Submitter : Mrs. Holly Bush **Date:** 04/17/2006

Organization : Nevada Regional Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

It is noted that the increase to 21 measurements is retrospective back to January 2006. This would create a re review of records for our facility and would create a hardship for our facility as we currently have one reviewer and this is not the only duty that reviewer has. I recommend that CMS not force facilities to review records again, if the requirement for measures is increased to 21, that this initiative become effective for future reviews.

Submitter : Mrs. Susan Pope **Date:** 04/17/2006

Organization : Wayne Medical Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I think it is good that all hospitals are required to submit core measure data for the 2007 update, but I have concerns that the reporting of these measures penalizes the hospitals (especially the small rural hospitals), not the physicians.
All of the measures, with exception to smoking cessation, documentation of flu and pneumonia vaccine and timeliness of abx, are all related to the physicians order. A physician or a nurse practitioner is the only medical professional cridentialed to order medications and procedures. A nurse nor Technician can order the test or medications. Why should the hospital be penalized for something the physicians should be responsible for. It's good to compare facilities, but it should not penalized the faclity for the physicians choices.

I also think that if the small rural hospitals are expected to treat the patients with the same medications and test and report on the same initiatives, as the large hospitals, they should be reimbursed at the same DRG rates. It would appear that if the small rural hospitals could effectively compare in their scores on the core measures, than they should be allowed the receive the same payment as the teaching and larger hospitals. As it stands CMS is putting more of a burden on the smaller hospitals instead of the larger hospitals. However the small hospitals will be penalized for not having the monies to effectively track, report and maintain their scores.

Submitter : Ms. kathy murphy **Date:** 04/18/2006

Organization : St Francis Hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

If CMS back-dates its requirement for submission of 21 measures to January 2006 - four months into the past, it will mean a retrospective review for those of us who abstract our quality charts shortly after dischg. Please reconsider this idea. It's not a good one.

Submitter : Mr. Ryan Wegrzyn **Date:** 04/18/2006

Organization : Poplar Bluff Regional Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I understand that changes need to be made to the system/abstraction process from time to time. However, this should be done in a manor that doesn't require our facilities to back track over 4 months to reabstract charts to find data. We abstract our charts while patients are in the hospital so that we can catch a mistake before it is to late to correct. When changes need to be made please give us notice and set a date in the FUTURE for when these changes will go in to affect (only data after that date is effect, not before as well). That seems only reasonable. I know of many hospitals that only have one nurse doing all core measure abstractions, and I believe it is alot to ask to do retrospective abstracting and still maintain the concurrent. Please think of the PEOPLE that this is going to effect. Thank you.

Submitter : **Mrs. Debby Sprandel** **Date: 04/19/2006**

Organization : **Saint Francis Medical Center**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

My current role is Director of Medical Mangement and one of my roles include working directly with Case Managers and physicians on core measure data collection, analysis, and improvement projects. We collect information concurrently in order to pick quickly on trends and intervene as appropriate. In light of this, when CMS announces submission requirements that are back dated for 3-6 months, this is extremely difficult and time consuming. We then have to go and retrospectively pull charts and complete data review on additional indicators for patients we have already previously reviewed. In speaking with many of my counterparts, it appears more and more facilites are moving toward concurrent review in order to have a more timely impact on identified problems. This is great when discussing quality improvement, but not great if faced with recollection of data after the fact. I am submitting this in hopes that other individuals are also bringing up similar concerns and that CMS will strongly reconsider this practice in the future. If additional data points are added, if institutions can be informed prior to the start date, these data collection points can then be appropriately incorporated into our data indicators prior and be collected concurrently. Thank you for your consideration into this matter!

Submitter : **Ms. roberta Carmack** **Date: 04/19/2006**

Organization : **Poplar Bluff Regional Medical Center**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

I feeel this is unfair. We abstract patient charts while they are in the hospital to ensure they receive the proper and required treatment. To require us to go back 9 months to a year and do retrospective review will place an extreme hardship on us and make it very stressful to keep up. We started in this position in December and had to pick-up 3rd and 4th quarter abstracting, as well as do the concurrent reviews. We are doing our best to be compliant, but, the requirements are changed every quarter and then some. It's very frustrating.

Submitter : Dana Stevens **Date: 04/19/2006**

Organization : Good Samaritan Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

It is unfair to post a new rule after the required time period. If CMS wants to include the submission of the 2 SIP indicators to HQA, include the indicators beginning 4/2006 to allow for the appropriate data collection. This will allow the data abstractor the appropriate notice time to become aware of the data collection requirements. Thank you.

Submitter : **Julie Olthof** **Date: 04/19/2006**

Organization : **Julie Olthof**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

It is unfair to post this rule after the time period. Please reconsider

Submitter : Angela Zaro **Date: 04/19/2006**

Organization : Good Samaritan Hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

It seems unreasonable to expect us to comply to a new rule months after the time period has begun.

Submitter : **Date: 04/20/2006**

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

The requirement to submit data on the expanded 21 measures starting with 2006 discharges would require that hospitals not currently submitting data on Surgical Infection Prevention would need to collect data for Jan - Jun 2006. The current measures, because of the complexity of the guidelines require that all progress notes, orders, cunsultations, nursing notes, ED records, H+Ps, discharge summaries be read line by line to ensure that one of the many exclusions/inclusions are not overlooked. With this intense level of chart review and quarterly revisions to the guidelines (requiring constant re-review of the already voluminous guidelines to be sure one is using the most curent version) an additional 6 months of data collection will require additional resources for which many hospitals are unprepared. I am assuming that final decisions will not be made until after the public comment period closes - allowing little time to establish processes with vendors, learning the guidelines and abstracting the additional records.
On the subject of validation - vendors requiring that hospitals submit 100% of their cases could submit well over 800 cases in one quarter. The results of 5 cases a quarter possibly abstracted by 4-5 staff memembers with feedback months later (after the following quarter has been submitted and with the subsequent quarter's in the processes of being abstracted) seems to be less than an ideal process.

Submitter : Mrs. Sandi Alls **Date:** 04/20/2006

Organization : Centennial Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

In consderation of the recommendation that mandate submision of 2 sip indicators to HQA beginning 1/2006 is unfair to post a rule that is effective after the actual effective date has passed.

Also there is clarification needed in regards to the Attestation required for data quality and completeness. This is not well defined in the Registry.

Submitter : **Dr. Donna Ettel** **Date: 04/20/2006**

Organization : **Brandon Regional Hospital**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

In regards to the Federal Register of 2 SIP indicators to HQA beginning January 2006. We feel it is unfair to post a ruling that is effective after that time. Please provide clarification of your statement requiring attestation for data quality and completeness.

Submitter : **Ms. Brenda Farnsworth** **Date: 04/20/2006**

Organization : **Lakeview Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

I feel it is unfair to retroactively penalize hospitals...ex the requirement to have been submitting data as of 1/06 on SIP measures. We are a small community hospital with limited resources..we need time to get ready for a change like this.

Submitter : **Ms. Janine Guillen** **Date: 04/20/2006**

Organization : **Swedish Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

From my understanding, the rule regarding submission of 2 SIP indicators to HQA for the APU was posted some time after the stated retro due date of 1/06. To post a rule after a due date for information is placing an undue burden on healthcare facilities. Our request is that you set a future due date so that meeting it can be addressed in a reasonable fashion.

Submitter : **Ms. linda taylor** **Date: 04/20/2006**

Organization : **poplar bluff regional medical center**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

THE PROPOSED CHANGES TO THE HOSPITAL INPATIENT DATA COLLECTION IS UNFAIR. IT SETS EVERY HOSPITAL UP TO FAIL BEFORE IT EVEN GOES INTO EFFECT. WE ARE NOT ALLOWED TO REENTER DATA ONCE THE TIME LIMIT HAS PASSED. WHY SHOULD THE GOVERNMENT BE ALLOWED TO DO THIS. THE WAY THAT WE ARE DOING THIS NOW AT LEAST GIVES A CHANCE TO CORRECT OUR MISTAKES BEFORE THE DEADLINE IS PAST.

Submitter : CHERYL PETRA **Date:** 04/24/2006

Organization : GREENVIEW REGIONAL HOSPITAL

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I DO NOT FEEL IT IS FAIR TO BACK DATE THIS RULE.

Submitter : Ms. Dianne Lanham **Date:** 04/24/2006

Organization : The Chester County Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on this important initiative. Our commitment to the Public Reporting Process will continue. However, we are concerned about the effective date of 1/1/06 discharges. This places a burden on the abstraction process which requires hospitals to scramble to meet this deadline. Normally, hospitals have a period of time to prepare systems and interfaces to streamline the abstraction process and lessen the workload burden. This new requirement for participation in the Public Reporting initiative will cause hospitals which want to continue to participate, like us, to alter interfaces and possibly add staff. These steps take time to implement. We would like to see the start date change from January 1, 2006 discharges to April 1, 2006 discharges. This would allow time for hospitals to set-up necessary resources.

Submitter : Mrs. Judy Dodson **Date:** 04/24/2006

Organization : Southcrest

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

The time frame of 1/2006 for submission of 2 SIP indicators would be a disadvantage to many, as this time frame has already passed.

Submitter : **Date: 04/24/2006**

Organization : **Good Samaritan Hospital**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

It is unreasonable to require this data this far into the data collection period.

Submitter : Mrs. Kathleen Reilly **Date:** 04/25/2006

Organization : Robert Packer Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Our organization is not currently collecting the SIP Measures data. In order for us to comply with submission deadline to Mediqual, we would need to collect the data and submit it by May 31, 2006. At this point there are no extensions. We confirmed this with Mediqual.
Because data for Jan and Feb have already been entered into the system, Mediqual does not have a process in place to allow us to turn on the SIP measure data collection for January and February. There could potentially be an additional fee for us to go back and re-enter data from prior months.

We will also require internal support from our IT department to write a program so we can identify charts for re-abstraction and submission.

Additionally, this will require Medical record assistance to pull charts (extra staff hours).

Our Abstractor staff will also require additional training in the SIP measures ---another unplanned cost to the facility.

Abstractor training to collect data.....we may need to hire that additional abstractor NOW. Abstractor overtime required to complete additional abstraction and data entry.

Penalty for not reporting would increase from 0.4% to 2%

We are supportive of adding the additional measures, but would prefer to have a significant amount of advance notice for planning and budgeting purposes. Perhaps once the measures are added organizations will not be expected to retroactively collect and submit data.....how about setting a time table that allows for a current data submission period?

Submitter : **Debra Ellis** **Date: 04/26/2006**

Organization : **Solucient**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Comment on "Medicare Code Editor", please see attachment.

CMS-1488-P-21-Attach-1.DOC

Solucient
Insight to Better Healthcare

Debra A. Ellis, RHIT, CCS
Nosologist
Solucient, LLC
5400 Data Court, Suite 100
Ann Arbor, MI 48108

Attachment #21

May 2, 2006

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Sir or Madam:

These comments are regarding "Medicare Code Editor" changes outlined in the Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. [CMS-1488-P] published April 25, 2006. We appreciate the inclusion of changes to the Medicare Code Edits in the Medicare HIPPS proposed rule. However, there are several other new codes that appear to meet the definition of these edits, as well as several newly invalid codes that should be removed from the code lists. They are as follows:

1. Pediatric Diagnoses Edit

   Add:
   V85.51 Body Mass Index, pediatric, less than 5th percentile for age
   V85.52 Body Mass Index, pediatric, 5th percentile to less than 85th percentile for age
   V85.53 Body Mass Index, pediatric, 85th percentile to less than 95th percentile for age
   V85.54 Body Mass Index, pediatric, greater than or equal to 95th percentile for age

2. Maternity Diagnoses Edit

   Add:
   649.00 Tobacco use disorder comp preg/labor/PP, unspecified as to episode of care or N/A
   649.01 Tobacco use disorder comp preg/labor/PP, delivered, w or w/o antepartum condition
   649.02 Tobacco use disorder comp preg/labor/PP, delivered, w postpartum complication
   649.03 Tobacco use disorder comp preg/labor/PP, antepartum condition or complication
   649.04 Tobacco use disorder comp preg/labor/PP, postpartum condition or complicaton
   649.10 Obesity comp preg/labor/PP, unspecified as to episode of care or not applicable
   649.11 Obesity comp preg/labor/PP, delivered, w or w/o antepartum condition
   649.12 Obesity comp preg/labor/PP, delivered, w postpartum complication
   649.13 Obesity comp preg/labor/PP, antepartum condition or complication
   649.14 Obesity comp preg/labor/PP, postpartum condition or complication
   649.20 Bariatric surgery status comp preg/labor/PP, unspecified as to episode of care or N/A
   649.21 Bariatric surgery status comp preg/labor/PP, delivered, w or w/o antepartum condition
   649.22 Bariatric surgery status comp preg/labor/PP, delivered, w postpartum complication
   649.23 Bariatric surgery status comp preg/labor/PP, antepartum condition or complication
   649.24 Bariatric surgery status comp preg/labor/PP, postpartum condition or complication
   649.30 Coagulation defects comp preg/labor/PP, unspecified as to episode of care or N/A
   649.31 Coagulation defects comp preg/labor/PP, delivered, w or w/o antepartum condition
   649.32 Coagulation defects comp preg/labor/PP, delivered, w postpartum complication
   649.33 Coagulation defects comp preg/labor/PP, antepartum condition or complication
   649.34 Coagulation defects comp preg/labor/PP, postpartum condition or complication
   649.40 Epilepsy comp preg/labor/PP, unspecified as to episode of care or not applicable
   649.41 Epilepsy comp preg/labor/PP, delivered, w or w/o antepartum condition
   649.42 Epilepsy comp preg/labor/PP, delivered, w postpartum complication
   649.43 Epilepsy comp preg/labor/PP, antepartum condition or complication
   649.44 Epilepsy comp preg/labor/PP, postpartum condition or complication

649.50 Spotting complicating pregnancy, unspecified as to episode of care or not applicable
649.51 Spotting complicating pregnancy, delivered w or w/o antepartum condition
649.53 Spotting complicating pregnancy, antepartum condition or complication
649.60 Uterine size date discrepancy, unspecified as to episode of care or not applicable
649.61 Uterine size date discrepancy, delivered, with or without antepartum condition
649.62 Uterine size date discrepancy, delivered, with postpartum complication
649.63 Uterine size date discrepancy, antepartum condition or complication
649.64 Uterine size date discrepancy, postpartum condition or complication

3. Diagnoses Allowed for Females Only

Add:
618.84 Cervical stump prolapse
629.29 Other female genital mutilation status
649.00 Tobacco use disorder comp preg/labor/PP, unspecified as to episode of care or N/A
649.01 Tobacco use disorder comp preg/labor/PP, delivered, w or w/o antepartum condition
649.02 Tobacco use disorder comp preg/labor/PP, delivered, w postpartum complication
649.03 Tobacco use disorder comp preg/labor/PP, antepartum condition or complication
649.04 Tobacco use disorder comp preg/labor/PP, postpartum condition or complicaton
649.10 Obesity comp preg/labor/PP, unspecified as to episode of care or not applicable
649.11 Obesity comp preg/labor/PP, delivered, w or w/o antepartum condition
649.12 Obesity comp preg/labor/PP, delivered, w postpartum complication
649.13 Obesity comp preg/labor/PP, antepartum condition or complication
649.14 Obesity comp preg/labor/PP, postpartum condition or complication
649.20 Bariatric surgery status comp preg/labor/PP, unspecified as to episode of care or N/A
649.21 Bariatric surgery status comp preg/labor/PP, delivered, w or w/o antepartum condition
649.22 Bariatric surgery status comp preg/labor/PP, delivered, w postpartum complication
649.23 Bariatric surgery status comp preg/labor/PP, antepartum condition or complication
649.24 Bariatric surgery status comp preg/labor/PP, postpartum condition or complication
649.30 Coagulation defects comp preg/labor/PP, unspecified as to episode of care or N/A
649.31 Coagulation defects comp preg/labor/PP, delivered, w or w/o antepartum condition
649.32 Coagulation defects comp preg/labor/PP, delivered, w postpartum complication
649.33 Coagulation defects comp preg/labor/PP, antepartum condition or complication
649.34 Coagulation defects comp preg/labor/PP, postpartum condition or complication
649.40 Epilepsy comp preg/labor/PP, unspecified as to episode of care or not applicable
649.41 Epilepsy comp preg/labor/PP, delivered, w or w/o antepartum condition
649.42 Epilepsy comp preg/labor/PP, delivered, w postpartum complication
649.43 Epilepsy comp preg/labor/PP, antepartum condition or complication
649.44 Epilepsy comp preg/labor/PP, postpartum condition or complication
649.50 Spotting complicating pregnancy, unspecified as to episode of care or not applicable
649.51 Spotting complicating pregnancy, delivered w or w/o antepartum condition
649.53 Spotting complicating pregnancy, antepartum condition or complication
649.60 Uterine size date discrepancy, unspecified as to episode of care or not applicable
649.61 Uterine size date discrepancy, delivered, with or without antepartum condition
649.62 Uterine size date discrepancy, delivered, with postpartum complication
649.63 Uterine size date discrepancy, antepartum condition or complication
649.64 Uterine size date discrepancy, postpartum condition or complication
795.06 Papanicolaou smear of cervix with cytologic evidence of malignancy

4. Procedures Allowed for Females Only

Delete (now invalid codes):
68.4 Total abdominal hysterectomy
68.6 Radical abdominal hysterectomy
68.7 Radical vaginal hysterectomy

Add:
68.41 Laparoscopic total abdominal hysterectomy
68.49 Other and unspecified total abdominal hysterectomy
68.61 Laparoscopic radical abdominal hysterectomy
68.69 Other and unspecified radical abdominal hysterectomy
68.71 Laparoscopic radical vaginal hysterectomy
68.79 Other and unspecified radical abdominal hysterectomy

5. Manifestations Not Allowed as Principal Diagnosis

Delete (now invalid codes):
323.0 Encephalitis in viral diseases classified elsewhere
323.4 Other encephalitis due to infection classified elsewhere
323.6 Postinfectious encephalitis
323.7 Toxic encephalitis

Add:
284.2 Myelophthisis
323.01 Encephalitis and encephalomyelitis in viral diseases classified elsewhere
323.02 Myelitis in viral diseases classified elsewhere
323.41 Other encephalitis and encephalomyelitis due to infection classified elsewhere
323.42 Other myelitis due to infection classified elsewhere
323.61 Infectious acute disseminated encephalomyelitis (ADEM)
323.62 Other postinfectious encephalitis and encephalomyelitis
323.63 Postinfectious myelitis
323.71 Toxic encephalitis and encephalomyelitis
323.72 Toxic myelitis
341.21 Acute (transverse) myelitis in conditions classified elsewhere

6. Non-Specific Principal Diagnosis

Delete (now invalid code):
793.9 Other nonspecific abnormal findings on radiological and other exams of body structure

Add:
523.30 Aggressive periodontitis, unspecified
523.40 Chronic periodontitis, unspecified
525.60 Unspecified unsatisfactory restoration of tooth
528.00 Stomatitis and mucositis, unspecified
649.00 Tobacco use disorder comp preg/labor/PP, unspecified as to episode of care or N/A
649.10 Obesity comp preg/labor/PP, unspecified as to episode of care or not applicable
649.20 Bariatric surgery status comp preg/labor/PP, unspecified as to episode of care or N/A
649.30 Coagulation defects comp preg/labor/PP, unspecified as to episode of care or N/A
649.40 Epilepsy comp preg/labor/PP, unspecified as to episode of care or not applicable
649.50 Spotting complicating pregnancy, unspecified as to episode of care or not applicable
649.60 Uterine size date discrepancy, unspecified as to episode of care or not applicable
793.99 Other nonspecific abnormal findings on radiological and other exams of body structure
995.20 Unspecified adverse effect of unspecified drug, medicinal and biological substance

Sincerely,

Debra A. Ellis, RHIT, CCS
Nosologist

Submitter : Ms. Diane Christie **Date:** 04/28/2006

Organization : Riddle Memorial Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

As of April 12, most hospitals have completed or almost completed data entry and export for the first quarter of 2006. Collection options for data collection and export cannot be set retroactively; thus, additional collection options cannot be added to start for discharge dates that are already entered into the system. In order to meet the requirement for this proposal, all of the patient records abstracted and entered after January 1, 2006 would have to be deleted, re-imported, re-abstracted, re-entered and re-exported. While CMS is allowing the additional data to be submitted by August 15, 2006, the other CMS measures, and the measures to JCAHO for the first quarter are due to the vendors no later than May 31, 2006; now one month away. It is impossible to make the changes only for the additional eleven measures without deleting and re-entering the entire database from January 1, 2006 onward. This would represent tremendous cost and rework for almost all of the hospitals participating in this project. We support CMS' efforts to increase and improve quality reporting, but feel that setting the date for the requirement retroactively places undue strain on the resources of the hospitals participating in this initiative. Since the comment period for this proposal does not close until June 12, 2006, hospitals will have had to complete data reporting for the first quarter two weeks prior to the end of the comment period and will be well into data abstracting and entry for the second period. Because of this, CMS should consider a start date that goes into affect following the closing period for comments on this proposal, such as July 1, 2006. To do otherwise will place a burden on hospitals that are participating in this program; either they waste limited resources by deleting and re-entering their entire database or risk a reduction in their reimbursement from CMS. Thank you.

Submitter : Mrs. Cindy Christenson **Date:** 04/28/2006

Organization : Eastern Idaho Regional Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

CMS 1488 retrospective review beginning January 1, 2006 will be unduly burdensome. We feel that the Surgical Infection Prevention data collection should begin July 1, 2006 as originally planned.

