. HANYS

Mark McClellan, M.D., Ph.D.
September 16, 2005
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encourages CMS to consider the alternative of conducting a series of microcosting analyses. Using this approach would not only eliminate the administrative burden of reporting C-codes, but would as MedPAC suggests, offer "the most promise for measuring resource use accurately."

BLOOD AND BLOOD PRODUCTS

CMS is proposing to establish payment rates for blood and blood products under the OPPS using 2004 claims data, utilizing actual or simulated hospital blood-specific cost-to-charge ratios. For blood and blood products whose 2006 medians would have otherwise experienced a decrease of more than 10% in comparison with their CY 2005 payment rates, CMS is proposing to adjust the simulated medians by limiting their decrease to 10%.

Under this proposal, 15 of 33 payment rates for blood and blood products decrease in 2006 compared to the July quarterly update. Since the inception of the OPPS, CMS has been diligent in attempting to appropriately pay for blood and blood products using a number of different methodologies to ensure adequate payment. While the proposed approach results in modest payment increases for many blood and blood product related APCs, HANYS joins AHA in recommending that CMS set the 2006 rates at the greater of the simulated medians calculated using the 2004 claims data or the 2005 payment rate. HANYS believes this is necessary to ensure continued beneficiary access to these blood products.

INPATIENT PROCEDURES

CMS identifies procedures that are typically provided only in an inpatient setting, and therefore, would not be paid by Medicare under the OPPS. These procedures comprise what is referred to as the "inpatient list." CMS is proposing to remove 25 procedures from the inpatient list.

HANYS joins AHA in recommending that the inpatient-only list be eliminated. Hospitals are unable to receive any payment for services on this list that are performed in the outpatient setting. Yet, physicians, not hospitals, determine what procedures should be performed and whether a patient's condition warrants an inpatient admission. We believe it is appropriate to leave this clinical decision-making process in the hands of physicians.

HANYS appreciates having the opportunity to comment on the proposed rule. If you have any questions regarding our comments, please contact me at (518) 431-7777 or sharwell@hanys.org if you have any questions.

Sincerely,

Stephen Harwell
Director, Economic Analyses
Economics, Finance, and Information

CMS-1501-P-556

Submitter :

Organization : American Health Information Management Association

Date: 09/16/2005

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-556-Attach-1.DOC



American Health Information
Management Association®

September 16, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
PO Box 8016
Baltimore, Maryland 21244-8018

Re: File Code CMS-1501-P

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule (70 *Federal Register* 42674)

Dear Dr. McClellan:

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 2006 Rates, as published in the July 25, 2005 *Federal Register*. Our comments focus on those areas that are of particular interest to our members.

AHIMA is a not-for-profit professional association representing more than 50,000 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, 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).

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phone (202) 659-9440 · fax (202) 659-9422 · www.ahima.org

AHIMA also 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.

III-C-3: Proposed Requirements for Assigning Services to New Technology APCs (70FR42707)

AHIMA supports CMS' proposal to require that an application for a code for a new technology service be submitted to the American Medical Association's CPT Editorial Panel before CMS accepts a New Technology APC application for review. As we have previously noted in our comment letters, the proliferation of G codes that potentially overlap CPT codes results in multiple ways of reporting the same service. HCPCS level II G codes are generally not accepted by payers other than Medicare, thus requiring hospitals to report the same procedure using two different codes. The goals of the regulations for electronic transactions and code sets promulgated under the Health Insurance Portability and Accountability Act (HIPAA) include promotion of uniformity and standardization in claims reporting and administrative simplification. Creation of duplicative methods of reporting the same service does not support either of these goals. Also, development of a National Health Information Network, a key initiative of the Office of the National Coordinator for Health Information Technology and President Bush, depends on data standardization and comparability in order to achieve information exchange across healthcare organizations – for this to happen we must get all data, data definitions, and guidelines to the point where the individual patient's payer or health plan reimbursement requirements do not dictate health information coding.

Requiring that an application for a new CPT code be submitted at the time of a New Technology APC application will minimize the need for expedited issuance of temporary G codes. It makes sense to first create a standard CPT code for a new technology service and then address special reimbursement considerations.

III-D-4: Vascular Access Procedures (70FR42711)

AHIMA supports the reconfiguration of the APCs for vascular access procedures, resulting in three new APCs differentiated by level. With the use of the CPT codes for vascular access procedures, the new APC configuration seems more logical and clinically homogenous.

IV-D-2-a: Surgical Insertion and Implantation Criterion (70FR42719)

We support CMS' proposal to modify the interpretation of the criterion that a device be surgically inserted or implanted in order to qualify for pass-through payment so that items surgically inserted or implanted either through a natural orifice or surgically created orifice are considered eligible. Advances in medical technology since the implementation of the OPSS allow many devices to be inserted or implanted without an incision.