Submitter : Mrs. Salinda Cowder **Date:** 05/02/2006

Organization : Clearfield Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Clearfield Hospital would like to comment on the proposed changes to the requirements for hospitals FY07 market basket. The proposal requires that all 21 HQA measures be submitted to CMS for calendar year 2006 (beginning January, 2006) and the penalty for not reporting would increase from .4% to 2%.

This is a definite issue for Clearfield Hospital for we are nearing the end of the CORE measure collection for the first quarter 2006 data and we are currently not collecting the surgical infection prevention measures.

Our vender, MediQual, is still in the process of investigating the impact of these additional measures and the options to comply are still unclear.

Clearfield Hospital is committed to efforts to reduce infections and have agreed to utilize the Medmined Surveillance Program, thereby freeing valuable Infection Control resources to devote necessary time to education and prevention. We feel that this is where our efforts should be concentrated and not with costly data abstraction.

The additional abstracting requirements will place a manpower strain on our facility and will force the addition of another abstractor. Training for competency of abstraction will be a factor due to submission deadlines. The data submission deadline of May 30, 2006 will be a hardship since collection of surgical procedures has not been initiated and the collection requirements have not yet been identified by MediQual. To propose changes that impact retrospective deadlines appears unrealistic, particularly for a small rural hospital, who desires to optimize its limited resources. At the least, we request that the addition of surgical infection prevention measure collection be delayed until calendar year 2007, to allow for adequate preparation and to not allow us to become penalized for our market share by not meeting the May 30, 2006 and subsequent deadlines.

Submitter : **Andrei Kuznetsov** **Date: 05/02/2006**

Organization : **Primaris**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Re: Hospital Quality Data
The problem with HCAHPS is that there is no no-cost alternative to using a vendor. With collection of clinical chart abstraction data, CMS made CART available to hospitals as a way to collect and submit the required data for free. With HCAHPS, no such tool is available and none is planned (per proposed regs and the hcahpsonline.org web site). This presents a significant potential burden to hospitals that will have no alternative to using commercial vendors in order to satisfy a federal mandate. Very few hospitals have the expertise required to competently sample the discharged patients, design a database for the responses, conduct the data entry from the returned surveys and export the responses into an XML format. In fact, a substantial proportion of hospitals do not presently conduct any patient experience surveys, and for them this is an entirely new business process that needs to be put in place.
All that the federal government has committed to providing is the interface to upload the data to QNet Exchange, which is a small portion of the process that needs to be deployed to comply with the HCAHPS data collection mandate.
To remedy this situation, a tool similar to CART is needed to enable hospitals to enter results of the survey into a database and export the data into an XML format. Clear and concise guidance on sampling for HCAHPS would also help.

Submitter :

Date: 05/03/2006

Organization :

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

While I believe that public reporting of quality data has contributed positively to patient outcomes as reported in peer-reviewed literature, the current proposal to begin reporting all 21 indicators retroactive to January 1, 2006, discharges places an undue burden on hospitals. Had we known about this ahead of time, we could have been abstracting the additional indicators concurrently. To go back now is burdensome -- and our main mission is to provide patient care, not abstract old data.

Also, the validation process based on 5 charts over 4 patient populations is not statistically reliable. This needs to be changed per statistician recommendations.

Submitter : Ms. Connie Chappelle **Date:** 05/04/2006

Organization : Bothwell Regional Health Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Under the proposed rule, acute care hospitals would need to collect and publicly report these 21 quality indicators to CMS retroactive to January 1, 2006 to receive full Market Basket for FY 2007. The time line proposed by CMS essentially requires hospitals to begin immediately collecting the four measure sets.

Under the proposed time line, January, February and March 2006 data will need to be abstracted and successfully submitted to CMS no later than Tuesday, August 15, 2006. For the Joint Commission accredited hospitals, the submission deadline for first quarter 2006 is Monday, July 31, 2006. The CMS comment period deadline is Monday, June 12, 2006, with an anticipated response time of 30 to 60 days by CMS. This means outcome of the proposed APU may not be known until immediately prior to the CMS submission deadline, August 15, 2006, for first quarter 2006 data. Operationally, most acute care hospitals have completed January and February 2006 data abstraction for AMI, HF and pneumonia to CMS. The measure set many hospitals have not been submitting to CMS is the surgical infection prevention measure set which will make the proposed time lines problematic for hospitals already over extended in meeting the current requirements for FY 2007 market basket.

Submitter : Ms. Staci Trudo **Date:** 05/04/2006

Organization : Ohio Valley Medical Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1488-P-28-Attach-1.DOC

AHCA # 28

OHIO VALLEY MEDICAL CENTER

May 4, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

Subject: "Hospital Quality Data"

Regarding the proposed changes to Reporting of Hospital Quality Data for Annual Hospital Payment Update, I would like to comment on the proposed expansion of the measure set.

If implemented as proposed, it will be required for hospitals to submit the additional quality measures effective with the first quarter of 2006. This will require retrospective data collection and reporting within a very short timeframe. This will impose an undue burden on both the hospital and hospital staff. There will also be financial impacts due to needing additional staff to collect the retrospective data that is not currently being collected. If the proposed additional quality measures are accepted, it would be beneficial to the hospitals to initiate the required data collection effective with first quarter of 2007. This will allow the hospital time to prepare staff for the additional workload, and prepare for any financial implications that would be incurred.

Respectfully,

Staci L. Trudo, BSN, RN, CCRN, CEN, REMT-P
Performance Improvement Coordinator
Ohio Valley Medical Center

SLT/slt

Submitter : Dr. Christine Matson **Date:** 05/06/2006

Organization : Eastern Virginia Medical School

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

The proposal to 'clarify' that time that resident physicians in training spend in didactic experiences would not 'count' toward a hospital's IME payment would be harmful to the country's current system for educating physicians. Spending an hour or so during the day of patient care to better understand the disease processes that result in hospitalization, to review the standards for highest quality medical care, and to discuss how to improve outcomes of the care such as occur during didactic sessions is an inherent part of excellent medical care and should be acknowledged in IME payments. While ultimately Congress needs to identify methods to better support the types of medical care that are most cost-effective in improving health (e.g. primary prevention through behavioral change and supporting a strong infrastructure for primary care - see Barbara Starfield's work). While federal support for medical education is tied to hospitals, failure to support those activities that improve the quality of that education would be short-sighted at best.

Submitter : Mrs. JoAnne Allen **Date:** 05/07/2006

Organization : Mrs. JoAnne Allen

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Comments re: Transparency of Healthcare Information:

Hospital prices in the U.S. are generally unregulated and methods for setting them are poorly understood--even by those who work within them. Publishing hospital charges may help, but there are many complexities involved in making them truly comparable. However, CMS already has information regarding hospital cost-to-charge ratios, and most consumers could readily understand that these values measure the relationship between hospital charges and their true costs of providing patient care. Most consumers can readily grasp the concept of an average mark up, but few are aware of the extent to which hospital charges exceed their costs. Having this information would empower uninsured and insured healthcare consumers to negotiate realistic prices for their care. I would urge CMS to consider making hospital cost-to-charge ratios readily available to the public.

Submitter : Mrs. Melody Ownby **Date:** 05/08/2006

Organization : Sparks

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Nursing care can be one of the highest costs that a hospital must bear in order to provide quality patient care. Acknowledging this fact should lead the revision of the Centers for Medicare & Medicaid (CMS) proposal for a rule change to modify the current Part A hospital reimbursement from a charge based prospective payment system to a cost based and severity adjusted system to include the following topics:

1. Creating separate direct and indirect nursing cost center at each provider hospital and include these data in the annual Medicare Cost Report (MCR).
2. Collecting daily nursing intensity data as actual direct nursing time expended per patient by nurses and other nursing personnel.
3. Summarizing daily nursing intensity for the hospital stay and calculate associated direct and indirect nursing costs and mean nursing intensity per discharge and including these data in the hospital discharge and billing abstract.
4. Adjusting hospital Medicare payment for severity of illness by modifying the proposed APR-DRG severity weights to incorporate nursing intensity and costs within each diagnosis and severity category.

Submitter : Dr. Camille Claibourne **Date:** 05/08/2006

Organization : Lafayette General Medical Center

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-32-Attach-1.DOC

Attachment #32

Lafayette General Medical Center

Your Health. Your Hospital. Your Choice.

Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8011
Baltimore MD 21244-1850

Date: May 8, 2006

RE: **File Code CMS-1488-P "Hospital Quality Data"**

Dear Sirs:

We welcome the opportunity to comment on the proposed revisions to the "Reporting of Hospital Quality Data for Annual Hospital Payment Update. The project has been beneficial as evident by the improvements in the indicators measured by participating hospitals.

One area that the regulation does not address is alignment of physician and hospital indicators. If not alignment, perhaps consideration could be given to having physician-driven indicators for physicians only.

Once again, thank you for allowing this public comment. We look forward to continued participation in the project.

Sincerely,

Camille Claibourne, RN, PhD
Chief Quality and Patient Safety Officer
Lafayette General Medical Center

Submitter : **Mrs. Kathy Doty** **Date: 05/10/2006**

Organization : **West Calcasieu Cameron Hospital**

Category : **Hospital**

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Department of Health & Human Services
Centers for Medicare & Medicaid Services

May 9, 2006

Re: Proposed Rules to Federal Register
CMS-1488-P
Hospital Quality Data

To Whom It May Concern:

West Calcasieu Cameron Hospital is committed to the improvement of processes and outcomes and is in support of CMS efforts, along with other quality partners, to improve care and outcomes. We have participated in the initial set of 10 quality indicators, and do see the importance of increasing that measure set to the proposed 21 indicators.

However, comments found in the proposed rules of the Federal Register regarding no additional burden to hospitals are incorrect. JCAHO-accredited facilities are required to submit Core Measure data, but we are not required to submit ALL Core Measures. Hospitals currently have a choice of 3 measures.

The August 15, 2006 deadline puts small hospitals under tremendous strain to comply with these new rules. We would recommend that the proposed requirements be re-evaluated to allow for hospitals to begin the collection of data going forward rather than retrospectively. This would allow for the implementation of processes by which the appropriate records could be targeted concurrently, and would not require additional financial burden to not only build these systems, but also complete abstractions to bring our facility on-line .

We sincerely hope that you will take our recommendations into consideration.

Thanking you in advance,

Raphael Fontenot, Chairman, Board of Commissioners
Frank LaBarbera, Board of Commissioners
Bob Davidson, Board of Commissioners
Bobby LeTard, Board of Commissioners
Joe Devall, Board of Commissioners
Tim Broussard, CEO
Theresa Woods, COO
Kathy Doty, Quality Management

CMS-1488-P-33-Attach-1.DOC

Attachment #33

Department of Health & Human Services
Centers for Medicare & Medicaid Services

May 9, 2006

Re: Proposed Rules to Federal Register
CMS-1488-P
Hospital Quality Data

To Whom It May Concern:

West Calcasieu Cameron Hospital is committed to the improvement of processes and outcomes and is in support of CMS' efforts, along with other quality partners, to improve care and outcomes. We have participated in the initial set of 10 quality indicators, and do see the importance of increasing that measure set to the proposed 21 indicators.

However, comments found in the proposed rules of the Federal Register regarding no additional burden to hospitals are incorrect. JCAHO-accredited facilities are required to submit Core Measure data, but we are not required to submit ALL Core Measures. Hospitals currently have a choice of 3 measures.

The August 15, 2006 deadline puts small hospitals under tremendous strain to comply with these new rules. We would recommend that the proposed requirements be re-evaluated to allow for hospitals to begin the collection of data going forward rather than retrospectively. This would allow for the implementation of processes by which the appropriate records could be targeted concurrently, and would not require additional financial burden to not only build these systems, but also complete abstractions to bring our facility "on-line".

We sincerely hope that you will take our recommendations into consideration.

Thanking you in advance,

Raphael Fontenot, Chairman, Board of Commissioners
Frank LaBarbera, Board of Commissioners
Bob Davidson, Board of Commissioners
Bobby LeTard, Board of Commissioners
Joe Devall, Board of Commissioners
Tim Broussard, CEO
Theresa Woods, COO
Kathy Doty, Quality Management

Submitter : Mrs. Jennifer Armstrong **Date:** 05/10/2006

Organization : Martha Jefferson Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

My Comment is regarding the validation chart audit process and the 80 percent reliability requirement.
In order for hospitals to receive the full APU, hospitals must pass "our validation requirement of a minimum of 80 percent reliability" Although I agree with the need for accurate data collection and submission, there seems to be no flexibility in validation because of the measure alignment which is happening between JCAHO and CMS. The alignment process has the measures, inclusions and exclusions, and abstracting guidelines changing nearly quarterly. Possible abstraction errors are increased due to the lack of consistency in the measure definitions and guidelines themselves. For example, Smoking cessation conseling; In some quarters, if here is conflicting documentation as to if the patient is a smoker you answer Yes they are a smoker, thus require counseling, in other quarters, if there is conflicting documentation as to if the patient is a smoker you answer No they have not smoked within the last 12 months, thus do not require counseling. Even the most accurate abstractor is prone to errors if the guidelines are not clear and consistent. I believe that the hospital's APU should not tied to validation until JCAHO and CMS have aligned the measures making the guidelines clear and most important consistent, meaning not changing 3 to 4 time a year.
Thank you for your consideration.

Submitter : Mrs. Sharon Knutson **Date:** 05/11/2006

Organization : Carondelet Health Network

Category : Hospital

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

My concern with the proposed changes is the human resource impact. We take these initiatives very seriously and continuously strive to impact the care of these populations while they are with us as patients. In order to be effective while maintaining current FTE's, would recommend that with the addition of the 11 new measures, hospitals be required to collect and report at a date in the future versus past. I.E. July 2006 or January 2007. Another reason for doing so is thru the current data submission process, January thru March 2006 data has already been submitted to our vendors, thus hospitals will be penalized before they've had a chance

Submitter : Ms. Connie Chappelle **Date:** 05/12/2006

Organization : Bothwell Regional Health Center

Category : Nurse

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Under the proposed rule, acute care hospitals will need to collect and publicly report these 21 quality indicators to CMS retroactive to January 1, 2006 to receive full Market Basket for FY 2007. The time line proposed by CMS essentially requires hospitals to begin immediately collecting the four measure sets.

Under the proposed time line, January, February and March 2006 data will need to be abstracted and successfully submitted to CMS no later than Tuesday, August 15, 2006. For the Joint Commission accredited hospitals, the submission deadline for first quarter 2006 is Monday, July 31, 2006. The CMS comment period deadline is Monday, June 12, 2006, with an anticipated response time of 30 to 60 days by CMS. This means outcome of the proposed APU may not be known until immediately prior to the CMS submission deadline, August 15, 2006, for first quarter 2006 data. Operationally, most acute care hospitals have completed January and February 2006 data abstraction for AMI, HF and pneumonia to CMS. The measure set many hospitals have not been submitting to CMS is the surgical infection prevention measure set which will make the proposed time lines problematic.

Under the proposal if a hospital does not participate, there will be a 2 percent Medicare payment reduction for annual payment update in FY 2007. The payment reduction was limited to 0.04 percent in FY 2005-06. Hospitals not submitting data in 2005 to CMS would have to begin submitting the necessary data with first quarter 2006 discharges to receive full Market Basket for FY 2007.

Validation Process for FY 2007 Annual Payment Update

In addition to abstracting and submitting the data for four measure sets to be publicly reported, each hospital would have to successfully meet the CMS validation requirements of data submitted to the data warehouse to receive full Market Basket.

Hospitals must pass the CMS validation requirement with a minimum of 80 percent reliability based upon CMS s chart audit validation process for the first three quarters of calendar year 2005. This data was due to the CMS warehouse August 15, 2005. Validation of hospitals who did not submit data in 2005 has not been addressed in the CMS proposal.

The CMS will use a two-step process to determine if a hospital is submitting valid data. In the first step the CMS calculates the percent agreement for all variables submitted to the warehouse. If the hospital falls below the 80 percent cutoff, CMS will restrict the comparison to those variables associated with the starter set of ten quality measures. The CMS will recalculate the percent agreement and the estimated 95 percent confidence limit and compare to the 80 percent cutoff point. If this upper limit is above the required 80 percent reliability, the hospital data is considered validated. This validation requirement was not in effect for the FY 2006 Market Basket.

Based upon prior analytical results for FY 2006, the CMS found confidence intervals using only five charts widely varied in size. As a result of these findings, CMS decided to combine multiple quarters of validation samples into a single stratified sample to decrease the variation.

Submitter : Mr. Stu Kavolis **Date:** 05/12/2006

Organization : Coventry Health Care

Category : Health Plan or Association

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

It is crucial that CMS takes steps to ensure that the forthcoming grouper and its underlying logic be made public. A proprietary system would undermine the effectiveness of such a change to the DRG system.

Submitter : Dr. Jonathan Weiss **Date:** 05/15/2006

Organization : LDS Hospital, Salt Lake City

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 400 bed tertiary care community hospital located in Salt Lake City, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,
J. Peter Weiss MD

Submitter : Chris Sauder **Date:** 05/15/2006

Organization : Adventist Health - West

Category : Hospital

Issue Areas/Comments

DRG Weights

DRG Weights

I am glad that CMS is reviewing its methodology for re-weighting the DRGs. I agree with the methodology concept of shifting towards a cost-based approach as opposed to charge-based. I am wondering if it would still be necessary to have separate PPS systems for IPF and IRF if the new DRG weights (e.g.-430) remove the mark-up bias. Did you examine the impact of some hospitals possibly decertifying units to take advantage of better reimbursement under the IPPS?

Submitter : Dr. Phyllis Bonham **Date:** 05/15/2006

Organization : MUSC College of Nursing

Category : Nurse

Issue Areas/Comments

DRG Weights

DRG Weights

I support the MUSC proposal to incoporate nursing costs and nursing intensity into the new Medicare hospital payment formula that recommends:
1.Creating separate direct and indirect nursing cost center at each provider hospital and include these data in the annual Medicare Cost Report (MCR).
2.Collecting daily nursing intensity data as actual direct nursing time expended per patient by nurses and other nursing personnel.
3.Summarizing daily nursing intensity for the hospital stay and calculate associated direct and indirect nursing costs and mean nursing intensity per discharge and including these data in the hospital discharge and billing abstract.
4.Adjusting hospital Medicare payment for severity of illness by modifying the proposed APR-DRG severity weights to incorporate nursing intensity and costs within each diagnosis and severity category.

Submitter : Dr. Kay Chitty **Date:** 05/15/2006

Organization : retired

Category : Individual

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

You have an unprecedented opportunity to reform a flawed system. I hope you will look beyond minor tinkering and consider incorporating nursing care and nursing intensity in the new payment scheme. This change can make a huge difference in the quality of care provided in our nation's hospitals. Thank you for your consideratin of my request.

Submitter : **Dr. Ronald McCowan** **Date: 05/16/2006**

Organization : **Arrhythmia Treatment Associates, PLLC**

Category : **Physician**

Issue Areas/Comments

Capital Payment Rate

Capital Payment Rate

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 900 bed hospital located in Charleston, WV, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments.

Sincerly,

Ronald McCowan, M.D., FACC

Submitter : **Mr. Donald Wilson** **Date: 05/16/2006**

Organization : **HMA/Charlotte Regional MEdical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-43-Attach-1.DOC

Attachment #43

Charlotte Regional Medical Center

May 23, 2006

Deleted: May 16, 2006
Deleted: May 16, 2006
Deleted: May 10, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8011
Baltimore, MD 21244-1850

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RE: CMS-1488-P; Proposed Changes to the Hospital Inpatient Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

I am a cardiology administrator with over 30 years experience in managing cardiology programs. Currently I am the Corporate Coordinator of Cardiology Services for Health Management Associates, which operates 62 hospitals in 16 states with approximately 8,917 licensed beds. I am based out of Charlotte Regional Medical Center in Punta Gorda, Florida, which serves the people of Charlotte and Southern Sarasota Counties. Charlotte Regional alone performs in excess of 3,000 cardiac cases per year. Cardiac volumes, particularly ICD and CRT-D implants, have significantly increased over the last two years due to recent medical studies demonstrating the benefits of this technology. We also provide a complete medical and surgical program including the cardiovascular care center.

We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' Proposed Changes to the Hospital Inpatient Payment Systems and Fiscal Year 2007 Rates (CMS-1488-P). While we are supportive of many of the provisions in the proposed rule, we are very concerned about the proposed methodologies resulting in

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READ and DELETE: This letter is an example only. As always, please ensure your comment letter reflects your own experiences and opinions. We strongly encourage you to write your letter on your own organization's letterhead. ¶

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Deleted: (Describe yourself and your hospital in this paragraph – your title and role; where your hospital is located, what areas you serve; how many beds you have, number of cases per year, etc.) We provide a complete medical and surgical program including a cardiovascular care center.

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inaccurate payment amounts, particularly for the cardiovascular services we provide our patients.

As such, we urge CMS to allow time for further study of the proposals until further analyses can be performed to understand the full impact to hospitals and patients, but in the meantime continue with the current charge-based system.

We agree that payment rates should accurately reflect the cost of services provided. Inaccurate rates could limit hospitals' capabilities to perform services, and thus limit patient access to some therapies. The current proposal, if implemented, could have unintended and inappropriate consequences.

- **Questions have been raised about CMS's proposed rate setting methodology.** Some of these issues include:

  - **CMS used old data to calculate the payment rates.** DRG weights under the new rule are based on data that are 3–5 years old. This particularly impacts technology-based DRGs. Medical technologies typically have a short lifecycle, meaning that many of the innovative technologies available today, such as cardiac resynchronization therapy defibrillation (CRT-D), were not widely in use at the time these data were collected.

  - **The use of nonstandard data leads to increased inaccuracy.** The current cost reports were designed for a different purpose; CMS should put more thought into how to improve and verify the accuracy of this data prior to making it the basis of its new payment system.

  - **Technical mistakes as well as questionable technical assumptions alter the estimated impact on payments.** In one example, CMS excluded approximately one-quarter of large hospitals' routine day charges in calculating cost-to-charge ratios, which almost doubled the cuts in some DRGs and raised the increase in equal amounts in others. Had these data been included, the large shift in payments for some DRGs would be reduced by nearly half. Another example is in how the cost-to-charge ratios were calculated; CMS failed to adjust for volume of care among hospitals, resulting in a small hospital having as much weight as a large-volume hospital.

  - **Charge compression continues to be a major issue, particularly for costly, high-value medical devices.** Despite continued pleadings from industry, hospitals, Congress, and others, charge compression was not addressed in the FY2007 rule, and is in fact, made worse. Instead of individually analyzing the high cost, high value devices to better understand real costs, CMS decided to put everything together in ten national cost centers. The problem is that there are no standards — most devices and supplies are put in a single cost center,

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Comment [PBP1]: This may be a bit much…I would suggest delete.

Deleted: When the proposed rule was released on April 12, 2006, Mark McClellan, CMS Administrator, stated, "The hospital payment reforms we are proposing today will mean payments for hospital inpatient services will more accurately reflect the costs of providing the services". ¶

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and hospitals across the country put them in different categories, so the real costs may never be captured.

- **The current proposed DRG payment rates are in some cases the same or lower than the purchase price for ICDs and CRT-Ds.** Proposed rates for ICD and CRT-D procedures are sometimes below the device acquisition cost, not allowing hospitals payment for operating procedures, supplies, and personnel. For example, DRG 515, where a majority of ICD implants fall, was paid at a base of $28,441 in 2006; for 2007 Medicare is proposing a sharp decrease in payment of 23%, down to $22,015 — one of the biggest percentage decreases any DRG faces this year.

- **If this change is implemented, hospitals could find themselves with limited capabilities to offer their patients leading-edge, high value lifesaving technologies.** Hospitals cannot sustain themselves economically when inaccurate payments do not cover the cost of supplies, equipment, staff, and medical devices. This could result in hospitals altering normal treatment patterns, restricting technology selection, and limiting patient access in order to avoid extraordinary financial losses. As a result, patients may be limited access to this lifesaving technology because hospitals are not receiving payment that recognizes the full cost of the services provided.

We urge CMS to delay the 2007 proposed changes until more careful analyses are performed, and the full impact to hospitals and patients is understood. Although the proposed changes are in many cases, directionally correct, the sheer magnitude of the changes, coupled with the many unintended flaws, requires CMS to delay implementation until a thorough and detailed analysis can be performed that results in more accurate payment for all hospitals.

- **This proposed system does not have precedence or transparency.** While the rule provides some description of the methodology for the changes, it does not provide adequate information to calculate the overall impact for the individual measures, nor for the complete proposal. Therefore we urge CMS to wait, at a minimum, until FY2008 to consider making such drastic and sweeping changes until such a time that more thorough and considered analyses can be performed, and a coalition of stakeholders can research the recommendations that will be better accepted by those affected.

- **The 60-day comment period does not allow the stakeholders adequate time to fully evaluate the consequences.** The major changes and the aforementioned errors in methodology require more than the typical 60-day comment period for stakeholders.

- **As such, CMS should continue with the stable, charge-based system that has been in place for 23 years until a better, more accurate alternative can be found.**

We appreciate CMS's efforts to improve the inpatient payment system, and agree that it is our mutual goal to improve the lives of Medicare beneficiaries. We all must work together with diligence and with dedication to address these complex issues.

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Sincerely,

Don Wilson
HMA Corporate Coordinator of Cardiology Services
809 East Marion Ave
Punta Gorda, Florida 33950
941-637-2437
Don.Wilson@crmc.hma-corp.com

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¶

Deleted: Your Name¶
Your Title¶
Your Address¶
Your City, State, ZIP¶
Your Phone¶
Youremail@address.com

cc: Senator Bill Nelson
Senator Mel Martinez
Representative Mark Foley
AHA Representative W. Thomas Deweese

Deleted: cc: Senator A¶
Senator B¶
House Representative from your district¶
American Hospital Association Representative¶
The Federation Representative¶
AAMC Representative¶

Submitter : **Dr. Jeff Williams** **Date: 05/16/2006**

Organization : **University of Pittsburgh Medical Center**

Category : **Physician**

Issue Areas/Comments

DRGs: MCVs and Defibrillators

DRGs: MCVs and Defibrillators

Sir or Madam:

This issue negatively impacts patient care and access to care. This proposal is 'too much, too soon and too fast.' The limited time to review and adjust to such fundamental changes is reason enough for CMS to consider withdrawing this proposal for this year.

Regards,

JL Williams, MD
University of Pittsburgh Medical Center

CMS-1488-P-44-Attach-1.DOC

ATTACHMENT TO #44

16 May 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a large tertiary care center located in Pittsburgh, PA, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation's number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital's ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were "thrown out" of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to "charge compression." The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing

specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient's illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

Jeff

Jeffrey L. Williams, MD, MS

B535 PUH, University of Pittsburgh Medical Center

Pittsburgh, PA 15213

Submitter : **Dr. John Raffoul** **Date: 05/17/2006**

Organization : **White Memorial Medical Center**

Category : **Hospital**

Issue Areas/Comments

DRG Weights

DRG Weights

The steep reduction in the cardiac DRGs weights is causing a great impact on our heart program as, I am sure, it is effecting many other hospitals as well. Cardiac problems are the number one cause of death in the United States. More resources are needed to take care of this problem. I find it very surprising that resources are being taken away for such a critical service, while steep increases are being proposed in less critical areas. Our cost of providing cardiac care has always exceeded the cumulative resources available. Such policy will ultimately reduce access to such critical service and cause program closures nationwide.

Submitter : Ms. Beverly Viertel **Date:** 05/17/2006

Organization : St Luke's Regional Medical Center

Category : Hospital

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Attachment with comments enclosed

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
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 : Ms. Bev Viertel **Date:** 05/17/2006

Organization : St Luke's Regional Medical Center

Category : Hospital

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Attachment with comments enclosted

CMS-1488-P-47-Attach-1.DOC

Attachment #47

St Luke's Regional Medical Center
190 E Bannock
Boise, ID 83712

To: Department of Health and Human Services
Centers for Medicare and Medicaid Services

From: Bev Viertel, RN MS
Director, Clinical Quality and Decision Support

Date: May 17, 2006

Re: File Code CMS-1488-P "Hospital Quality Data"

After reviewing the section on "Hospital Quality Data," we have five areas of comment that we are requesting you to consider in your final proposal:

1) You have indicated that to receive full payment in FY 2007, hospitals will need to include the expanded set of 21 indicators for AMI, CHF, and pneumonia starting with January 1, 2006 discharges. Your proposal will not take effect until October 1, 2006, which is well past the August 15th, 2006 submission deadline for 1st quarter 2006 data. It is incongruent that a final proposal for FY 2007 payments would be based on a retrospective data submission deadline that has already expired.

2) Not all hospitals are currently submitting the expanded measure set. To request that this be completed requires time for facilities, in particular larger facilities, to hire and train the required staff to complete the increased data abstraction, validation, and data entry for submission. This places additional financial burden on hospitals. It would be more reasonable that the expanded measure sets be required with January 1, 2007 discharges.

3) You have indicated that validation guidelines for payments in FY 2007 will be based on the aggregate results for the first 3 quarters of 2005. Again, because additional resources will be in place in order to acquire the data, it seems incongruent that you would use prior results rather than stating an expectation on validations with an effective date that is after data submissions of October 2006 (when the proposal becomes final.)

4) You have indicated that the Secretary of HHS has the authority to determine the measures that need to be reported for full payment. As long as enough lead-time is provided to hospitals to hire the resources and implement necessary processes to accomplish the reporting that is not an issue. Having a minimum of 6 months lead-time is suggested.

5) Finally, you have identified a desire to have hospitals adopt electronic medical records so that data can be submitted directly from that source rather than going through a vendor. This is the direction health care is headed, but it is important to recognize the financial and technical support that will be required to accomplish this. Having at least a 10-year window to accomplish this is a good initial timeframe.

Thank you for your consideration of the above concerns as you develop your final proposal for October 2006.

Submitter : Michael DeMott **Date:** 05/17/2006

Organization : Tri-City Medical Center

Category : Hospital

Issue Areas/Comments

Update Factors

Update Factors

As relates to Core Measures, mandatory submission of SIP measures should be considered for prospective review only. To go back into patient charts to extract historical data (e.g. collect data from Jan. 1, 2005) places a severe burden on hospitals, both in terms of personnel available for this task, and cost.

Submitter : Mrs. Mary Ann Davidson **Date:** 05/17/2006

Organization : Saddleback Memorial Medical Center

Category : Nurse

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

I would like to comment on the proposed chart-audit validation requirement for the RHQDAPU program. Specifications for the quality measures change at least quarterly and sometimes more often. It is almost impossible to keep current with all the rules and interpretations. As a Quality Manager that supervises 4 abstractors I can tell you that we are in permanent white water trying to keep up with all the nuances. The CDAC validation feedback process lags behind the data submission requirements by several months. Therefore, by the time we get feedback that we have mis interpreted an abstaction specification, another quarter of data has been submitted. This resulted in our failing two quarters of audits in a row before we could re-educate the abstraction staff regarding the very confusing "pneumonia as a working diagnosis". Our audit scores before and since those quarters have been > 95%. If you are going to increase the monetary penalties for failure there needs to be more timely feedback so organizations can course correct. My recommendation is that the validation process should take into account at least 6 quarters of data to allow for learning and the constant change of specs.

Submitter : **Dr. Todd Rudo** **Date: 05/18/2006**

Organization : **Lankenau Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 350 bed hospital located in Wynnewood,PA, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

Todd Rudo

Submitter : **Dr. Simone Musco** **Date: 05/18/2006**

Organization : **Lankenau Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

Simone Musco, MD

Submitter : Dr. Andrew Lawrence **Date:** 05/18/2006

Organization : Rush University Medical Center

Category : Physician

Issue Areas/Comments

HSRV Weights

HSRV Weights

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 900 bed hospital located in Chicago, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Andrew Lawrence MD

Submitter : **Dr. Michael Isaac** **Date: 05/18/2006**

Organization : **Sherman Cardiovascular Care Assoc.**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 200 bed hospital located in Sherman, Texas, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Michael Isaac, MD FACC

Submitter : **Mr. Daniel Brinkman** **Date: 05/18/2006**

Organization : **Vanderbilit Univ Medical center**

Category : **Hospital**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an administrator, at a _900 bed hospital located in _Nashville TN_____, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

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Sincerely,

Dan Brinkman

Submitter : **Mrs. deidra culbreth** **Date: 05/18/2006**

Organization : **stern cardiovascular center**

Category : **Nurse**

Issue Areas/Comments

HSRV Weights

HSRV Weights

As a practicing heart rhythm research coordinator at a _500__ bed hospital located in _Memphis, TN. I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

Deidra Culbreth, R.N._____

Submitter : Mr. Paul Spaude **Date:** 05/18/2006

Organization : Borgess Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-56-Attach-1.PDF

CMS-1488-P-56-Attach-2.PDF

Attachment #56

1521 Gull Road
Kalamazoo, MI 49048
(269) 226.4800

Paul A. Spaude
President's Office

BORGESS HEALTH

ASCENSION HEALTH

May 15, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Sir or Madam:

Borgess Medical Center is a 424 bed acute care hospital located in Kalamazoo, Michigan. As a major health care provider in our area, we implant medical devices and perform other cardiac procedures on a significant number of Medicare beneficiaries in the inpatient setting. Because inpatient services are a key component of what we provide, I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to change the way Medicare pays for inpatient services.

First, it adopts a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver cardiology services. Second, it adopts a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. And finally, even within the new CMS methodology, there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by about 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.

With regard to the severity adjustment proposed for next year (FY08), severity does not include the technology costs paid by hospitals for more complex cases. As a result, my technology costs could be underpaid.

The payment methodology changes that CMS has proposed would have a severe financial impact on my hospital – without accurate data to justify the change. This is particularly true for device intensive cardiology DRGs where the proposed payment level is often significantly less than my hospital's actual cost to deliver the service.

The reduction in payment for cardiology services would also have a severe impact on the infrastructure I have built up over the years to treat the number one killer in America today - heart disease. In addition to requiring the potential dismantling of this infrastructure I would now face the uncertainty of knowing that next year, or any other year, CMS could decide to under-fund whatever service area I build up next to meet patient needs. Obviously, as I'm forced to scale back or not develop service capacity due to payment swings and financial uncertainties, patient access could be negatively affected.

I respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity adjusted DRGs should not be implemented until the technology costs incurred by my hospital can be appropriately reflected in the DRG payments.

Thank you for your consideration.

Sincerely,

Paul A. Spaude, FACHE
President & CEO

J. Patrick Dyson
Executive Vice President

Robert Brush, M.D.
Interim Chief Medical Officer

Edward Millermaier, M.D.
CMO and Medical Director
Borgess Ambulatory Care Division

cc: State Senator Tom George
US Representative Fred Upton
US Senator Carl Levin
US Senator Debbie Stabenow
Michigan Health and Hospital Association

Submitter : **Mr. Patrick Dyson** **Date: 05/18/2006**

Organization : **Borgess Health**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-57-Attach-1.PDF

Attachment 57

1521 Gull Road
Kalamazoo, MI 49048
(269) 226.4800

Paul A. Spaude
President's Office

BORGESS HEALTH

ASCENSION HEALTH

May 15, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
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Thank you for your consideration.

Sincerely,

Paul A. Spaude, FACHE
President & CEO

J. Patrick Dyson
Executive Vice President

Robert Brush, M.D.
Interim Chief Medical Officer

Edward Millermaier, M.D.
CMO and Medical Director
Borgess Ambulatory Care Division

cc: State Senator Tom George
US Representative Fred Upton
US Senator Carl Levin
US Senator Debbie Stabenow
Michigan Health and Hospital Association

Submitter : Dr. Robert Brush **Date:** 05/18/2006

Organization : Borgess Health

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1488-P-58-Attach-1.PDF

Attachment #58

1521 Gull Road
Kalamazoo, MI 49048
(269) 226.4800

Paul A. Spaude
President's Office

BORGESS HEALTH

ASCENSION HEALTH

May 15, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Sir or Madam:

Borgess Medical Center is a 424 bed acute care hospital located in Kalamazoo, Michigan. As a major health care provider in our area, we implant medical devices and perform other cardiac procedures on a significant number of Medicare beneficiaries in the inpatient setting. Because inpatient services are a key component of what we provide, I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to change the way Medicare pays for inpatient services.

First, it adopts a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver cardiology services. Second, it adopts a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. And finally, even within the new CMS methodology, there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by about 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.

With regard to the severity adjustment proposed for next year (FY08), severity does not include the technology costs paid by hospitals for more complex cases. As a result, my technology costs could be underpaid.

The payment methodology changes that CMS has proposed would have a severe financial impact on my hospital – without accurate data to justify the change. This is particularly true for device intensive cardiology DRGs where the proposed payment level is often significantly less than my hospital's actual cost to deliver the service.

The reduction in payment for cardiology services would also have a severe impact on the infrastructure I have built up over the years to treat the number one killer in America today - heart disease. In addition to requiring the potential dismantling of this infrastructure I would now face the uncertainty of knowing that next year, or any other year, CMS could decide to under-fund whatever service area I build up next to meet patient needs. Obviously, as I'm forced to scale back or not develop service capacity due to payment swings and financial uncertainties, patient access could be negatively affected.

I respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity adjusted DRGs should not be implemented until the technology costs incurred by my hospital can be appropriately reflected in the DRG payments.

Thank you for your consideration.

Sincerely,

Paul A. Spaude, FACHE
President & CEO

J. Patrick Dyson
Executive Vice President

Robert Brush, M.D.
Interim Chief Medical Officer

Edward Millermaier, M.D.
CMO and Medical Director
Borgess Ambulatory Care Division

cc: State Senator Tom George
US Representative Fred Upton
US Senator Carl Levin
US Senator Debbie Stabenow
Michigan Health and Hospital Association

Submitter : Dr. Ed Millermaier **Date:** 05/18/2006

Organization : Borgess Health

Category : Physician

Issue Areas/Comments

GENERAL

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See Attachment

CMS-1488-P-59-Attach-1.PDF

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cc: State Senator Tom George
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US Senator Carl Levin
US Senator Debbie Stabenow
Michigan Health and Hospital Association

Submitter : **Mr. Edward McDonald** **Date: 05/18/2006**

Organization : **St. Helena Hospital**

Category : **Hospital**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Dear Sirs:

I am commenting on the FFY 2007 CMS proposed regulations to convert the DRG reimbursement system to a cost based methodology. While I support the concept of a CMS reimbursement system based on costs vs. charges, I believe the conversion plan and cost based calculation methodology is flawed and inaccurate.

I do not believe that CMS currently has the ability to properly determine costs on a procedural, or DRG level. The methodology of using overall department cost to charge ratios to calculate DRG level costs understates the costs associated with the more complex and costly procedures. St. Helena Hospital, and I believe most Hospitals, use a descending mark up formula to set the prices of supplies in the charge master. The most expensive supplies and implants receive a very small markup. Lower cost supplies receive a higher markup percentage. Using an overall department cost to charge ratio to determine costs does not capture the true cost of procedures that utilize these expensive supplies and implants. If the goal is to set DRG weights based on accurate cost determinations, the proposed methodology of using overall department cost to charge ratios, does not accomplish this. Hospitals that perform a high share of the complicated, invasive procedures that require costly supplies and implants, are severely penalized for treating the sickest patients. CMS needs to develop a more accurate methodology of determining the actual costs for these procedures.

St. Helena is a community Hospital that developed the first open heart surgery program and cardiac center in the San Francisco North Coast region. St. Helena Hospital has a very busy and progressive cardiovascular laboratory. As such, while we have a small acute inpatient census, we serve as a regional cardiac and thoracic surgery referral center for the rural communities of Napa, Lake and Mendocino counties. Consequently, our discharge distribution is 55% surgical and 45% medical. The published regulations, as they are currently proposed, would severely threaten our ability to continue to provide cardiac and tertiary services for the rural communities in our region.

Than you for considering these comments in evaluating the best methodology of improving the inpatient DRG payment system.

Sincerely,

Edward McDonald
Sr. VP., Finance
St. Helena Hospital

Submitter : **Dr. jeff stidam** **Date: 05/18/2006**

Organization : **university of Louisville**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a ___550__ bed hospital located in ___Louisville, KY____, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

__Jeff Stidam_____

Submitter : **Dr. Jeff Olson** **Date: 05/18/2006**

Organization : **St Vincent Hospital**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a __650___ bed hospital located in __Indianapolis_____, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

_Jeffrey A. Olson, D.O._____

Submitter : **Mrs. Kathleen Poulin** **Date: 05/18/2006**

Organization : **Sierra Nevada Cardiology**

Category : **Nurse**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist at a private physician practice located in Reno, Nevada, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Kathleen Poulin, RN

Submitter : **Mrs. Laurie Newmark** **Date: 05/18/2006**

Organization : **Sierrra Nevada Cardiology Ass.**

Category : **Nurse**

Issue Areas/Comments

HSRV Weights

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Sincerely,

Laurie Newmark R.N.

Submitter : Dr. Craig Cameron **Date:** 05/18/2006

Organization : Baylor University Medical Center

Category : Physician

Issue Areas/Comments

GENERAL

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Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

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Sincerely,

Craig S. Cameron, MD

Submitter : **Dr. Rajjit Abrol** **Date: 05/18/2006**

Organization : **Baylor Heart and Vascular**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

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Rajjit Abrol

Submitter : **Dr. Leo Polosajian** **Date: 05/18/2006**

Organization : **University of CT**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

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Leo Polosajian, MD

Submitter : **Dr. Amit Shah** **Date: 05/18/2006**

Organization : **Cedars Sinai Medical Center**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 700 bed hospital located in Los Angeles, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

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Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

amit shah

Submitter : Ms. June Howland-Gradman **Date:** 05/18/2006

Organization : Ms. June Howland-Gradman

Category : Nurse

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

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Sincerely,

_____

June Gradman, RN

Submitter : **Date: 05/18/2006**

Organization :

Category : **Nurse**

Issue Areas/Comments

EMTALA

EMTALA

I am concerned that under the new rule a non-physician could identify false labor. The US, as one of the more advanced contries in the world should have less premature labors, less mal-formed and mal-presented neonates in the world. Because our nation allows nurses to perform physcian duties, and physicians with limited scope and education to 'deliver' patients, we are in the same ranking as many third world countries. I would say that a physician, and one who has demonstrated competency and specialty in obstretrics is the one who determines not only false labor, but active labor.

The proposed change that 'any' hospital with specialized capabilites to treat a patient - even if there is no dedicated ED is an excellent move. The private sector psychiatric hospitals have been 'protected' if you will from EMTALA complaints because there is no position that they must take a patient if they do not provide emergency services. Yet many such hospitals hold an 'emergency' bed for such patients! The end result is true dumping into the not-for-profit facilities. And EMTALA was created just for the purpose to prevent dumping.