VIII-B: Proposed Coding and Payment for Drug Administration – Proposed Changes for CY 2006 (70FR42737)

We support CMS' proposal to continue to use CPT codes to bill for drug administration services provided in the hospital outpatient setting. Using CPT codes simplifies the administrative burden for the coding of drug administration since hospitals can use the same codes for Medicare and non-Medicare payers. We believe the same codes should be reported to all payers for the same services. The use of duplicative, overlapping code sets is extraordinarily costly and can result in coding confusion and errors, compromises of clinical data, and the inability to conduct analysis longitudinally and across healthcare settings.

Because of the significant changes expected with the new 2006 CPT codes for drug administration, hospitals will need instruction and clarification on the application of these new codes under the OPSS. For example, clarification will be needed regarding the following:

- How the use of the codes may be similar or different for the hospital outpatient setting as compared to the physician setting;
- Definitions of what constitutes an "initial" vs. "subsequent" infusion vs. "concurrent" infusion;
- Definition of "hydration" and how it is different from a hydration that is given for therapeutic reasons;
- How should infusions or titrations be reported? Many times they are established with a documented start time and are administered via pump. As such, many infusions are maintained by equipment function rather than manual intervention. In these cases, a nurse may be aware of the start time of an infusion and may document it, however, it is unlikely that the stop time will be documented.

The AHIMA would welcome the opportunity to work with CMS on coding education.

IX: Hospital Coding for Evaluation and Management (E/M) Services (70FR42740)

We are increasingly frustrated and disappointed by CMS' failure to implement a national set of E/M guidelines for hospital outpatient reporting purposes. Since the implementation of the OPSS, hospitals have coded clinic and emergency department (ED) visits using the same CPT codes as physicians. CMS and the hospital industry acknowledge that existing CPT E/M codes do not adequately describe hospital resources.

It has now been more than two years since the independent panel convened by the American Hospital Association and AHIMA submitted its recommendations for a set of national guidelines. In the 2004 and 2005 OPSS rules, CMS stated it was considering proposed national coding guidelines recommended by the panel, and planned to make any proposed guidelines available on the OPSS Web site for public comment. CMS also proposed to implement new E/M codes only when it is also able to implement guidelines for their use. In the meantime, hospitals must continue to use hospital-specific guidelines that are not comparable across hospitals and are not compliant with HIPAA.

Further delay in adoption of a national set of guidelines is unacceptable. While we understand the need for CMS to develop and test new codes, CMS has had more than two years to complete this process. Meanwhile, hospitals are still without a standard methodology for reporting E/M services. At the time the AHA/AHIMA independent panel was convened, we were under the impression that there was some

urgency in moving forward with a standardized set of guidelines because of the variability and non-comparability of the current approach. The lack of uniformity in the present system not only puts hospitals at compliance risk for multiple interpretations of the level of service that should be coded and billed, but also affects CMS' ability to gather consistent, meaningful data on services provided in the emergency department and hospital clinics. This is especially important because CMS uses the mid-level clinic visit (APC 601) as the anchor for establishing the relative weights within the outpatient PPS, and, due to a lack of national coding guidelines, there is no agreement on what a mid-level clinic visit encompasses.

XI -B: Proposed Payment for Observation Services – Proposed CY 2006 Coding Changes for Observation Services (70FR42743)

AHIMA commends CMS' proposal to shift determination of whether or not observation services are separately payable under APC 0339 from the hospital to the OPSS claims processing logic. These changes will significantly ease the administrative burden on hospital personnel and allow more of the steps involved in submitting claims for observation services to be automated.

However, we believe that CMS could go one step further and eliminate the need for proposed new code GYYYY. If the hospital bills the GXXXX code and the claim does not include a 45X (emergency department) or 516 (urgent care center) revenue code, then claims processing logic should determine that this was a direct admission to observation care. If the hospital bills the GXXXX code with a 45X or 516 revenue code, then it is clear that the patient came in through the emergency department or urgent care center. Thus, the claims processing logic would determine whether or not the observation services are a result of a direct admission.

AHIMA seeks clarification regarding the reference to inpatient status in the statement on page 42743 in the proposed rule that states "That is, hospitals would bill GXXXX when observation services are provided to any patient admitted to 'observation status,' regardless of the patient's status as an *inpatient* [emphasis added] or outpatient." We are concerned about this statement because if a patient is admitted as an inpatient, the hospital would not report HCPCS codes, but instead would be using the ICD-9-CM codes, since ICD-9-CM is the Health Insurance Portability and Accountability Act (HIPAA) code set standard for reporting procedures for hospital inpatient reporting.

XII-B: Procedures that Will Be Paid Only as Inpatient Procedures – Proposed Changes to the Inpatient List (70FR42745)

AHIMA agrees with CMS' proposal to retain codes 59856 and 65273 on the inpatient list because the descriptors of these codes indicate hospitalization is included in these codes. We also agree with the proposal to remove code 62160 from the inpatient list because it is an add-on code to procedures that are separately payable under the OPSS.