Submitter : **Dr. Hina Siddiqui** **Date: 05/19/2006**

Organization : **Univ of Tx-Houston**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a _300____ bed hospital located in __Houston, TX_____, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

__Hina Siddiqui, MD_____

Submitter : **Dr. James Strickland** **Date: 05/19/2006**

Organization : **University of Texas- Houston**

Category : **Physician**

Issue Areas/Comments

GENERAL

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Sincerely,

James Strickland, MD

Submitter : **Mr. Fred Williams** **Date: 05/19/2006**

Organization : **Kaiser Permanente Mid- Atlantic**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, at a major managed care orginization, located in Mid-Atlantic, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Fred m Williams, RCIS
Pacemaker and ICD Clinic Coordinator

Submitter : **Dr. JASVINDER SIDHU** **Date: 05/19/2006**

Organization : **BAYLOR COLLEGE OF MEDICINE**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a cardiology fellow at a _400____ bed hospital located in Houston_____, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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JASVINDER S SIDHU

Submitter : **Dr. Mitchell Cohen** **Date: 05/19/2006**

Organization : **Arizona Pediatric Caridiology Consultants**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

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Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 250bed hospital located in Phoenix, AZ, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Submitter : **Dr. Jennifer Avari** **Date: 05/19/2006**

Organization : **St. Louis Children's Hoapital**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

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Jennifer Avari, MD

Submitter : Dr. Anthony Navone **Date:** 05/19/2006

Organization : Cardiology PC

Category : Physician

Issue Areas/Comments

HSRV Weights

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Sincerely,

Anthony J. Navone, MD, FACC

Submitter : Mrs. Dawn Silvestri **Date:** 05/19/2006

Organization : Baystate Medical Center

Category : Nurse

Issue Areas/Comments

GENERAL

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Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

____Dawn Silvestri, RN_____

Submitter : **Dr. Rafael Pena** **Date: 05/19/2006**

Organization : **MCV-VCU**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 700 bed hospital located in Richmond (VA), I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Rafael E. Pena, MD

Submitter : **Ms. Susan Lattanzi** **Date: 05/19/2006**

Organization : **Baystate Medical Center**

Category : **Nurse**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing nurse manager in an electrophysiology lab, at a 600 bed hospital located in Springfield MA, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

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Susan Y Lattanzi RN BSN

Submitter : **Phyllis Styspeck** **Date: 05/19/2006**

Organization : **Mercy Medical Cemter**

Category : **Nurse Practitioner**

Issue Areas/Comments

HSRV Weights

HSRV Weights

As a practicing electrophysiology Nurse Practitioner, at a 250 bed hospital located in Massachusetts, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Phyllis Styspeck, FNP-c

Submitter : Dr. Francisco Perez **Date:** 05/19/2006

Organization : MCV-VCU Medical Center

Category : Physician

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 700 bed hospital located in Richmond, VA, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Francisco J. Perez, MD

Submitter : **Dr. Yumiko Kanei** **Date: 05/19/2006**

Organization : **Beth Israel Medical Center**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing cardiologist, at a __550___ bed hospital located in __New York_____, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Yumiko Kanei, MD_____

Submitter : Dr. Robert Canby **Date:** 05/19/2006

Organization : Texas Cardiovascular

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at several 400 bed hospitals located in central Texas, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Robert Canby

Submitter : **Dr. meir friedman** **Date: 05/19/2006**

Organization : **beth israel medical center**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing cardiology fellow, at a _600__ bed hospital located in _NY____, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Meir friedman

Submitter : **Dr. Prashant Sinha** **Date: 05/19/2006**

Organization : **Columbia University Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

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Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing cardiac surgeon at a 1000 bed hospital located in New York City, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Prashant Sinha,MD

Submitter : Dr. Matthew Levy **Date: 05/20/2006**

Organization : University of Washington Medical Center

Category : Physician

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 500 bed hospital located in Seattle, Washington, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

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Matthew T. Levy, MD

Submitter : **Ms. Jessica Khatri** **Date: 05/20/2006**

Organization : **Meritcare Medical Group**

Category : **Nurse**

Issue Areas/Comments

HSRV Weights

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: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

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Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

Jessica S. Khatri RN

Submitter : **Dr. A B** **Date: 05/20/2006**

Organization : **Dr. A B**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a _____ bed hospital located in _____, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Submitter : Dr. Sean Mazer **Date:** 05/20/2006

Organization : Columbia University

Category : Physician

Issue Areas/Comments

HSRV Weights

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Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 800 bed hospital located in New York, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Sean Mazer, MD

Submitter : **Dr. Tariq Salam** **Date: 05/20/2006**

Organization : **Cardiac Studies Center, Inc. , PS**

Category : **Physician**

Issue Areas/Comments

DRGs: MCVs and Defibrillators

DRGs: MCVs and Defibrillators

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a hospital located in Tacoma WA, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Tariq Salam, MD FACC

Submitter : Dr. Leo Polosajian **Date: 05/21/2006**

Organization : University of Connecticut

Category : Physician

Issue Areas/Comments

HSRV Weights

HSRV Weights

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 350_ bed hospital located in __Hartford_____, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Submitter : **Dr. Rajiv Verma** **Date: 05/21/2006**

Organization : **Hamilton Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 300 bed hospital located in dalton, Georgia, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Rajiv Verma MD, FACC

Submitter : Mrs. Margaret McLamara **Date:** 05/21/2006

Organization : Trinity Health System

Category : Nurse

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Comment regarding: Hospital Quality Data.

Organizations were initially required to select reporting for two orxy measures. Eventually this number was increased to three categories. According to the proposed changes, an additional category is to be selected for those organizations which did not select the surgical improvement category. Our organization began with Heart Failure and Pneumonia. We then added Acute MI. While it is agreed monitoring and improving our performance for care of the surgical patient is very important, the retrospective suggested requirement for data collection does come with some additional burden.

It would be extremely beneficial when rules/requirements are to be implemented, the implementation be considered to be prospective, versus retrospective. The proposed requirement calls for collection of data for specified procedures from January 2006. Our facility intends on focusing on the surgical patient, monitoring our performance and making improvements. We are designing our process so that this process will be evaluated concurrently in order that appropriate interventions take place while care is being delivered. Therefore as we design this process, the retrospective data collection requirements additional place a burden in pulling discharged records, assigning data collection responsibilities as well as data entry.

This entails two performance improvements initiatives, one retrospective and one prospective. In todays healthcare arena, some organizations may not be in a position in which they have staff that are in place to take on additional duties without impacting current responsibilities. Sufficient time must be allotted for quality planning.

Submitter : Mrs. Judy Wilson **Date:** 05/22/2006

Organization : Park Nicollet Health Services

Category : Other Health Care Professional

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

The proposed requirement to collect data retroactively to January 1st on the 21 Quality Measures will put a data collection burden on most hospitals. PNHS' would propose the data collection start with July 1st 2006 discharges, to allow Hospitals a chance to prepare for the additional resources required to collect this data.

Submitter : Mr. **Date:** 05/22/2006

Organization : Mr.

Category : Hospital

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Addition of SIP to measure set for discharges on or after January 1, 2006 is absurd and should be delayed to July 1, 2006. This will allow hospitals to hire and train staff to collect these measures.

Submitter : **Francine Baia** **Date: 05/22/2006**

Organization : **Hernando Healthcare**

Category : **Hospital**

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Good Day. The following are concerns/comments/questions after reviewing the proposal for changes to the IPPS for Operating Costs and GME Costs in Vol 71, No 79 pg 97.

The reduction in payment for hospitals not meeting the indicated standards are proposed to be across the board whereas, the incentive seems to only affect the Premier hospitals and not expanded to all participating hospitals. The incentive would best serve the communities by providing the financial boost to those who have shown improvement from base-line data. This would also encourage participation in sharing methods that prove effective for compliance (better outcomes for patients) rather than a competitive atmosphere (benefiting only those hospitals with the resources to try various methods).

The number of indicators should be expanded, however, there should be an added option to the validation process whereby, any indicator can be appealed even if overall validation score is greater than 80%. This change would allow hospitals an opportunity to improve validation scores that may affect market basket payments should they have a poor performance limited to a single quarter.

Submitter : Mrs. Vicki Fridle **Date:** 05/22/2006

Organization : Medical Center of Southeastern Oklahoma

Category : Other Health Care Professional

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

We should be allowed to appeal any validation score, not just the ones below 80%. The reviewers have missed some of the required documention when they have done their reviews--stating that there is no documentation when we know that the documentation is present. Since you are averaging the quarterly results, we need to be able to clarify and correct any and all incorrect reviews done by the CDAC reviewers.

Submitter : Mrs. Vicki Camp **Date:** 05/22/2006

Organization : Swedish Medical Center

Category : Nurse

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

I would like to register my objection to the requirement that the submission of Surgical Infection Prevention (SIP) data for the 2007 Annual Payment Update Reference be retroactive to the beginning of calendar year 2006. I request that hospitals be given a begin date that is not retroactive so as to not cause an undue burden. To date the SIP measure has not been a requirement for core measures, simply an option. Thank you for your consideration.

Submitter : **Dr. Lisa Abrahams** **Date: 05/23/2006**

Organization : **SMDC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-100-Attach-1.DOC

I would like to express my concern about the proposed change to the inpatient payment rule for FY07 as it relates to cardiology services. Specifically I am concerned about the effect on implantable devices such as Stents and pacemakers and defibrillators.

These changes will have a negative effect on patient care in our institution. I think if you want to cut costs and save money it would be better to go after the over utilization of services. Ask yourselves: Why is there a marked difference in length of stay and ICU days per patient depending on where you live?

We have a respectable length of stay and are not over users of services. Cutting our reimbursement will have a significant impact on our ability to deliver care. Please do not cut our device reimbursement.

Submitter : **Dr. Robert Goldstein** **Date: 05/24/2006**

Organization : **Univ Hosp of Cleveland/CWRU Medical School**

Category : **Physician**

Issue Areas/Comments

DRGs: MCVs and Defibrillators

DRGs: MCVs and Defibrillators

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 750 + bed hospital located in Cleveland, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Sincerely,

Robert N. Goldstein, M.D.

Submitter : **Dr. Mark Kestner** **Date: 05/24/2006**

Organization : **Legacy Health System**

Category : **Hospital**

Issue Areas/Comments

Impact Analysis

Impact Analysis

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

Open Comment regarding CMS-1488-P
Proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2207 Rates

Response to CMS assessment on page 337 that this requirement will not pose a significant burden on hospitals as they are already submitting the data to JCAHO. JCAHO only requires submission on three populations. This proposed new rule will affect hospitals that do not currently submit Surgical Infection Prevention (SIP) as part of their Core Measures submission process. The proposed CMS rule expects hospitals to begin submitting SIP data starting with 1st quarter 2006 discharges. This 1st quarter data will need to be submitted to QNet by August 15, 2006. Third party vendors will require this additional data submission by June 30, 2006 in order to meet the August 15th submission. This is an unrealistic expectation.

The data validation process for accuracy is still subject to large fluctuations in interpreting the data dictionary guidelines. The large number of postings on the Qnet FAQ validates the confusion that exists with abstracting guidelines.
As addressed by The Government Accountability Office (GAO) there are also significant issues with the completeness and adherence to sampling requirements.

Submitter : Dr. Richard Greenberg **Date:** 05/24/2006

Organization : Temple University

Category : Physician

Issue Areas/Comments

DRGs: MCVs and Defibrillators

DRGs: MCVs and Defibrillators

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a large hospital located in Philadelphia, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

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Submitter : Dr. George Frangos **Date: 05/24/2006**

Organization : SUNY Downstate Medical Center (Brooklyn, NY)

Category : Academic

Issue Areas/Comments

GME Payments

GME Payments

May 24, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

Attention: CMS-1488 P Resident Time in Patient-Related Activities

Dear Administrator McClellan:

The State University of New York (SUNY) Downstate Medical Center welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

We strongly urge the CMS to rescind the purported clarification in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician s office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care .

This position is in stark contrast to CMS s position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. We concur with CMS s 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

With the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician s educational development into an autonomous practitioner.

To reiterate, we urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

George Frangos
Associate Dean for Graduate Medical Education
and Designated Institutional Officer
SUNY Downstate Medical Center
450 Clarkson Avenue
Brooklyn, NY 11203-2098

Submitter : Dr. Ruel Wright **Date:** 05/24/2006

Organization : Illinois Cardiovascular

Category : Physician

Issue Areas/Comments

Impact Analysis

Impact Analysis

The proposed hospital inpatient payment rule for FY07 is flawed in it's methodology and would create severe negative impact on Medicare beneficiaries with life threatening cardiac disease. The reduction in payments for such devices as stents, ICDs, and pacemakers will restrict the number of Medicare beneficiaries receiving these therapies. The result will be increased mortality and morbidity and increased cost of future care due to lack of treatment. I urge CMS to reconsider the proposed changes which employ unproven and flawed methodology.
Thank you.

Submitter : **Date: 05/25/2006**

Organization :

Category : **Nurse**

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

I currently collect and submit the data required for CMS, JCAHO, HQA and APU, at the hospital I am employed at. The data has been based on AMI, PN, and HF. It is already very time consumming to collect this data. Adding the SIP measure will require time and planning. If you are going to pass this proposal please reconsider the time frame. Going back retrospectively to January 1,2006 is asking too much when hospitals are already overwhelmed with what has to be collected. I would prefer that nothing change but if it has to, then give us some time to add the measure. Thank you for listening.

Submitter : **Dr. Jon Lehrmann** **Date: 05/25/2006**

Organization : **Medical College of Wisconsin**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter.Sincerely,
Jon A. Lehrmann, M.D.

CMS-1488-P-107-Attach-1.TXT

May 25, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

Attention: **CMS-1488—P "Resident Time in Patient-Related Activities"**

Dear Administrator McClellan:

The Department of psychiatry and Behavioralmedicine at the Medical College of Wisconsin welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006). We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. We concur with the Agency's 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

At the department of Psychiatry and Behavioral Medicine at the Medical College of Wisconsin, we have many affiliate hospitals where our residents rotate (clearly a strength of our training program is the diversity of sites and patient populations). This has made it

necessary to have a centralized office and classroom space that is not in the hospital (nor would it be fair to the other affiliates to base ourselves in one hospital where there would be better funding with the new proposal). At our department's home base, our residents have Wed morning didactics and case conferences. It would be ridiculous to say that these didactics which cover everything from psychopharmacology to psychotherapy and evidence based medicine did not benefit patient care.
To reiterate, we urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Jon A. Lehrmann, M.D.
Residency Training Director
Department of Psychiatry and Behavioral Medicine
Medical College of Wisconsin

Submitter : **Dr. John Murphy** **Date: 05/25/2006**

Organization : **Rhode Island Hospital/Brown Medical School**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

5/25/06

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

Attention: CMS-1488 P Resident Time in Patient-Related Activities

Dear Administrator McClellan:

Rhode Island Hospital welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006). We strongly urge the Agency to rescind the purported clarification in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
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Residency Program Activities and Patient Care
With the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician s educational development into an autonomous practitioner. Didactic activities such as journal clubs, classroom lectures, and seminars are directly related to patient care activities and resident time spent in these activities should not be excluded from IME and DGME payments.

To reiterate, we urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

John B. Murphy, MD
Director of Graduate Medical Education and DIO, Rhode Island Hospital
Professor of Medicine and Family Medicine, Brown Medical School
Aldrich 120, Office of Graduate Medical Education
Rhode Island Hospital
593 Eddy St
Providence, RI 02903
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401-444-5088 (fax)
Jmurphy5@lifespan.org <mailto:Jmurphy5@lifespan.org>

CMS-1488-P-108-Attach-1.DOC

President Bush's 2007 Budget
Selected Summary

HRSA Programs:

Health professions training programs – reduced to zero, from $99 m currently. The exception is the scholarships for disadvantaged students which would be funded at $10 m, down from $47 m.

Children's Hospital GME – takes a big hit this year, down to $99 m, from $296 in FY06

Bioterrorism Training and Curriculum Development - $12 m, down from $21 m.

Rural Health - $27 m, down from $160 m

Winners:

- Nursing training programs – to be funded at current levels - $150 m
- National Health Service Corps – level funded at $126 m
- Community Health Centers – Increased from $1.8 billion to just under $2 billion.

Centers for Disease Control:

CDC takes a hit this year – down$179 m for a total of $8.2 billion in program level dollars. Also includes reductions of $367 m from other sources such as vaccines for children and PHS evaluation transfers, leaving CDC with a discretionary budget authority of $5.8 b, rather than the current $6.2 b in budget authority. The biggest loss areas include: building and facilities (-129m), preventive health and health services block grant (-99m), public health improvement and leadership (-75m), chronic disease prevention and health promotion (-20m).

NIH:

NIH received level funding overall in the budget this year, at $28.6 billion. However, within NIH there was some shifting of funding. $40 m from the NCI, $21 m from NHLBI, $11 m from NIDDK, $10 m from NINDS, $12 m from the NIGMS, and lesser amounts from other institutes were shifted mainly to the Office of the Director ($140 m) with a smaller amount ($12 m) to the NIAID.

Specific new or increased authorities within NIH include:

- $1.9 b for NIH biodefense efforts, a net increase of $110 m, a 6.2% increase

- New $160 m within the Office of Director appropriation to devote to the advanced development of biodefense countermeasures that are priority Project BioShield acquisition targets. This represents a comparable $110 m increase over the $50 m included within the FY2006 base of the NIAID.
- Also included in the Office of the Director is $96 m, the same level as in FY06, to continue targeted research efforts devoted to developing medical countermeasures against nuclear, radiological, and chemical threats that could be used as weapons of mass destruction.
- In support of the HHS Pandemic Influenza Preparedness Plan, the FY2007 request is $35 m in NIH to expand international and domestic pandemic influenza research, an increase of $17m over FY06.
- **NIH Roadmap**: An increase of $113 m, over FY06, to a total of $443 m to continue support of the Roadmap, including $111 m, an increase of $28 m, in the Office of the Director, and $332 m, an increase of $85 m, in the budgets of the Institutes and Centers for use in a coordinated effort to support the Roadmap.
- **New Investigators**: $15 m to establish a new program to provide increased and stable support for new research investigators, with NIH identifying and tracking the progress toward research independence of all predoctoral and postdoctoral researchers supported by NIH, regardless of funding mechanism.
- **Clinical Research Translation**: Developed a new Clinical and Translational Science Award (CTSA) program. The goal is to provide the academic home and integrated resources necessary to advance a new intellectual discipline of clinical and translational sciences, create and nurture a cadre of well-trained investigators, and advance the health of the nation by transforming patient observations and basic discover research into clinical practice. FY07 funding for CTSA is estimated to be $361 m, which includes an additional $3 m requested in NCRR for this program.

AHRQ:

AHRQ remains in a steady state, with funding planned to be the same for FY07 as it was for FY06 and FY05. Initiatives within AHRQ that will continue to be funded at the same rates as before include: Health Information Technology Initiative ($50m), Other patient safety ($34m), Quality and Cost effectiveness research ($162) and Medical Expenditures Panel Surveys ($55m). The newest program area the Administration is emphasizing is the Effective Health Care program which includes three components: Comparative Effectiveness Reports, (building on existing 13 Evidence-based Practice Centers), Network of Research Centers (a new network of 13 developing Evidence to Inform Decisions about

Effectiveness research centers (DEcIDE)), and Making Findings Clear for Different Audiences.

Medicare:

The budget includes several FY07 legislative initiatives. If included in law, the net savings of the package would be $2.5 b in FY07 and $35b over 5 years. The proposals include:

- Fostering productivity: zero percent payment update for SNF, home health agencies and inpatient rehabilitation facilities. For hospitals, an update of the market basket minus 0.45%. In 2008 and 2009, the payment update for all of these provider categories would be market basket minus 0.4 percent. Also proposed is a .4% reduction for hospice and ambulance services for each of the years 2007-2009.
- Clarifying secondary payer rules, especially with respect to Durable Medical Equipment (DME).
- Provider payment reforms that "encourage quality" and promote more efficient and high quality physician services." It emphasizes the Administration's focus on holding providers accountable for quality care. The budget points out the portion of the CMS website that allows consumers to compare hospitals, skilled nursing facilities, etc., and also underscores the new voluntary reporting system for physicians. The document states that the Administration continues to "support provider payment reforms that would encourage quality and efficiency" and "differential updates initially for physicians that report on quality measures and later for physicians that achieve efficient and high-quality care." Building on the Medicare Modernization Act, the budget includes a legislative proposal whereby action is required by Congress when the portion of Medicare funded by dedicated revenues falls below adequate levels. If Congress does not act, then the system requires a slowdown in the rate of growth, i.e., four-tenths of one percent reduction in all payments. This reduction would continue by four-tenths of one percent every year unless the shortfall was eliminated, or, the Congress enacted other reforms.
- Require higher income beneficiaries to pay a greater share of the part B premium beginning in 2007.
- Offer of new Medicare-based Health Savings Accounts.
- Laboratory competitive bidding.
- Assorted hospital and other proposals.

Medicaid:

The budget provides $199.45 billion for Medicaid in FY 2007, an increase of $7.11 billion from FY 2006. It commends Congress for passing the Deficit Reduction Act (DRA), particularly since it "achieves savings in Medicaid while promoting effective Medicaid policy."

- Includes a new waiver initiative encouraging market-based approaches to health care. The goal of the waiver process is to "broaden choices and encourage competition in the private market."
- The Administration also stresses that it believes recommendations from the Medicaid Commission, as well as the DRA, will provide the foundation for future reforms.
- Rein in states' use of intergovernmental transfers. Specifically, cut down on these activities and "identify and recover diverted payments."
- Work on program integrity within Medicaid and the State Children's Health Insurance Program (SCHIP), building on current efforts to measure incorrect Medicaid and SCHIP payments and start reporting error rates.
- Allow the states to use managed formularies in their Medicaid programs.

Submitter : **Dr. Bradley Knight** **Date: 05/25/2006**

Organization : **University of Chicago**

Category : **Physician**

Issue Areas/Comments

DRGs: MCVs and Defibrillators

DRGs: MCVs and Defibrillators

The proposed payments for implantable defibrillators for 2007 is clearly inadequate based on the fact that the reimbursement is less than the cost of the device.

Submitter : Dr. James Kennedy **Date:** 05/25/2006

Organization : Individual

Category : Physician

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

I write to comment on the potential implementation of Consolidated Severity-Adjusted DRGs.

I trained as a internal medicine physician in 1979. In 2001, I received Certified Coding Specialist credentials from the American Health Information Management Association. Over the past five years, I have worked with over 25 hospitals to help their medical staffs accurately document illness severity using ICD-9-CM terminology and to educate coders in appropriate query processes required by ICD-9-CM.

I believe that the refinement in illness severity proposed is a good idea. I see difficulties in using 3M's APR-DRG versions for the following reasons:

1) While the APR-DRG methodology was made freely available to commenters with the announcement of the CSA-DRGs, 3M had previously required an interested individual to pay $400 for this information. I had access to it only because I helped a hospital in Maryland implement their APR-DRG education program using their license. Practically no one besides 3M truly understands how the methodology works.

2) The "CC" methodology under APR-DRGs is so different than that with Medicare that coders and physicians will have to relearn most everything they currently know about DRGs. For example, stable angina is a CC in Medicare but is not a CC in APR-DRGs. To qualify for a CC in CSA-DRGs, physicians will have to use the rarely considered term "angina at rest". Currently, Medicare does not split pancreatitis (DRG 204) into severity levels. While APR-DRGs do split pancreatitis into its 4 severity-levels, physician have to use the uncommon term of "SIRS due to a non-infectious cause" for APR-DRGs to appropriately work.

3) 3M has not made APR-DRGs available to consultants to help hospitals understand how to use it, even when APR-DRGs became the payment methodology for inpatient care in Maryland in July, 2005. If a hospital wanted to understand how to use APR-DRGs, they had to hire 3M. Should CSA-DRGs be approved by CMS, practically no one outside of 3M will be able to train hospitals in how to appropriately document and code its records to accurately and compliantly reflect severity of illness. 3M's DRG Assurance program is one of the most expensive in the country; for them to have the monopoly as to maintain their high consulting rates will be a burden upon other providers.

3) 3M's website, http://www.aprdrgassign.com, is a wonderful website. My concern, though, is that once the comment period is over, that website will be dismantled. I will lose my only tool I have available to learn about CSA-DRGs.

4) I currently use an encoder from HSS to audit my medical records. I would have wanted to use a 3M encoder; however their fee for one license was over $25,000/year. HSS charges me less than $3000 a year. HSS tells me that they can't even get the APR-DRG grouper for me to use with their software. When I inquired with 3M about an APR-DRG license, I was told that I had to buy their Medicare license first. I predict that if Medicare CSA-DRGs is implemented, the only vendor that will have software capable of using it will be 3M. It happened in Maryland that way; it likely will happen to everyone else.

5) I understand that an alternative methodology is being proposed, HSS's All-Payer Severity Model. I have been accustomed to using APS-DRGs for the past 5 years through my affiliation with The Delta Group in Greenville, SC. APS-DRGs is the severity-adjustment methodology for several state's all-payer data, including my home state of Tennessee. While information about this methodology is not as well published as APR-DRGs, from what I understand is that it is similar to Medicare's current methodology and allowed for the "Major CCs" seen in APR-DRGs. I believe you will find this to be an easier transition for hospitals rather than the "black box" APR-DRGs.

I thank you for listening to my comments. I may be reached at 615-223-9290 or JKennedyMD@vp-ma.com. Jim Kenned

Submitter : **Dr. Gregory Michaud** **Date: 05/26/2006**

Organization : **Lahey Clinic Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates:

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a tertiary care hospital located in Burlington, MA I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents additional personnel the hospital has had to hire for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center, such as ours.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand its impacts and so that CMS devotes the time necessary to get this right.

Sincerely,
GF Michaud, MD

Submitter : **Date: 05/26/2006**

Organization :

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS - 1488-P:

I am concerned that the data and formula's being used to determined these changes do not provide satisfactory information such that appropriate changes can be determined. These changes will hurt the community in total but more specifically will be detremental to the individual patients over time.

Please reconsider these proposed actions steps until more reliable information is available.

Respectfully Submitted.

MedPac Update Recommendation

MedPac Update Recommendation

I am concerned about the methodology utilized to obtain the information used to determine new rates under this proposed plan. I would ask that you reconsider the proposed changes until more reliable information is available. The changes as written will be detrimental to the communities which translates into patients being negatively affected by these proposed changes.

Respectfully Submitted.

Submitter : Diane Wolff **Date:** 05/26/2006

Organization : Diane Wolff

Category : Nurse

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Hospital Quality Data

Prior to initiating payment according to validation scores, more attention should be focused on improving the current data submission process and the process for appealing validation scores.
The rules for abstraction change too frequently, sometimes on a weekly basis. Using Quest as a repository of answers to abstraction questions has become a nightmare and it is impossible for abstractors to keep up with the ever-changing opinions to questions asked. One can query Quest for a question and receive any number of varying and contradicting answers based on how the question is asked. One only needs to sit with a room of abstractors and ask a How do you abstract this question to understand the flaws in the current system. There are infinite numbers of patients that stray from the normal pattern of care that require the abstractor to seek assistance on how to answer the measure. It is these questions that require assistance from Quest and the answers to the question are many and varied. Basing hospital reimbursement on such chaos is unfair.
Second is the appeals process. One can only appeal the CDAC s decision if the validation score is less than 80%. Many times there are discrepancies when the score is above 80% and the only recourse is to notify the QIO, the score can never be affected. The cumulative score will be directly affecting the hospital reimbursement. If a hospital receives scores of 80%, 80%, 80%, and 74%, this may negatively affect the reimbursement. The score of 74% can be appealed if errors are noted but the scores of 80% cannot, so if there are errors by CDAC in these measures there is no recourse to affect the score.
In summary, before expanding the program that could cost hospitals reimbursement money the program should be nearly flawless. This program has not reached that plateau.

Respectfully submitted

Submitter : Mrs. Terrie Bauer **Date:** 05/29/2006

Organization : Saint Luke's Hospital of Kansas City

Category : Nurse

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Financial impact - if enacted, this will change our reimbursement for public reporting from 0.4% to 2.0% - that's 1.75 million dollars for our hospital.
1.CMS is asking hospitals to "go back" and abstract data as of January 1. This is an alarming precedent to set since it would require significant HR activity for those hospitals who have to "catch up" and what's more, why are we being judged on something retrospectively (or after the fact)?
2. The measures as outlined will increase from the current measures of 10 to 21. This will also make a significant impact on hospitals as they will need to hire or reassign these abstraction duties to staff for these additional indicators.
3. In order for a hospital to achieve full market reimbursement, they must have "validated" data. For this to occur, on a quarterly basis, CMS requests 5 records from each hospital throughout the U.S. They reabstract records we have already provided to them and their data abstractors must agree with our data abstraction at a rate of 80% or greater. When we get our validation rates back, we review these records from front to back so that we can learn from our mistakes. More often than not, we discover that it is not our hospital who errored but CMS Clinical Data Abstraction Center. If they made the mistake but the mistake did not result in us "failing" validation (i.e., we still had a score >80%), CMS will not allow us to appeal their incorrect decision. With this new regulation, 3 quarters will be combined and an overall score will be awarded. If, for example, the hospital barely pass (through no fault of their own as outlined above) and they then flunked just one quarter, their reimbursement will be significantly impacted for 3 quarters because of this roll up.
4. Significant amount of funds will be dependent upon indicators which reflect poor reliability, i.e., whether or not a patient has a "working diagnosis of pneumonia." One record where there is a disagreement between hospital and CMS can "invalidate our data for the quarter" which will impact our reimbursement.
5. Last, but not least, we will not even know whether or not this mandate will go into effect until after our January 1 data is due. As a result, hospitals will have to turn in their 1st quarter data (21 measures) assuming the law will go into effect.

Submitter : Dr. John Welton **Date:** 05/30/2006

Organization : Medical University of South Carolina

Category : Academic

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

See Attachment

DRG Weights

DRG Weights

See attachment

DRGs: Severity of Illness

DRGs: Severity of Illness

See Attachment

GENERAL

GENERAL

See Attachment

HSRV Weights

HSRV Weights

See Attachment

Hospital Quality Data

Hospital Quality Data

See Attachment

CMS-1488-P-115-Attach-1.PDF

Attachment # 115

THE COLLEGE OF NURSING
THE MEDICAL UNIVERSITY OF SOUTH CAROLINA

99 Jonathan Lucas Street
PO Box 250160
Charleston, SC 29425

May 30, 2006

Mark B. McClelland, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8011
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1488-P** "Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates"

Dear Dr. McClelland,

Enclosed is a counter proposal to CMS-1488-P to directly incorporate nursing costs and nursing intensity into the revised hospital reimbursement formula. Nursing care represents approximately 30% of all hospital expenditures and nearly half of all direct care costs. The current Part A inpatient prospective payment system (IPPS) uses the medical diagnosis as the sole determinant of payment – essentially ignoring the contribution of nurses to patient care at US hospitals. Recent studies have indicated that nursing care has both an independent outcome and cost function related to hospitalization. The enclosed nursing proposal meets the stated goals of CMS to align future hospital payment with actual costs expenditures by incorporating direct and indirect nursing costs for individual patients and uses nursing intensity for severity of illness adjustment within the APR-DRG severity weights as discussed in the proposed rule. Data from the Medical University of South Carolina are provided to map nursing intensity and nursing costs within the APR-DRG severity adjustment framework as a potential model.

The specific **recommendations** of the nursing proposal are:

1. [DRG Weights] Create a unique **Nursing Cost Center** (NCC) within each provider hospital that identifies the inpatient direct and indirect costs expended by registered nurses, licensed practical nurses, and unlicensed assistive personnel. **Direct nursing costs** are those associated with licensed and assistive nursing personnel assigned to care for an individual patient. **Indirect nursing costs** are all other salary and benefits related to licensed and assistive nursing personnel not directly assigned to care for individual patients. The annual Medicare Cost Report (MCR) will be modified to reflect these new line items and will include an estimate of the mean daily direct and indirect nursing costs expended for patient care (cost per patient day). The Nursing Cost Center will replace the proposed routine and intensive care cost centers noted in the Hospital Specific Relative Value cost center (HSRVcc) methodology. We propose a second Facility Cost Center (FCC) to identify the non nursing cost component of care. The nursing cost center data will be used to adjust for the variable component of hospital nursing care described below.
2. Collect **Nursing Intensity** (NI) data that identifies the daily expended direct hours of care for each patient by registered nurses, licensed practical nurses, and unlicensed assistive personnel assigned to care for each individual patient. Daily direct nursing costs will be the product of nursing intensity and mean hourly wage for each.
3. Summarize nursing intensity and nursing costs for each patient hospital stay as 1) a hospital **mean nursing intensity**, 2) **direct nursing costs** for the hospitalization as the sum of daily direct nursing costs for RN, LPN, and UAP, 3) **Indirect nursing care costs** as the product of the mean daily indirect nursing costs and length of hospital stay. Total nursing costs for each discharge will be the sum of direct and indirect nursing costs.

4. New nursing data will be added to the hospital discharge abstract and summary billing abstract for each hospitalized patients as follows: mean nursing intensity, direct and indirect nursing care costs.
5. [DRGs: Severity of Illness] Adjust the DRG payment based on the mean direct and direct costs of nursing care within each severity weight of the proposed **APR-DRG severity adjustment formula**. We recommend that CMS aggregate national hospital discharge data to calculate normative national and regional nursing intensity and nursing cost data to be used in the APR-DRG severity adjustment formula. Actual dollar adjustment of hospital payments will be determined by mean percent of nursing costs (direct and indirect) of total hospital costs. Any new IPPS payment formula incorporating nursing intensity will be cost neutral and not require additional expenditures by CMS for Part A reimbursement to hospitals.
6. [Hospital quality data] We recommend that CMS, in conjunction with national nursing organizations and researchers use the new nursing intensity and nursing cost data to identify the distribution of severity adjusted nursing resources at US hospitals and produce a method for comparing nursing care across hospitals.
7. Sufficient funds are requested to **study and implement** the above recommendations using methodologically sound research and demonstration projects.

It is the overall intent of CMS to change the current prospective payment system to better reflect the cost of care and accommodate varying levels of severity of illness.[1] This public comment advocates a strategy to accomplish those two goals by adjusting DRG payments using nursing care as the cost basis and nursing intensity as a variable measure of patient severity of illness. Supporting information and study findings are detailed in the following sections.

This proposal to adjust the DRG by incorporating nursing care into the payment formula is a product of ongoing research and clinical care at Medical University of South Carolina Medical Center and College of Nursing. The nursing proposal has received broad support within the US nursing community and other health providers and organizations. We have asked individuals and organizations to reply separately to this proposal via the public comment mechanism.

Sincerely,

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[1] http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/cms1488p.pdf

Background and Significance

Nursing care accounts for 30% all hospital expenditures and nearly half (44%) of all direct costs of care (Kane & Siegrist, 2002; McCue, Mark, & Harless, 2003; Thompson & Diers, 1991). Approximately 58% of the 2.7 million registered nurses in the US (1,341,840) work in hospitals (U.S.Department of Labor Bureau of Labor Statistics, 2006). In 2004, US hospital expenditures totaled $551 billion (Heffler et al., 2005). Based on the above, hospital nursing care accounted for approximately $165 billion in total expenditures for the period. Heffler predicts that hospital expenditures will double by 2014 and the expected nursing expenditures could reach an unprecedented quarter of a trillion dollars in the coming years.

One of the primary reasons nursing costs have soared over the past several years is the increasing complexity of care and decreasing lengths of stay (Graf, Millar, Feilteau, Coakley, & Erickson, 2003). This rise in patient acuity has created a greater demand for nurses in hospitals, an upward pressure on wages, and a need to decrease patient to nurse staffing ratios. This compression of days of stay has also created greater variability in nursing care needs of hospitalized patients and increased nursing intensity measured as hours of direct nursing care per day per patient. For example, in the past, a nurse on a routine medical/surgical floor may have been assigned 12 patients during a twelve hour shift. Now, a more typical assignment is 4 patients assigned to each nurse or a three fold increase in the actual care delivered by nurses in hospitals. Despite these substantial clinical and cost issues, nursing care is invisible at the policy and health financing levels of the health care system. Nursing care is not identified as a separate cost center, is billed at a flat daily rate as "room and board", and is not accounted for in the current DRG reimbursement to hospitals. This represents one of the major weaknesses of the current inpatient prospective payment system. If CMS is prepared to create a payment system that more closely represents actual resource expenditures at US hospitals, it must consider the contribution of nurses and the unique nursing costs associated with patient care.

It is difficult to accurately account for US hospital nursing care expenditures because the annual Medicare Cost Report (MCR) does not itemize the direct and indirect costs of nursing care (Kane & Magnus, 2001). Nursing care is allocated to department overhead costs and is not linked to individual patients (Finkler & Ward, 2003). Billing for nursing care is subsumed within fixed routine or intensive care fees and there is no separate billing code for inpatient nursing care separate from other facility related costs. These fixed daily billing rates do not acknowledge the known variability of nursing care within a particular nursing unit. Since routine and other daily charges are used to set DRG payment rates, using fixed rate routine and intensive care billing negates the individual relationship between nurses and patients creating an assumption that all patients received the same nursing care – they do not. This weakness can only be overcome by measuring the actual expenditure of nursing care time and costs associated with individual patient care. The relevance of separating out billing based on routine or intensive care is also becoming irrelevant from a clinical perspective as increasing number of patients with invasive monitoring, vasoactive intravenous drips, and mechanical assisted ventilation are found on the "routine care" nursing units. This outdated billing practice hides the growing complexity of care in hospitals by creating only two billing rates of routine and intensive care (and proposed cost centers in the CMS-1488-P). Since the amount of nursing care (nursing intensity) is directly proportional to the complexity of medical care (treatment intensity) and underlying severity of illness, creating a financial and accounting system based on the variability of nursing care for individual patients more closely fits actual expenditure of nursing resources, their associated costs, and reimbursement for patient care.

Several studies have shown an independent relationship between nursing care and patient outcomes. For example, one series of studies compared summary data from a daily nursing classification instrument to the DRG and APR-DRG in explaining hospital charges, length of stay, and probability of death. Adding the nursing data to regression models significantly improved overall explanation of these outcome variables (Welton & Halloran, 2005; Welton & Halloran, 2000). Other research has identified an association between nursing workload and patient outcomes. The amount of daily nursing care, typically measured as patient to nurse ratios or nursing hours per patient day (NHPPD), is associated with several quality outcome indicators and mortality (Aiken, Clarke, Cheung, Sloane, & Silber, 2003; Needleman, Buerhaus, Mattke, Stewart, & Zelevinsky, 2002). These research findings demonstrate a clear relationship between the amount of nursing care delivered in hospitals and the associated direct costs of that care.

Nursing Cost Center

In their original conceptualization of the DRG, Thompson, Averill, and Fetter (1979) argued that nursing care costs should be allocated to a separate cost center and not subsumed within individual department cost centers (Figure 1). This was an acknowledgement of the substantial nursing labor costs associated with each hospitalization. In a subsequent paper describing the collection of nursing intensity data at Yale University Hospital, Thompson and Diers (1988) found considerable differences in nursing resource use across clinical services. Recent findings from the Medical University of South Carolina Medical Center (MUSC) Nursing Intensity Database (NID) project has shown significant cost differences in similar medical/surgical inpatient units supporting Thompson and Diers findings (Welton, Fischer, DeGrace, & Zone-Smith, 2006b). These costs were associated with variations in daily nursing intensity calculated as hours of direct nursing care for each patient (Figure 2). For example, a nurse may be assigned four patients during a twelve hour shift and on average give each patient three hours of care. However one patient may require twice or three times the amount of nursing care compared to other patients on a particular shift. A follow up study comparing the daily room and board billing rate for each of twelve nursing units found considerable differences between the actual fixed charge for daily care and the associated direct nursing costs (Welton, Fischer, DeGrace, & Zone-Smith, 2006a). When the daily room rate was selected using nursing intensity rather than patient location, the cost to charge ratios narrowed, and over $4 million in additional reimbursement were identified. In this particular setting, the room and board rate (routine care) did not accurately reflect the actual direct nursing costs.

Nursing direct costs, intensity, skill mix, and patient to nurse ratios were examined across all Massachusetts hospitals using recently published planned unit staffing levels (Welton, Unruh, & Halloran, 2006b).[2] A similar nursing cost differential was seen across hospitals as well as units (Table 4). For example, the mean nursing cost per patient day was $204 for acute community hospitals vs. $248 for academic medical centers. There were significant differences in costs, skill mix and nurse to patient ratios in other types of nursing units as well. This can be explained by the higher Case Mix Index (CMI) of the academic medical centers. Overall, the tertiary care hospitals had sicker patients and used more nursing resources.

The initial conceptualization of a separate nursing cost center by Thompson and colleagues as well as recent published findings supports the need to change existing hospital accounting structures, in particular, how nursing costs are identified. The primary recommendation of this proposal is to identify direct nursing care intensity and costs by individual patients rather than mean department based approaches. This would effectively change the underlying nursing cost function from a fixed to a variable cost directly associated with expenditure of nursing resources. Such an approach would create a fairer reimbursement scheme by aligning actual consumption of nursing resources with billing and reimbursement for that care as nursing care represents nearly a third of all hospital expenditures and nearly half of all direct care costs.

Nursing Intensity Index

One of the major goals of CMS-1488-P is summarized as: "we placed most of our attention and resources on the [MedPAC] recommendations related to refinement of the current DRGs to more fully capture differences in severity of illness among patients" (p. 56). There have been a myriad of studies designed to refine the original DRG to accomplish the above. For example, Iezzoni and Feldman both raised the issue of medical meaningfulness of risk adjustment methods (Feldman, 1992; Iezzoni, 1994). The results of any risk or severity of illness adjustment must have unambiguous clinical referents and be easily understood by the professionals performing patient care, hospital administrators, and policy makers. Although the medical diagnosis and various algorithms to refine the DRG have been the mainstay of current health service evaluation methods and reimbursement policy, the contributions of nurses to patient hospital outcomes has been largely ignored.

Thompson proposed nursing intensity as one of four original Nursing Minimum Data Set (NMDS) elements that would represent nursing care in the hospital discharge abstract (Thompson & Diers, 1985; Thompson, 1988; Thompson & Diers, 1988). He argued that the DRG alone does not account for the variability of nursing care during the hospital stay. This raises two interesting issues. The first is whether a single summary variable, such as

[2] http://www.patientsfirstma.org/staffing/

mean nursing intensity during the hospital stay, could adequately represent the total nursing care. The second issue is whether nursing intensity is a predictor of hospital costs, independent from the medical diagnosis expressed as the DRG. The DRG only explains 34% of the variability of costs of care (Evers et al., 2002). There is also variability between hospital types in their average costs per weighted case, cost structure and financial performance (Watson, Finlayson, & Jacobs, 2002). Academic health centers receive a disproportionate number of admissions of low-volume, high-variation DRGs. This translates into financial risk to some hospitals because of the fixed payment and lack of severity adjustment (Taheri, Butz, Dechert, & Greenfield, 2001). We propose that nursing intensity provides a method to partially adjust DRG payment to reflect the differences in nursing resources associated with different levels of severity of illness. For example, "sicker" patients receive more nursing care and result in higher costs. This nursing intensity difference can be measured directly as hours of care and associated direct costs of that care. There is a difference in how nursing resources are expended related to medical complexity however. For example, there is a significant difference in medical complexity for a cardiac catheterization, balloon angioplasty, and coronary artery stent placement but post procedure nursing care is similar for all three types of cases. Simple medical diagnoses such as pediatric concussion have little medical complexity but relatively high nursing intensity as the nurse is constantly assessing the patient, dealing with symptoms such as pain and vomiting, and potentially dealing with significant anxiety in both the child and parents.