XII-C. Ancillary Outpatient Services When Patient Expires (70FR62747)

Based on CMS' review of claims where modifier -CA was reported, it would seem that there may be some confusion regarding the correct use of this modifier. We recommend that CMS issue clarification explaining the limited circumstances in which this modifier should be used.

Conclusion

We appreciate 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 either 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

Submitter : Dr. Daniel Brown
Organization : SWUC, PLLC, AUA, ABU
Category : Physician

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

See attached document

CMS-1501-P-557-Attach-1.DOC

**Southwestern Washington Urology Clinic,
P.L.L.C.**

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Phone (360) 943-9400

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September 16, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

RE: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for **APC 674: Cryosurgery of the Prostate**

Dear Dr. McClellan:

My name is Daniel Mark Brown. I am a board certified Urologist in Washington State. I am a certified Prostate Cancer Cryosurgeon and I am very concerned about the report that I have received about the proposed CMS re-imburement for Prostate Cryotherapy in 2006 in the July Federal Register.

You should know that it costs our hospital up to \$9000.00 for me to perform Prostate Cryotherapy and so the proposed re-imburement of only \$5659.13 will make it impossible for us to offer this vital treatment option for our patients with prostate cancer. This action on the part of CMS will in effect deny patients their right to choose this treatment option and may force them to accept less efficacious therapy and thereby increase costs to Medicare when their cancers become metastatic and have to be treated with years of Hormone Therapy, Radiation Therapy, or Surgery.

You should be aware of the fact that Cryotherapy is much less invasive than Radical Surgery for prostate cancer and gets the patients back into the workforce much sooner and with fewer complications.

I would prefer not to have to be forced by your actions to deny patients prostate Cryotherapy and I am requesting that you reconsider your decision. Please adjust the proposed payment rate for APC 674 upward--to reflect a hospital's actual cost to perform the procedure. Please be aware that if an appropriate reimbursement rate is established for APC 674, Medicare patients will benefit with improved clinical outcomes at less cost to the government.

Sincerely,

D. Mark Brown M.D.

Submitter : Mr. Randy Davis
Organization : Community Health Systems
Category : Hospital

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1501-P-558-Attach-1.DOC

In managing the Charge Master for a 70+ hospital system, the decision to require the reporting of a separate HCPCS code for specified covered outpatient drugs presents extreme operational issues. Attempting to ensure the proper reporting of the appropriate handling code in an automated system requires extensive set up and possible programming issues, if it can be done at all. If the proper reporting can not be achieved via set up and programming, the codes must be entered into the system manually. Our facilities would not be able to use automatically generated fill lists or automatic medication dispensing machines. The end result would be an increase of man hours, an increase in 'handling' time, and in the end 2% of the ASP would not cover the increased costs associated with meeting this proposed CMS requirement.

The need for these handling codes is unclear. If one was to look at all the descriptions associated with the HCPCS II codes, one would quickly notice that the majority already have the administration route in the description. Most medications that fall into the 'specified' outpatient drug list would always fall into only one category. The use of another code to note the administration route is redundant and unnecessary. If any codes do not have the route in the description, or if a medication falls into two categories, the burden should fall on CMS to create a code for each possible route of administration.

The AHA is mistaken in the belief that these changes do not present any operational issues or any additional administrative burden. The changes, as proposed, appear redundant and they are administratively burdensome. Payment for drug handling is fair, but simply increasing the payment rate for specified outpatient by an additional 2% of ASP on top of the ASP +6% appears to be the most logical method.

Submitter : Mr. Michael Powe
Organization : American Academy of Physician Assistants
Category : Physician Assistant

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

AAPA Comments on "Physician Oversight of Nonphysician Practitioners"
See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. William Harders
Organization : Jupiter Medical Center
Category : Health Care Professional or Association

Date: 09/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Gentleman, I am greatly concerned about the repeated decreases in reimbursement for hospital-based outpatient imaging. I have recently performed a detailed study comparing one month worth of financial impact with the proposed changes in out patient imaging. Our institution will realize a decrease annually of over \$300,000 at a time when all of our costs are increasing. For you information a similar case mix under the Physician reimbursement schedule receives \$1,300,000 more than we do and they are not experiencing any decrease in reimbursement. If the goal is to provide quality care in a cost effective manor for all Medicare recipients why not reduce the Physician reimbursement for Out patient Imaging to the current level for Hospital reimbursement. You will save far greater funds and not impact care delivered at all. The reason I am so certain about this are because it is exactly what all other insurance companies do, ONE fee schedule for all out patient imaging regardless of setting.

Respectfully,

William J.Harders
Director of Imaging
Jupiter Medical Center