The New York State Nurses Association (NYSNA) has successfully argued to adjust Medicaid payments in that state by creating a separate Nursing Intensity Weight (NIW) for each DRG (Ballard, Gray, Knauf, & Uppal, 1993). An expert panel is assembled every few years to determine the NIW for each DRG, and these weights are used to adjust payment to hospitals in New York State. The use of a fixed Nursing Intensity Weight for each DRG acknowledges the unique contribution of nursing care and the associated costs. The main disadvantage of using fixed NIW scores is that they do not address the potentially wide variability of nursing care within a particular DRG group, adjust for severity of illness, or acknowledge the independent relationship of nursing care and medical care.

A different approach to using nursing intensity is the Nursing Intensity Database (NID) developed at the Medical University of South Carolina Medical Center in Charleston (MUSC). Nurses enter direct time spent for each patient across eleven dimensions for each shift (Zone-Smith, 2004; Welton et al., 2003). These data are independent of the medical diagnosis, but can be aggregated into a mean daily NID score for the hospital stay and joined to existing cost and discharge data sets. This data set has been in place across the 596 bed academic medical center since January 1, 2003. Initial pilot results indicate that this instrument is valid and reliable. The NID has been linked with the UB92 and cost accounting data set at MUSC, allowing direct measurement of the interaction between nurses and patients to determine time expended across eleven dimensions of care. The NID is a patient specific rather than diagnosis or department specific method of measuring the nursing care resource utilization during hospitalization. Nursing intensity provides a concurrent and clinically meaningful set of data embedded in the routine processes of patient care at US hospitals. These data can provide direct care time and a reasonable estimate of direct care costs expended by nurses for individual patients.

The main argument of this proposal is that nursing costs are best captured as the interaction between an individual nurse and patient. These data provide relevant information about the complexity of care, severity of illness, as well as the nursing resources expended for that care. Since nursing intensity is measure as time, a cost estimate can be calculated as the product of nursing time and wages. This is a both a direct and variable cost function. Can nursing intensity be measured accurately, reliably, and without undue administrative burden across US hospitals? The simple answer is yes. Hospitals now collect these data in every unit of every hospital as the charge nurse report which includes patient data and nurses assigned to patients. To date, both Seago and Welton have used the staffing data to estimate nursing intensity (Welton, Unruh, & Halloran, 2006a; Seago, Spetz, Coffman, Rosenoff, & O'Neil, 2003) – see also Table 4. An information system to capture the staffing data from the charge nurse report could be easily implemented at even small rural hospitals and reliably calculate mean nursing intensity from the nurses' assignment. Simple adjustments for differential levels of care, e.g. one patient in the assignment needed more care than the others, can be accommodated. Establishing mean hospitalization nursing intensity for the discharge abstract is a simple database function. More sophisticated methods to capture nursing intensity can be deployed as in the NID. Since this proposal advocates capturing actual time expended rather than some idealized notion of time required by patients, any patient classification tool can be calibrated to the assignment or patient to nurse ratio of the respective unit in which care is delivered.

Nursing Intensity as a Severity of Illness Adjustment to the DRG

The proposed rule seeks comment on a suitable method for measuring severity of illness. Nursing intensity provides one method of accomplishing several goals. There is a direct relationship between complexity of care and nursing intensity. In the most basic example, patients with critical illnesses are admitted to intensive care units. These patients receive more nursing hours of care than patients admitted to the floor for routine care. Since the amount of nursing care (nursing intensity) is an expression of direct care costs, nursing intensity could meet the two fundamental goals of the proposed rule change – direct costs allocation and adjustment for severity of illness for each patient. Table 1 shows the Pearson Correlation of the MUSC nursing intensity scores expressed as a mean for each discharge and compared to the DRG cost weight and severity score. The moderate correlation (Pearson $R = .330$, $P < .001$) indicates that nursing intensity reasonably maps to diagnosis specific severity weights, but also indicates that nursing intensity is somewhat independent of the APR-DRG. This is a favorable property and demonstrates the strength of using nursing intensity as a proxy measure of complexity of care related to nursing resources expended for patient care and the associated labor costs associated with that level of care.

The DRG cost weight has been used as a proxy measure of complexity of care with the understanding that more medically complex cases are more costly. Welton and Halloran (2005) studied the relationship between nursing care and medical care at an academic medical center in Ohio. A nursing classification tool based on nursing diagnosis was used to compare nursing diagnosis and medical diagnosis and their relationship to commonly studied resource utilization and outcomes of hospitalization: hospital and ICU length of stay, total charges, probability of death, and discharge to a nursing home. They found that nursing diagnosis was an independent predictor of these dependent variables and when the nursing data were added to the DRG or APR-DRG, explanatory power (R^2 or c statistic) doubled for charges, length of stay, probability of death and discharge to a nursing home. The authors conclude that the nursing data are complimentary to the medical data and explains a different portion of the variability of the studied dependent variables. The findings suggest that the DRG has only a weak association with the care delivered by nurses. In an unpublished analysis of the MUSC nursing intensity data summarized by discharge, the normalized mean nursing intensity score for each discharge was regressed on the normalized DRG cost weight. The R^2 was .326, meaning that just over 32.6% of the variability in nursing intensity was explained by the DRG cost weight. The depiction of the two variables (Figure 3) demonstrates areas of high nursing intensity (and assumed high nursing costs) and low DRG payment. This discordance between nursing intensity and reimbursement cannot be improved by refining or adding new DRGs. The findings of these two studies provide a basis for arguing for an independent nursing adjustment to the DRG rather than an adjustment to the DRG cost weight. If the goal of the proposed rule is to better align costs with reimbursement, an independent nursing intensity adjustment to the payment formula within the APR-DRG provides a superior approach as this is directly aligned with nursing labor costs associated with care rather than a refinement of medical coding. Physicians are not paid under Part A therefore attempts to better define cost functions in relationship to refined medical diagnosis may not be successful.

CMS-1488-P proposes to use the APR-DRG severity weights to adjust payment to hospitals. Since the overall goal is to align actual costs with reimbursement, nursing intensity can be used within the APR-DRG weights to accomplish this. In a study of mean daily nursing intensity summarized for the hospitalization, estimated intensity and costs of nursing care were mapped within each severity weight. When nursing intensity is allocated within APR-DRG severity categories, mean nursing intensity increases proportional to the underlying severity level and disease category (Table 2). Using mean daily nursing intensity for each discharge, the direct nursing costs per day and costs per admission were estimated using $30.00 per hour for a series of patients admitted to an academic medical center from Jan 1, 2003 through Jul 31, 2005. Table 3 describes the relationship between the APR-DRG severity categories and nursing intensity, nursing direct costs per day, and nursing total direct costs per discharge.

There are a number of salient points related to the MUSC nursing intensity and APR-DRG severity adjustment comparison. Nursing intensity and direct costs rise with each higher level of severity. The actual distribution of nursing intensity and associated costs are different across APR-DRG categories within each severity category. For example, the estimated direct nursing costs per day for a level 1 patient after vaginal delivery is $173 and for a post craniotomy patient is $514. These two patients would be billed at the same routine care rate under the current DRG reimbursement scheme. The combination of the APR-DRG severity category and the mean nursing intensity and direct and indirect nursing costs will be a useful tool to separate out nursing care from other hospital costs. These data are preliminary and are not representative of all patients and care at other hospitals. However, the

method used in this pilot study can be readily adapted to any hospital that collects daily nursing intensity information and nursing cost data.

Implementation

The implementation of the recommendations in this public comment will require extensive development and testing before they can be used at all hospitals. There are several components:

- Each hospital will need to collect daily nursing care hours and direct/indirect nursing costs for each patient day, incorporate these data into the billing process separate from current routine and intensive care fixed billing;
- Hospitals will need to collect data specific to full and part time nursing and nursing assistive personnel and adapt local accounting systems to accommodate these new data. The Medicare Cost Report will also have to be adapted to report the separate nursing data.
- The daily nursing intensity and cost data will need to be incorporated into the hospital discharge and billing abstract. This will require changes to the current database structure and any associated reports.
- A method will need to be developed to incorporate the nursing intensity and cost data into the APR-DRG severity weight framework. Additional methods will need to be investigated to analyze aggregate data across hospitals using the new data fields to estimate local, regional, and national norms for nursing intensity and costs. Ultimately these data will provide valuable information to analyze hospital quality of care and outcomes.

This public comment document will not detail specific means to accomplish the above, but will call upon CMS to set aside necessary funds to allow development of methods to implement these recommendations using methodologically sound research and demonstration projects. The magnitude of this change will require several years to implement.

Summary

In the past decade, hospital length of stay has shortened while the underlying severity of illness has increased. This creates a "sicker and quicker" element of care and a significant need for more nurses and more nursing time devoted to inpatient care. At the present time, nursing costs are hidden in department budgets and daily costs billed at fixed rates. This hides both the contribution of nurses and the known variability of nursing intensity and associated costs. Any future changes in the inpatient prospective payment system should be guided by nursing intensity and the contribution of nurses to patient care.

The specific recommendations in this public comment to proposed rule CMS-1488-P are directed toward identifying the unique characteristics of hospital nursing care, the costs associated with the expenditure of that care, and the alignment of these direct and indirect costs of care with reimbursement for hospitalization in the United States. It was the original intent of the designers of the current DRG system to incorporate nursing costs and intensity of care into the IPPS payment. The specific recommendations of this public comment provide a basis for implementing the original recommendations by Thompson, Averill, Fetter, and Diers (Thompson, Averill, & Fetter, 1979; Thompson et al., 1991). This nursing proposal also meets the stated goals of proposed rule change to align Medicare reimbursement with actual cost expenditures and adjust for severity of illness. The use of nursing intensity as a means to identify hours of nursing care expended for patients as well as the direct cost of nursing care meets this intended goal.

Tables and Figures

Table 1 Nursing Intensity, DRG Cost Weight, and APR-DRG Severity[3]

Correlations

		Mean 7P-7A nursing intensity	Mean 7A-7P nursing intensity	PatientAge	APR-DRG Severity	DRG Cost Weight
Mean 7P-7A nursing intensity	Pearson Correlation	1	.614**	.287**	.330**	.303**
	Sig. (2-tailed)	.	.000	.000	.000	.000
	N	32746	29850	32746	32746	31439
Mean 7A-7P nursing intensity	Pearson Correlation	.614**	1	.335**	.319**	.304**
	Sig. (2-tailed)	.000	.	.000	.000	.000
	N	29850	31215	31215	31215	30125
PatientAge	Pearson Correlation	.287**	.335**	1	.076**	.141**
	Sig. (2-tailed)	.000	.000	.	.000	.000
	N	32746	31215	71646	71646	69531
APR-DRG Severity	Pearson Correlation	.330**	.319**	.076**	1	.669**
	Sig. (2-tailed)	.000	.000	.000	.	.000
	N	32746	31215	71646	71646	69531
DRG Cost Weight	Pearson Correlation	.303**	.304**	.141**	.669**	1
	Sig. (2-tailed)	.000	.000	.000	.000	.
	N	31439	30125	69531	69531	69531

**. Correlation is significant at the 0.01 level (2-tailed).

Table 2 Nursing Intensity within APR-DRG Severity (Selected Diagnoses)

		All	Severity Level 1		Severity Level 2		Severity Level 3		Severity Level 4	
APR-DRG	Description	N	N	Mean NI	N	Mean NI	N	Mean NI	N	Mean NI
	All APR-DRGs	71,646	27,145	[redacted]	28,644	[redacted]	12,327	[redacted]	3,507	[redacted]
021	Craniotomy	979	436	12.6	370	13.9	132	15.6	41	17.0
053	Seizure	771	298	9.4	319	10.4	126	11.5	28	17.5
139	Oth pneumonia	1,015	197	8.9	480	10.9	268	12.0	70	15.3
141	Asthma	534	323	8.8	182	9.5	22.0	10	7.0	16.1
161	Cardiac defib implant	605	61	10.1	260	10.3	261	11.1	23	16.1
166	Coronary bypass w/o cath	419	91	13.2	249	13.1	66	14.1	13	18.4
229	Digest sys procedures	131	30	10.1	49	13.8	37	14.8	15	18.9
420	Diabetes	676	212	9.9	338	10.2	113	12.8	13	15.4
463	Kidney and urinary inf	500	87	10.7	230	11.7	149	11.7	34	13.9
540	Cesarean del	1,507	512	5.9	530	6.1	433	6.8	32	11.1
560	Vaginal del	3,077	1,208	4.7	1,381	5.0	481	5.8	7	9.9
640	Normal newborn	3,504	2,987	6.5	433	8.6	84	9.9		
662	Sickle cell crisis	877	481	9.6	306	10.8	80	11.8	10	16.5
693	Chemotherapy	792	462	9.7	247	11.4	64	12.2	19	14.7

[3] Unpublished data, Medical University of South Carolina Nursing Intensity Database, summary of daily Nursing Intensity by patient discharge (N=71,646) from Jan 1, 2003 through Jun 30, 2005.

Table 3 Estimated Direct Nursing Care Costs by APR-DRG Severity (Selected Diagnoses)

APR-DRG	Description	LOS	RN Cost	Cost/d	LOS	RN Cost	Cost/d	LOS	RN Cost	Cost/d	LOS	RN Cost	Cost/d
021	Craniotomy	4.2	2,157	[illegible]	6.7	3,908	[illegible]	15.2	10,120	[illegible]	31.8	22,756	[illegible]
053	Seizure	2.4	839	[illegible]	2.7	1,123	[illegible]	4.8	2,426	[illegible]	10.9	8,740	[illegible]
139	Other pneumonia	2.5	772	[illegible]	3.8	1,455	[illegible]	5.6	2,648	[illegible]	10.6	6,108	[illegible]
141	Asthma	1.9	625	[illegible]	2.8	946	[illegible]	3.3	813	[illegible]	4.4	2,800	[illegible]
161	Cardiac defib implant	3.0	1,337	[illegible]	3.4	1,556	[illegible]	6.2	3,047	[illegible]	22.0	11,309	[illegible]
166	Coronary bypass w/o cath	5.9	2,825	[illegible]	7.0	3,262	[illegible]	11.7	5,550	[illegible]	20.2	12,706	[illegible]
229	Digest system procedures	4.5	1,543	[illegible]	7.8	3,684	[illegible]	10.6	4,254	[illegible]	30.2	27,460	[illegible]
420	Diabetes	2.7	1,003	[illegible]	3.1	1,276	[illegible]	4.4	2,151	[illegible]	9.3	5,985	[illegible]
463	Kidney and urinary infection	2.7	1,035	[illegible]	3.3	1,479	[illegible]	5.2	2,443	[illegible]	11.9	4,557	[illegible]
540	Cesarean delivery	2.8	587	[illegible]	3.8	868	[illegible]	5.3	1,518	[illegible]	13.7	8,045	[illegible]
560	Vaginal delivery	1.8	311	[illegible]	2.1	404	[illegible]	3.3	781	[illegible]	7.3	4,227	[illegible]
640	Normal newborn	1.9	489	[illegible]	2.9	998	[illegible]	3.9	1,226	[illegible]	0.0	0	[illegible]
662	Sickle cell crisis	3.1	1,166	[illegible]	4.2	1,865	[illegible]	5.8	2,731	[illegible]	7.3	4,134	[illegible]
693	Chemotherapy	3.0	1,063	[illegible]	4.6	1,994	[illegible]	11.0	5,721	[illegible]	20.0	10,651	[illegible]
	Mean within severity group			350			401			432			577

LOS: mean hospital length of stay
RN Costs: $30.00 per hour is used as an aggregate salary estimate
RN Costs: total per diagnosis is product of direct nursing costs per day based on mean Nursing Intensity and mean length of stay (LO
Cost/d: mean direct nursing care costs per day within severity group and diagnosis

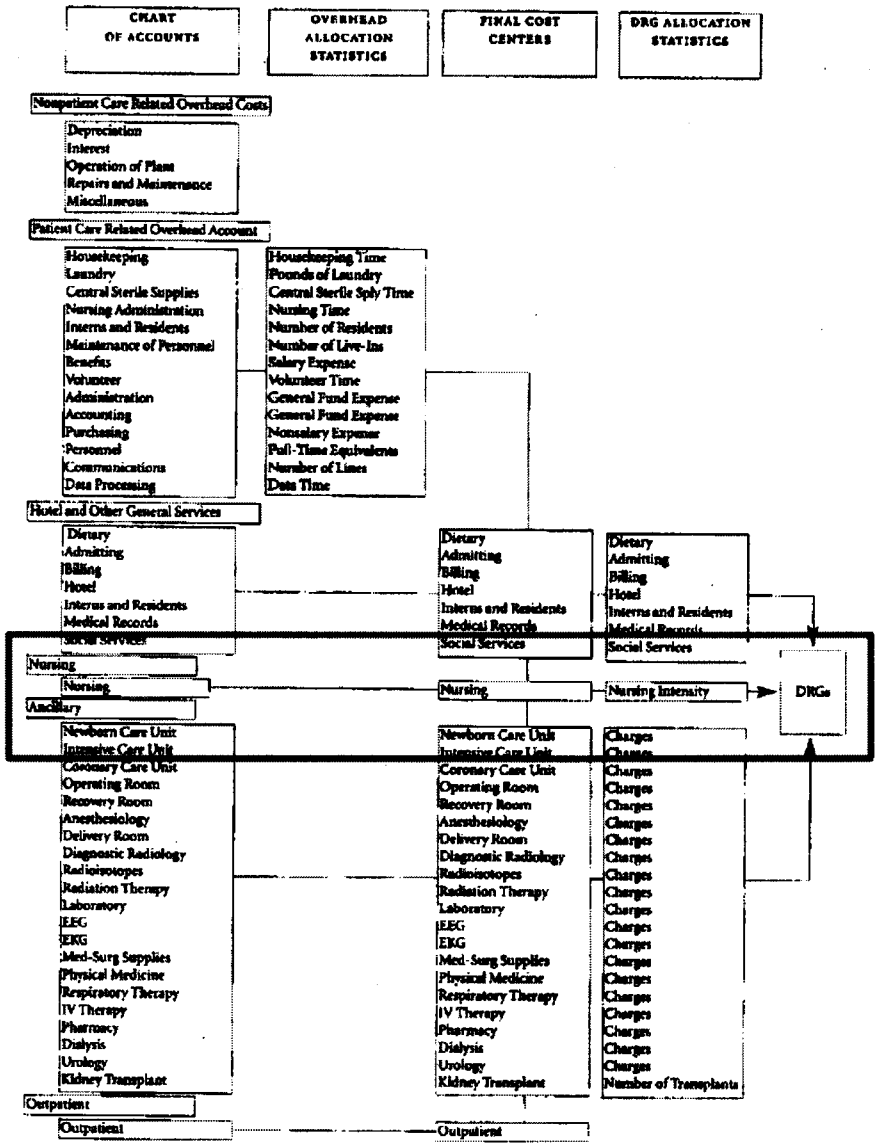
Table 4 Massachusetts Hospitals Nursing Intensity and Nursing Direct Costs[4]

		Hospital Type							
		Acute Community Hospital				Academic Medical Center			
		Unit Nursing Intensity (tot hrs RN care)	Unit Patient to Nurse Ratio (daily mean)	Estimated Direct Nursing Cost Per Patient Day		Unit Nursing Intensity (tot hrs RN care)	Unit Patient to Nurse Ratio (daily mean)	Estimated Direct Nursing Cost Per Patient Day	
		Mean	Mean	Mean	Standard Deviation	Mean	Mean	Mean	Standard Deviation
Unit Type	Adult Med/Surg	5.1	5.2	204	69	6.2	4.1	248	60
	Pediatric Med/Surg	15.2	2.0	610	303	8.3	3.0	333	67
	Adult Step-Down	8.3	3.1	333	102	8.5	3.1	339	168
	Adult Critical Care	15.2	1.6	610	164	18.1	1.4	723	143
	Pediatric Critical Care	.	.	.	.	17.5	1.4	701	92
	Neonatal Lvl II	10.8	2.4	434	125	5.9	4.1	235	.
	Neonatal Lvl III/IV	12.9	1.9	516	.	13.0	1.9	520	118

[4] Data from journal submission currently under review, there were 601 nursing units in the study reflecting nearly all acute inpatient beds in Massachusetts.

Figure 1 DRG Cost of Accounts[5]

Figure 2:
Typical Hospital Chart of Accounts with Examples
of the Overhead and DRG Allocation Statistics



[5] Used with permission from Thompson, J. D. & Diers, D. (1991). Nursing Resources. In R.B.Fetter, D. F. Brand, & D. Gamache (Eds.), DRGs. Their Design and Development (pp. 121-183). Ann Arbor: Health Administration Press.

Figure 2 Distribution of Direct Nursing Costs (Med/Surg Units)

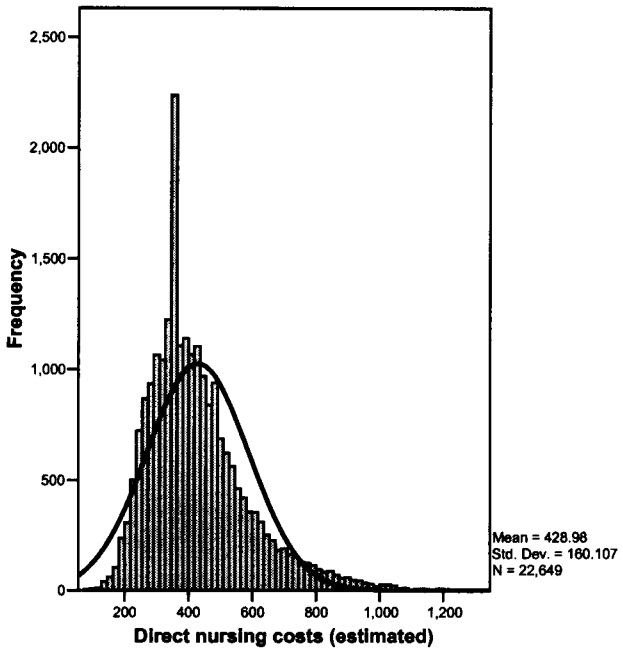
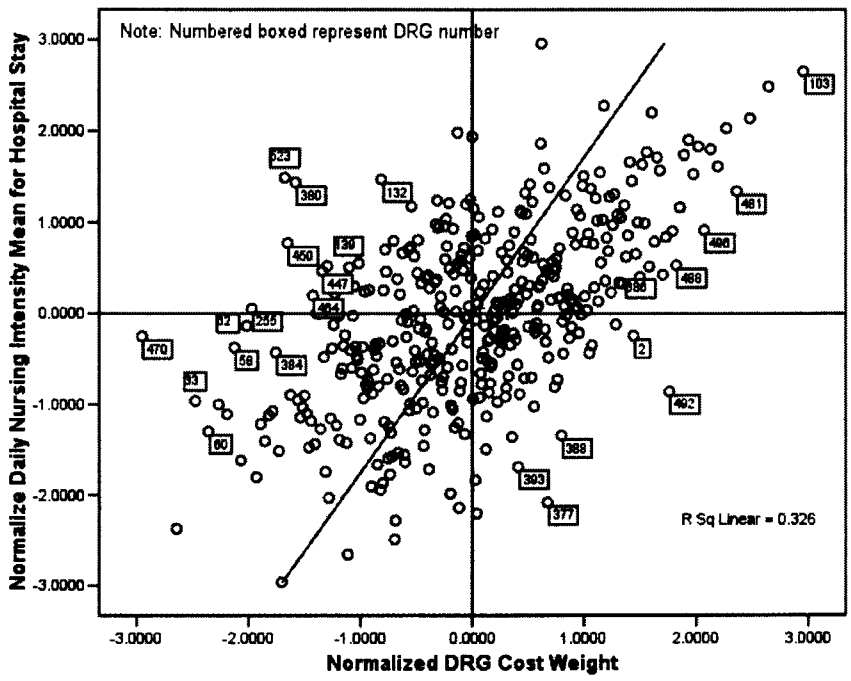


Figure 3 Normalized Mean Nursing Intensity vs. DRG Cost Weight[6]



[6] Unpublished data, Medical University of South Carolina Medical Center

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Submitter : **Mrs. Sharon DelPuppa** **Date: 05/30/2006**

Organization : **Venice Regional Medical Center**

Category : **Hospital**

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Under the section "Reporting of Hospital Quality Data for annual hospital payment update" -
for the 2007 update, we request that the hospital be allowed to appeal to their QIO any results, even if it achieves > 80% (passing) validation for that quarter. We feel this is significant due to the aggregation of validation results for multiple quarters, as well as for clarification of discrepant issues between the hospital and CDAC. Thank you.

Submitter : **Mrs. Melinda Toth** **Date: 05/30/2006**

Organization : **Christus Spohn Hospital Corpus Christi**

Category : **Nurse Practitioner**

Issue Areas/Comments

Update Factors

Update Factors

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 450 bed hospital located in Corpus Christi,TX I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Submitter : Mrs. Patricia Newcomb **Date:** 05/30/2006

Organization : CARING

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Nursing adjustment to DRG - I support the development of a new classification/DRG code for nursing. We are professionals that offer unique services to the patients that are admitted to hospitals and our activities and how they promote quality outcomes are not going to be captured in the present system. I support the recommendation by the Medical College of South Carolina.

Submitter : **Peter Broderick** **Date: 05/30/2006**

Organization : **Stanislaus Family Medicine Residency**

Category : **Academic**

Issue Areas/Comments

GENERAL

GENERAL

I am attaching a letter regarding the CMS ruling on FY 2007 Inpatient PPS Rule where CMS purports to clarify its policy to exclude the time residents spend in nonpatient care activities for purposes of calculating Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

CMS-1488-P-119-Attach-1.PDF

Attach FF
119

Stanislaus
FAMILY
MEDICINE
Residency Program

1975-2005
30 Years
of Teaching
Excellence

May 30, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8011
Baltimore, MD 21244–1850

Attention: CMS–1488–P

Dear Administrator McClellan:

The Stanislaus Family Medicine Residency welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006). We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. We concur with the Agency's 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

Stanislaus

FAMILY MEDICINE
Residency Program

1975-2005
30 Years
of Teaching Excellence

Residency Program Activities and Patient Care

With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

In our residency, we incorporate into all of our lectures specific cases that the residents have dealt with during their direct patient care duties. This not only makes the learning more tangible and relevant, but it has been shown to encapsulate the experience for future practice. Under the strict interpretation CMS is contemplating where didactic time is exempted from payment, any discussion of patient care for the purpose of learning rather than health care delivery would be disqualified from GME payment. I can't believe that is the intention of CMS, which has long supported the investment in our future health care by supporting training excellence in our residencies.

To reiterate, we urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

PBroderick

Peter Broderick, M.D., M.Ed.
Program Director
Stanislaus Family Medicine Residency Program
U.C. Davis-affiliated Family Medicine Network
Doctors Medical Center
1441 Florida Ave.
Modesto, CA 95352
(209) 576-3528

Submitter : Ms. Jane Harding **Date:** 05/31/2006

Organization : Consultant Manager

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I support the Medical College of South Carolina's proposal to adjust the DRG payment rate to reflect the level of nursing care required to achieve positive patient outcomes. I think it is long overdue that DRGs reflect the cost of the one reason that patients are hospitalized and that is nursing care.

Submitter : **Mrs. Pamela Rollins** **Date: 05/31/2006**

Organization : **Shands at the University of Florida**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-121-Attach-1.DOC

CMS-1488-P-121-Attach-2.DOC

Comments Regarding Proposed Changes to DRG System
From Shands at the University of Florida
Gainesville, Florida

Introducing further complexities to the current DRG system will decrease coder productivity. Hospitals are already dealing with a nationwide shortage of experienced inpatient coders. Even though the intention of the changes is to make payment rates more accurate, the actual effect is that hospitals will have an even more difficult time receiving the payment that they deserve. As CMS increases the processing complexity it is simultaneously increasing the administrative cost of providing services. These increases will ultimately be passed on to payors and patients.

George Hachey, BA, CCS
Coding Manager
Shands UF

From the documentation improvement perspective, I would anticipate a huge increase in the number of physician queries written. I currently review the record to identify the probable PDX along with at least one CC. If the proposals are accepted into the final rule, I would then have to write queries for every diagnosis indicated or implied in every chart - a potential huge impact to productivity.

Donna Fisher, RHIA, CCS
Clinical Documentation Improvement Specialist
Shands UF

Just from a coding perspective alone, the proposed changes will have a big impact and require lots of education for all of us as well as physicians. We would need to "relearn" the DRG system, and we may have to alter the way we think about co-morbid conditions. How we sequence codes may also need to change. Also, trying to determine "Present on Admission" is going to be a time-consuming challenge. Case mix and reimbursement changes will probably also be impacted.

Carol Bosworth, RHIT, CCS
Coding Educator
Shands UF

Submitter : Ms. Beth Wolf **Date:** 05/31/2006

Organization : Dartmouth-Hitchcock Medical Center

Category : Hospital

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

I am a Department Director for Cardiac Services at my academic medical center. My concern about the planned reclassification has to do with the analyses that has led to the proposed changes. Cardiac Services have evolved very rapidly over the past few years, such that supply costs and procedure complexity have increased substantially. In a great many cases, percutaneous interventions to achieve revascularization have replaced surgery. Needless to say, this has been a boon to society with fewer people having to undergo open heart surgery. However, with the increasing complexity of these percutaneous procedures, any analysis that does not consider the cost and procedure types occurring in the last year, will not present the reality of today's situation. We are using more drug-eluting stents per case with little to no restenosis occurring. A rather remarkable advance in the management of patients with coronary artery disease! With the aging of the population and the prevalence of this disease, many more patients will be seeking these less invasive alternatives, which, I might add, are more costly now, but highly effective. The proposed reimbursement reductions will undoubtedly affect the ability of hopsitals to provide this highly effective treatment. I do truly understand the need to reduce healthcare costs and would suggest that you look very carefully at the data indicating that some facilities and areas of the country spend far more money than others, with no appreciable difference in the health of the communities they serve. Dr. Jack Wennberg of Dartmouth Medical School has been demonstrating this fact for many years and these data imply that there is the possibility of selectively reviewing high cost areas, rather than make a wholesale 'one size fits all' decision based on old data that can have serious consequences on the availability of this very effective treatment. I strongly urge reconsideration using current information and using creative alternatives to reduce costs. Thank you for the opportunity to provide comment.

Submitter : **Date: 05/31/2006**

Organization :

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

I support the Medical University of South Carolina proposal to adjust DRG payment by nursing intensity and to include direct nursing costs in the payment formula rather than routine/intensive care fixed rates.

Submitter : **Ms. Karen Schneider** **Date: 05/31/2006**

Organization : **Health Systems Consultants, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

See Attachment

CMS-1488-P-124-Attach-1.DOC

Attachment #124

CMS-1488-P

Submitter: Karen C. Schneider
Organization: Health Systems Consultants, Inc.
Category: Health Care Industry

May 31, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: DRGs: Severity of Illness

Dear Ladies and Gentlemen:

Health Systems Consultants, Inc. respectfully submits this comment on the proposal to refine the DRG system under the IPPS to more fully account for severity of illness among patients. We applaud this effort and believe that such a refined system will provide more accurate Medicare IPPS payment rates, as will the proposed shift to a hospital-specific relative value cost center weighting methodology.

We have two major areas of concern where we believe additional consideration may be required.

One area of concern is with respect to the use of a classification system that is based on the APR DRGs, rather than the CMS DRGs. As noted in the Federal Register of April 25, 2006, this represents a major shift for hospitals. One area affected by the shift is the way hospitals view their products; more specifically, the extent to which the added complexity of the APR DRG system, coupled with its differences from the CMS DRGs, will impact hospital management based on DRGs. This is somewhat exacerbated by the structural problem you have mentioned, in that APR DRGs lose some of the complexity based distinctions incorporated in the CMS DRG system. In addition, there may be situations where the APR DRG system produces a significantly less meaningful classification from a clinical perspective, as for example with the amputation DRGS (Federal Register, page 24014).

The difficulties in providing a blended or phased payment system seem to stem largely from the significant differences between the base APR DRGs and the CMS DRGs. Given the financial impact on some hospitals of a shift to a severity-based system, we believe this to be a critical deficiency. As the Federal Register discusses, there is also a significant risk due to the potential aggregate financial impact of changes to documentation and coding practice. It will be impossible to predict the real impact of these changes, and therefore a phased transition approach appears to us to be essential.

A second major area of concern has to do with the merging of dissimilar patient groups. To some extent, as mentioned with amputation DRGs, this is a function of the APR DRG system. In addition, combining clinically dissimilar groups across the severity dimension, a key aspect of the consolidated APR DRGs, has the potential to render the groups far less clinically meaningful. In addition, we foresee that such groups would have to be restructured frequently as treatment patterns change for (primarily) very ill patients. One approach that might be more effective is to keep the patient groups separate from a classification perspective, but merge them from a payment analysis perspective.

In the Federal Register, interest was expressed in soliciting public comments on alternative DRG systems that would better reflect severity of illness than the "consolidated severity-adjusted DRGs." The RDRG severity of illness system is one alternative that has been in continuous use since 1989. We believe that this system has advantages over the APR DRG system and should be considered in your further evaluations. We are happy to offer the RDRG software and appropriate definitions and usage manuals at no charge to CMS for their review and examination of the most recent MedPar database.

The research for the RDRG system was undertaken between 1986 and 1989 under the Health Care Financing Administration (now CMS) cooperative agreement nos. 15-C-98930/1-01 and 17-C-98930/1-0251, when it was thought that DRGs, first widely used in 1983, did not adequately account for severity of illness. Professor Robert Fetter at Yale University, the "inventor" of the DRGs (along with Professor John Thompson, also from Yale University) was the Principal Investigator of the study. The RDRG and the APR DRG systems both owe their origins to this early work.

The RDRG system is supported by Health Systems Consultants under President Karen Schneider, the Project Director for the above severity study. The system is widely used in the United States and is currently used by hospitals and academic centers in several foreign countries. The system is updated annually based on the annual DRG updates. Currently there are 1274 groups with 350 base DRGs (175 medical base DRGs and 175 surgical base DRGs). Each of the medical base DRGs is divided into 3 severity classes and each of the surgical base DRGs is divided into 4 severity classes. In addition, there are neonate groups based on birthweight, 7 DRGs that do not have severity classes, and an early death group in each MDC (created to remove low outliers). The early study had tracheostomy groups in each MDC (created to remove high outliers), but these groups were eliminated when CMS (formerly Health Care Financing Administration) developed tracheostomy DRGs based on the study. An article describing the RDRG system is available (Med Care 1995; 33:806-827).

Since 1989, the RDRG system has been updated annually in such a way that it could easily become the nation's DRG severity system for its Medicare hospital inpatient prospective payment system (IPPS). To determine severity of illness, the RDRG system uses only the complications and comorbidities (CC) list and the CC exclusions list as defined each year by CMS. The CMS DRGs provide the base for the RDRG system thereby accommodating complexity as determined by CMS. The base DRGs used by the RDRG system are essentially the same as those used by the DRG system, with only a few exceptions. The RDRG system preserves the principal diagnosis and MDC classification process long used by the DRGs. This is the way medical care is organized and practiced. The RDRG system provides severity classes within each DRG; severity classes are specific to principal diagnoses and primary procedures.

The RDRG system uses a 4-digit numbering system that preserves the DRG numbering system by keeping the DRG number and adding a 4th digit denoting severity class. For example, DRGs 089 – 091 are simple pneumonia & pleurisy medical DRGs. The RDRG system uses the base DRG for simple pneumonia & pleurisy and numbers it 089, the first number in this series of DRGs. Patients with the lowest severity class (minor) in this DRG are numbered 0890; those with the next level of severity (moderate) are numbered 0891; and those with the highest severity (major) are numbered 0892.

Developing consolidated severity-adjusted DRGs could be easily accomplished with the RDRG system as there are small differences between the lowest severity classes in each DRG for both medical and surgical patients. Early death groups could be eliminated and those patients classified into DRGs and severity classes. We note that the RDRG four-digit numbering system could represent the same problem as the original APR DRG numbering system: there are too many groups to fit into three digits. This problem would go away if a similar consolidation were applied; otherwise, four digits (or potentially three alphanumeric digits) would be required.

Although time consuming, with the relevant definitions manuals RDRG groups can be manually assigned, as can the DRGs. The RDRG system is simple, and therefore it is as transparent as the CMS DRG system.

Its simplicity, its close relationship with the CMS DRGs and its clinical meaningfulness make the RDRG system worth further analysis by CMS. We therefore propose that CMS examine the RDRG system with its FY 2004 MedPar database to provide a comparison with the consolidated severity-adjusted DRGs they have developed using this database. We believe the RDRG system provides a potentially superior substrate for a consolidated severity-adjusted DRG system than do the APR DRGs.

Sincerely yours,

Karen Schneider
President
Health Systems Consultants, Inc.
340 Whitney Avenue
New Haven, CT 06511
Tel: 203-785-0650
Email: karen.schneider@healthsyst.com

Submitter : Melissa Foster **Date:** 05/31/2006

Organization : Homestead Hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I support the Medical University of South Carolina proposal to adjust DRG payment by nursing intensity rather than routine/intensive care fixed rates.

Submitter : Mrs. Deborah McKnight **Date:** 05/31/2006

Organization : Crenshaw Community Hospital

Category : Hospital

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

In reference in the proposed changes in the Deficit Reduction Act of 2005, I would like to offer the following comments. The proposed change of having hospitals increase the quality measures reported on from 10 to 21 would require us to hire a full-time RN. The consequence of not reporting on the 21 would increase the reduction penalties from 0.4% to 2.0%. As a small rural hospital whose reimbursement continues to shrink while salaries and costs continue to rise, we oppose this new measure. Our hospital's existence is important to our community, but it is the sad fate that many rural hospitals are closing because they can't meet expenses. Our staff is stretched to the limit as it is, because we do not have the luxury of dedicated CQI staff to track and report additional measures. We are also currently participating in the National Quality Safety Measures which will further impact reimbursement. These measures are aimed at setting up a culture of safety which will improve patient safety and subsequent quality as well. The rings and hoops being required to show you are giving quality care, however, are impacting the actual patient care. Instead of having the staff time to give a better quality of care, our staff is being required to fill out reports and do more paperwork to prove it. These initiatives need to address the need for more support for rural hospitals instead of creating barriers to their existence.
Debbie McKnight RN, Case Management, Crenshaw Community Hospital

Submitter : Ms. Eric Hoesing **Date:** 05/31/2006

Organization : BryanLGH Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attached

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
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 : **Ms. Eric Hoesing** **Date: 05/31/2006**

Organization : **BryanLGH Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

May 31, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.

I am the Director of Cardiac and Vascular Services for a 500+ bed acute care hospital system located in Lincoln, Nebraska. The inpatient cardiac business is a major service line for our organization and thus the proposed changes being presented have a huge impact on our organization.

The proposal will adversely impact payment to hospitals such as our that deliver cardiology services at a time when our financial stability is already under attack by physician owned heart hospitals that offer no other emergency or community services. In addition, it is utilizing the cost report system to determine reimbursement. Hospital cost reports were never intended to be used to develop procedure-specific payment rates and are an inaccurate reflection of the true expenses associated with providing these services to our patients.

The proposed changes will decrease reimbursements for drug eluting stents by 24%-34%, ICD implants reimbursement will be reduced by 22% -24% and pacemakers will be reduced 12% - 14%, severely impacting these services. While there is some adjustment in regards to severity it in no way reflects the technology costs associated with developing the infrastructure necessary to provide these services in an effective and efficient manner.

I believe that the proposed changes will have a severe financial impact on my department and my community based hospital without data to support or justify the change. It will limit the infrastructure I can support going forward and as a result will have a negative impact on patient care in the long run.

I respectfully request that CMS delay the inpatient payment revision, with a return to the current methodology until a more relevant and appropriate methodology can be incorporated in order to accurately account for the costs associated with providing these services.

Sincerely,

Eric R. Hoesing
Director of Cardiac Services
BryanLGH Medical Center

Submitter : Dr. Linda Thede **Date:** 05/31/2006

Organization : Dr. Linda Thede

Category : Nurse

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

I support the Medical University of South Carolina proposal to adjust DRG payment by nursing intensity. Medical diagnosis alone do not reflect the intensity of medical care that a patient receives as research has shown. See Welton, J., & Halloran, E. (2005). Nursing Diagnoses, Diagnosis-Related Group, and Hospital Outcomes. Journal of Nursing Administration, 35(12), 541-549.

Submitter : Mrs. Emilie Martin **Date:** 05/31/2006

Organization : Monroe County Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Financial Impact for hospitals is high already at 0.4 percent. This increase to 2.0 could close some small hospitals that struggle to provide equal or better care than others with less reimbursement.
Human Resource Impact is also a major factor in smaller institutions where one staff member is responsible for many jobs. By adding additional data collection to data that is already being submitted now seems very redundant. If these measures are to be publically reported move the time frame to Discharges beginning July 1 2006.

Submitter : Mr. J. Michael Coffman **Date:** 06/01/2006

Organization : Saint Luke's Hospital

Category : Hospital

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

We are interested in providing feedback on the proposed Deficit Reduction Action of 2005 which will reduce the Annual Payment Update (APU) to hospitals that fail to report the required measures of quality. If the proposed legislation goes through, it will have a significant financial impact on our hospital and we believe it is important that we provide feedback related to this important piece of legislation. Please find our comments below:

As proposed, the number of quality measures will increase from 10 to 21. This will require additional staff support to collect and transmit this additional information.

This proposed legislation requires hospitals to go back and abstract data from January 1, 2006. This is an alarming precedent to set and places an undue burden on a hospital to provide this additional data. In addition, our data will be publicly reported dating back before we had process improvement initiatives in place to address our performance.

In reviewing the hospital data, CMS plans to combine the samples for first quarter, second quarter and third quarter of 2005 into a single stratified sample to determine whether or not the 80-percent reliability level is met. We believe this is problematic because hospitals have not had an opportunity to appeal CMS Clinical Data Abstraction Center (CDAC) errors if the error did not result in the hospital failing for the given time period. As a result, a hospital may be negatively impacted by the decision to combine these three quarters into a single stratified sample as proposed. For example, a hospital could have errors (as abstracted by CMS) in their 1st and 2nd quarter report providing them with an 80% passing rate (which they could not appeal) and actually fail the third quarter which would result in failure of all 3 quarters based on the plan to combine the first three quarters as proposed).

The payment update for 2007 will be reduced by 2.0 percentage points for indicator performance that has a track record of poor reliability, especially working diagnosis of pneumonia. Some hospitals resort to answering working diagnosis for pneumonia as a yes for all pneumonia charts regardless of actual documentation, since the penalty is disproportionately more severe if the no answer is found to be incorrect. A couple of mismatches on the no to working diagnosis can drive the hospital to the brink of losing their APU.

Under the proposed timeline, January, February and March 2006 data will need to be abstracted and successfully submitted to CMS no later than July 31, 2006. With the CMS comment period deadline of June 12, 2006 and an anticipated response time of 60 days by CMS, the outcome may not be known until August 12, 2006. Hospitals will have to proactively submit data on the 21 indicators & in anticipation of the legislation going into effect. The proposed timelines as outlined are problematic.

Thank you for the opportunity to provide feedback on this important legislation. We believe it will have a negative impact on our organization and wanted CMS to consider the weaknesses and understand the implications. We look forward to your comments and feedback.

Submitter : Christine deVries **Date:** 06/01/2006

Organization : American Association for Geriatric Psychiatry

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1488-P-132-Attach-1.DOC

AAGP
American Association for Geriatric Psychiatry

June 1, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Attention: CMS-1488-P
"Resident Time Spent in Nonpatient Care Activities as Part of Approved Residency Programs"

Dear Dr. McClellan:

The American Association for Geriatric Psychiatry (AAGP) is pleased to submit these comments on the proposed rule for Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. The AAGP is a professional membership organization dedicated to promoting the mental health and well-being of older people and improving the care of those with late-life mental disorders. Our membership consists of more than 2,000 geriatric psychiatrists as well as other health care professionals who focus on the mental health problems faced by senior citizens.

AAGP strongly urges CMS to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position is in stark contrast to CMS's position as recently as 1999, at which time the Director of Acute Care clarified that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." We concur with CMS's 1999 position. These activities are an integral component of the patient care activities engaged in by residents during their residency programs.

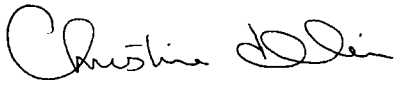
7910 Woodmont Avenue, Suite 1050, Bethesda, MD 20814-3004 Phone: (301) 654-7850 Fax: (301) 654-4137 Email: main@aagponline.org

With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of a fully trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

We urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and to recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

AAGP appreciates your consideration of our views on this proposal.

Sincerely,



Christine M. deVries
Executive Director

Submitter : Mrs. Geri Seavey **Date:** 06/01/2006

Organization : Saint Luke's Hospital of KC

Category : Other Health Care Professional

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

We are interested in providing feedback on the proposed Deficit Reduction Action of 2005 which will reduce the Annual Payment Update (APU) to hospitals that fail to report the required measures of quality. If the proposed legislation goes through, it will have a significant financial impact on our hospital and we believe it is important that we provide feedback related to this important piece of legislation. Please find our comments below:

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2. This proposed legislation requires hospitals to go back and abstract data from January 1, 2006. This is an alarming precedent to set and places an undue burden on a hospital to provide this additional data. In addition, our data will be publicly reported dating back before we had process improvement initiatives in place to address our performance.
3. In reviewing the hospital data, CMS plans to combine the samples for first quarter, second quarter and third quarter of 2005 into a single stratified sample to determine whether or not the 80-percent reliability level is met. We believe this is problematic because hospitals have not had an opportunity to appeal CMS Clinical Data Abstraction Center (CDAC) errors if the error did not result in the hospital failing for the given time period. As a result, a hospital may be negatively impacted by the decision to combine these three quarters into a single stratified sample as proposed. For example, a hospital could have errors (as abstracted by CMS) in their 1st and 2nd quarter report providing them with an 80% passing rate (which they could not appeal) and actually fail the third quarter which would result in failure of all 3 quarters based on the plan to combine the first three quarters as proposed).
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5. Under the proposed timeline, January, February and March 2006 data will need to be abstracted and successfully submitted to CMS no later than July 31, 2006. With the CMS comment period deadline of June 12, 2006 and an anticipated response time of 60 days by CMS, the outcome may not be known until August 12, 2006. Hospitals will have to proactively submit data on the 21 indicators & in anticipation of the legislation going into effect. The proposed timelines as outlined are problematic.

Thank you for the opportunity to provide feedback on this important legislation. We believe it will have a negative impact on our organization and wanted CMS to consider the weaknesses and understand the implications. We look forward to your comments and feedback.

Submitter : Dr. Thomas Ahrens **Date:** 06/01/2006

Organization : Barnes-Jewish Hospital

Category : Nurse

Issue Areas/Comments

DRGs: Severe Sepsis

DRGs: Severe Sepsis

As most clinicians in critical care understand, sepsis is a devastating clinical condition. As severe sepsis develops, mortality changes markedly. Everything that could be done to help better recognition and treatment of this leading ICU cause of death is essential. A DRG that specifically targets severe sepsis would go a long way to helping achieve the goal of better recognition and treatment. There are two key reasons why this DRG would be helpful, one is clinical and the other is cost. I will address clinical first.

The clinical reason to address the DRG for severe sepsis relates to proper recognition and treatment. Sepsis is a time based condition, meaning earlier identification and treatment are essential. As sepsis presents with organ dysfunction, treatments must be rapid or mortality rapidly increases. Clinicians are getting better at understanding the importance of early recognition and treatment. However, a common mistake is to call severe sepsis something else (e.g. worsening pneumonia, post operative complication). This mistake often causes severe sepsis to not be properly identified. Patient treatment is often delayed or missed altogether. Why this mistake is made is likely a combination of inadequate education and resistance to change. If severe sepsis could be a separate DRG, it would highlight the identification of this condition and likely improve optimal identification and better timing of treatment.

Economic Reasons: Many clinicians are also aware that patients who develop sepsis become outliers in terms of resource utilization. Certainly, a coding system that would allow better reimbursement of sepsis patients would be an incentive to better manage this dangerous condition. Hospitals lose extensive amounts of monies on septic patients and would be anxious to try to offset some of these losses. Even if there is no net increase in reimbursement (decrease in another area to offset the sepsis funding increase), better reimbursement of sepsis patients would encourage hospital administration and clinicians to focus on this problem. Hospital administration would be more likely to support evidenced based practices for sepsis with appropriate resources, e.g. nurse and physician education, bundle implementation and tracking of results. I strongly encourage the DRG for sepsis to be adopted as soon as possible. Thanks for your consideration.

Submitter : Ms. Wanda Tillery **Date:** 06/01/2006

Organization : Medical Center of Central Georgia

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

We are asking for a consideration regarding the timeframe. Please consider either making the proposed addition of SIP Core Measure reporting effective for FY2008 or requiring that the reporting not be retroactive to Q12006, but instead start with 3rd Quarter 2006.
We are conservatively estimating the abstraction time to be 40 minutes per chart. Our volume will necessitate an average of 34 charts per month. Therefore, to retroactively abstract data will be disruptive and will impede efforts which focus on other quality initiatives. Additionally, we need time to aquire additional human resources that will be necessary to accomadate the additional workload.
We appreciate your consideration on these matters.

Submitter : Ms. Deborah Luttrell **Date:** 06/01/2006

Organization : D. W. McMillan Memorial Hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Hospital Quality Data

I fully support the progressive implementation of additional quality measures geared to providing data for informed consumer choice. However, I do not support the 'back-dating' requirement to submit data prior to the actual approval of the rule. This creates additional demands to pull records and review them for data submission prior to official approval. I believe the implementation date should be deferred for new quality measure sets until January 2007.

Sincerely,

Deborah G. Luttrell
Director of Performance Improvement
D. W. McMillan Memorial Hospital
(251) 809 - 8279

Submitter : Ms. Margaret Cox **Date:** 06/01/2006

Organization : CARING

Category : Nurse

Issue Areas/Comments

Nursing and Allied Health Education Activities

Nursing and Allied Health Education Activities

I support the Medical University of South Carolina proposal to adjust DRG payment by nursing intensity. Nursing is a major component to determining how a patient recovers and the work is should be considered for reimbursement.

Submitter : Dr. Hector Vila **Date:** 06/01/2006

Organization : H. Lee Moffitt Cancer Center

Category : Physician

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Hospital Quality Data -- my comments referred to the SIP project.

1. The antibiotic "administration time" needs to be clearly defined as the midpoint of the start of administration -- and end of administration. The one-hour time window from incision does not have adequate clinical support.... and does not take into account many of the activities that are required to prepare a patient for surgery such as positioning, cranial pinning, etc..

2. Many surgical procedures are preceded by another surgical procedure such as a cystoscopy or colonoscopy that seed bacteria into the blood. The "incision time" should be taken as the start of this procedure.

Submitter : Mrs. Rebecca Kobler **Date:** 06/01/2006

Organization : Cushing Memorial Hospital

Category : Individual

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

We are interested in providing feedback on the proposed Deficit Reduction
Action of 2005 which will reduce the Annual Payment Update (APU) to hospitals that fail to report the required measures of quality. If the proposed legislation goes through, it will have a significant financial impact on our hospital and we believe it is important that we provide feedback related to this important piece of legislation. Please find our comments below:

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Thank you for the opportunity to provide feedback on this important legislation. We believe it will have a negative impact on our organization and wanted CMS to consider the weaknesses and understand the implications. We look forward to your comments and feedback.

Submitter : Mr. Mike Myers **Date:** 06/01/2006

Organization : Southeast Alabama Medical Center

Category : Hospital

Issue Areas/Comments

DRG Weights

DRG Weights

Effective 10/1/2006 CMS is restructuring the Medicare inpatient short term acute DRG weights to be cost based rather than charge based. As we understand it, the change will redistribute reimbursement from surgical patients to medical patients, but will be somewhat budget neutral. The proposed rule includes a huge error in application of RCCs to average DRG charges to derive DRG costs and must not be implemented as proposed. Any DRG that is supply cost intensive will be grossly understated due to the average RCC being applied to the reverse graduated mark-up tables used by most hospitals.

For example, DRGs 515, 535, and 536 capture patients who receive an AICD. Most hospitals report an overall RCC of 20% to 30% on cost report line 55, which is one of the 10 specific lines chosen by CMS to calculate cost-based weights. Most hospitals mark up AICDs 1.2 to 1.6 times, since the purchase price is so high. For example, our hospital's RCC for line 55 is 20% and the actual cost of an AICD with attachments is about $28,000. Therefore, our hospital charges $44,800 for the AICD (1.6 x 28,000). Under the CMS cost-based DRG weight formula, our hospital's apportioned cost would be $8,960 (20% x 44,800). As a result, for DRG 515, our hospital will pay the vendor $28,000 for the AICD and receive a payment from Medicare of $18,700 ($4,500 x 4.1471). For every AICD IP discharge, our hospital would loose $9,300 on the implant alone before labor, capital and other costs are covered. Our hospital does about 90 Medicare AICD s per year. This will result in an annual loss of $900,000 (90 x $10,000).

Please reconsider the drastic restructuring of IP DRG weights for AICD DRGs (515, 535, and 536) and other supply intensive DRGs. This gross misapplication of accounting data will cause rationing of AICDs. Hospitals will not be able to sustain the losses from implanting AICDs into Medicare patients. Please correct this before implementation.

Submitter : Melvin Houghton **Date:** 06/02/2006

Organization : Wright Memorial Hospital

Category : Nurse

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

We are interested in providing feedback on the proposed Deficit Reduction Action of 2005 which will reduce the Annual Payment Update (APU) to hospitals that fail to report the required measures of quality. If the proposed legislation goes through, it will have a significant financial impact on our hospital and we believe it is important that we provide feedback related to this important piece of legislation. Please find our comments below:

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Submitter : Melvin Houghton **Date:** 06/02/2006

Organization : Wright Memorial Hospital

Category : Hospital

Issue Areas/Comments

Hospital Quality Data

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Thank you for the opportunity to provide feedback on this important legislation. We believe it will have a negative impact on our organization and wanted CMS to consider the weaknesses and understand the implications. We look forward to your comments and feedback.

Submitter : Mr. Gary Lukuc **Date:** 06/02/2006

Organization : United Government Services, LLC.

Category : Other

Issue Areas/Comments

SCH/MDH Volume Decrease Adjustment

SCH/MDH Volume Decrease Adjustment

Comments to the FY07 Hospital IPPPS Proposed Rule published 4/25/06
CMS-1488-P

SCH/MDH Volume Decrease Adjustment (p. 24103). The current occupational mix survey form does not separate the nursing salaries and hours in the routine and ICU areas from the nursing salaries/hours in the other areas of the hospital. Therefore, it appears that using the occupational mix data to develop an average of nursing hours per patient day will yield the same result as using the AHA data. Specifically, data for primarily outpatient ancillary cost centers, such as hospital-based clinics, ambulatory surgical centers, and emergency rooms will also be included. The data for the general acute care portion of the hospital cannot be separately identified using the current structure of the occupational mix data.

Submitter : Mr. Michael Fox **Date:** 06/02/2006

Organization : Mercy General Health Partners

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

My comments pertain to the overall plan to redistribute Medicare payments for inpatient hospital services based on costs.

Specialty hospitals do pose a threat to the financial stability of community-based acute care hospitals. A viable solution would be to set up special payment terms for the specialty hospitals that are based on their lower costs. Blue Cross Blue Shield of Michigan pays freestanding ASC's at lower rates than hospitals in recognition of the higher costs of operating a 24/7 multispecialty organization. CMS should consider a similar approach.

The methods used to calculate the costs that will serve as the basis for the DRG weight calculations are flawed and will most certainly result in a negative financial for multispecialty hospitals that support high volume, high technology procedures such as spine fusion, stents, and pacemakers. We currently produce a negative contribution margin on lumbar spine fusion. The proposed changes will only make it worse.

This proposal will not produce financial stablity for community hospitals that support high volume, high tech procedures. CMS must delay this change until it can be redesigned to adequately address the issue of specialty hospitals without jeopardizing the stability of community hospitals.

Submitter : Dr. Christopher Cole **Date:** 06/02/2006

Organization : Colorado Springs Cardiologists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 250 bed hospital located in Colorado Springs, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

Christopher R. Cole, M.D.

Submitter : Mr. Robert Smanik **Date:** 06/02/2006

Organization : Ellis Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-146-Attach-1.DOC

Ellis HOSPITAL

1101 Nott Street • Schenectady, NY 12308 Phone: (518) 243-4000 • www.ellishospital.org

June 1, 2006 #146

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

We are writing on behalf of Ellis Hospital in Schenectady, NY, to express our concern and opposition to the changes to the Medicare inpatient Diagnosis Related Groups (DRGs) and weight calculations being proposed by the Centers for Medicare and Medicaid Services (CMS). We believe this new methodology creates a bias against, and penalizes hospitals that treat clinically complex cases. Additionally, we take issue with the short implementation period that is being proposed.

While we applaud CMS's efforts to update these policies, we feel the proposed changes unfairly penalize specialty hospitals like Ellis that provide such services as cardiac surgery. Ellis Hospital will lose $1.5 million for fiscal year 2007 as a direct result of these changes. This amount of money would be financially devastating because Ellis, like not-for-profit hospitals across New York State and the nation, is in a year-to-year struggle to make ends meet. *The proposed DRG methodology penalizes our hospital by providing significantly less reimbursement for treatment of cardiac surgery patients – far less than what is required to provide care in such clinically complex cases. This stands in stark opposition to the relatively higher reimbursements that hospitals with less clinically complex cases will receive under the proposed new system.* In the end, this new DRG methodology will strip funding from specialty service hospitals like Ellis, while rewarding hospitals that do not offer specialty services like cardiac surgery.

Ellis Hospital has a 121-year tradition of serving its community, providing high quality care to anyone who walks through its doors regardless of their ability to pay. Our quality is exceptional, as we are ranked among the top 5% of hospitals nationwide for clinical excellence by HealthGrades, an independent rating agency. *Ellis Hospital is the only hospital in New York State to earn this distinction in 2005 and 2006.* Ellis' cardiac program, in particular, has achieved national recognition from HealthGrades as being top 5% in the nation, top three in New York State and the best in New York State's Capital Region for overall cardiac care. *Despite our high quality cardiac program, a case mix that reflects our ability to treat high acuity patients, and the correspondingly higher costs associated with providing care to more clinically complex cardiac cases, Ellis will lose a significant amount of reimbursement under the proposed severity-adjusted DRGs and revised weight calculations. The result of CMS' proposed changes is inadequate reimbursement for specialty hospitals like Ellis.*

Furthermore, we strongly suggest an extended and blended phase-in period for the proposed reimbursement changes. A blended transition model that gradually phases in the new methodology over a multi-year period would enable hospitals like Ellis to more readily adapt to new rates, and absorb the negative financial losses that will result if the proposed changes are implemented as currently written. The estimated impact from the change in DRG weights, in conjunction with the estimated impact of the severity-adjusted DRGs proposed for fiscal year 2008, will result in drastic swings to a facility's revenue stream and will bring volatile operating impacts to an already fragile and unstable health care environment. Historically, CMS has implemented significant changes to the Medicare program over a longer period of time. We hope that CMS will follow its past practices and extend the proposed DRG changes beyond a two-year time frame.

We strongly urge CMS to revise the proposed Medicare inpatient DRGs and weight calculations to ensure that changes are fair across the board, and to allow a sufficient period of time for changes to be implemented. **These proposed changes unfairly penalize specialty hospitals like Ellis Hospital that treat clinically complex cases with the highest provision of care.**

Thank you for your time and consideration.

Sincerely,

Robert E. Smanik, FACHE
President & CEO

G.E. (Jay) Hoffman, Jr., CPA
Chief Financial Officer

Submitter : **Mr. Michael Rodgers** **Date: 06/02/2006**

Organization : **Catholic Health Association**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment - applies to both 1488-P and 1488-P2

CMS-1488-P-147-Attach-1.DOC

THE
CATHOLIC HEALTH
ASSOCIATION
OF THE UNITED STATES

#147

June 2, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-1488-P and CMS-1488-P2

RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Payment Rates; Proposed Rule.

Dear Dr. McClellan:

The Catholic Health Association of the United States (CHA) is pleased to submit the following comments on the notice of proposed rulemaking (NPRM) for the Fiscal Year 2007 Hospital Inpatient Prospective Payment System (*Federal Register*, Vol. 71, No. 79) published April 25, 2006, as revised by the May 17, 2006 Centers for Medicare and Medicaid Services (CMS) notice "Medicare Program; Hospital Inpatient Prospective Payment Systems Implementation of the Fiscal Year 2007 Occupational Mix Adjustment to the Wage Index." We also note the notice of the two typographical clarifications published May 9, 2006 on the CMS website.

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www.chausa.org

The proposed rule, if adopted as proposed, would make the most significant changes to the hospital inpatient prospective payment system (IPPS) since its implementation.

The major factors in the proposed rule include:

1. Significant changes in the methodologies used to calculate the relative weights of the diagnostic related groups (DRGs). Such weights determine Medicare's payments for hospital inpatient services. The proposed changes include a move, beginning FY 2007, to an estimated "cost-based" system, rather than a charge-based system (used since 1983), for determining the payment weights for each diagnostic category.
2. Changes in the method for identifying the variation in patients' severity of illness. CMS said that the latter change would be implemented in FY 2008, but possibly earlier.
3. The court-mandated expansion of the occupational mix adjustment to apply to 100 percent of the wage index. The initial proposal for FY 2007 would have applied the occupational mix adjustment to 10 percent of the wage index, however, the May 17, 2006 revision to the initial proposed rule would apply the occupational mix adjustment to 100 percent of the wage index.

These changes, due to their re-distributional impact, will certainly bring as many as three potentially major de-stabilizing factors (if implemented simultaneously) to bear on the financial situation of many hospitals. Our recommendations and comments on these and other aspects of the proposed rule are as follows:

DRG Reclassifications

1. ***We recommend that CMS postpone until at least FY 2008 implementation of the proposed hospital specific cost-based DRG relative weight determination policy. During this extended period, CMS should complete an analysis, which includes a parallel pilot test of the proposed changes in order to identify any unintended consequences.***
2. ***We further recommend that the proposed hospital specific cost-based DRG relative weight determination policy and the proposed severity adjustment policy be implemented simultaneously but no earlier than FY 2008. This simultaneous implementation approach should help to insure that redistribution of hospital payments is not unduly disruptive to selected individual hospitals..***
3. ***Finally, we recommend that CMS provides at least a three year transition period of the proposed policies during which hospitals are protected from major payment disruptions.***

This recommendation for postponement also reflects our concerns regarding the need for an appropriate lead time to modify hospitals' coding systems.

And, recognizing that the court mandate limits CMS implementation flexibility of the proposed FY 2007 occupational mix adjusted wage index, the above recommendation also reflects our desire to minimize the impact of the potentially disruptive major policy changes on hospitals.

The proposed hospital specific DRG relative value weight policy change would base the DRG relative weights on the estimated cost of providing care. Such weights would be based on the national average of the hospital specific relative values for each DRG. CMS says that the purpose of the proposed change is to help reduce the bias by accounting for the differences in charge markups across cost centers. The proposed change was initially recommended by the Medicare Payment Assessment Commission (MedPAC), however, while agreeing with MedPAC, CMS did not accept MedPAC's proposed methodology. Instead, CMS asked for comments on an alternative methodology, which it proposed to fully implement October 1, 2006.

While we appreciate CMS's concern with MedPAC's recommended methodology, i.e., the administrative burden on hospitals to develop and maintain, we are concerned that the alternative methodology being proposed by CMS has not been thoroughly evaluated. For instance, the CMS methodology assumes a uniform hospital markup – but in fact, markups vary from product to product. In addition, the proposed changes would further distort the estimation of accurate costs by combining multiple costs centers on hospital cost reports into ten CMS-designated cost centers. CMS would then determine ten national average cost-to-charge ratios for each of the designated costs centers, however, such ratios would not be weighted by each hospital's Medicare charges. This would allow very small hospitals to have just as much of an impact on the national cost-to-charges ratios as larger hospitals. These and other methodological issues seem reason enough to invest additional time and energies in the assessment and, as appropriate, further refinement of this proposed change.

In addition, CMS is proposing to implement October 1, 2007, if not earlier, another major payment policy change to refine DRGs based on severity of illness. And here again, while accepting a MedPAC recommendation, CMS did not propose to adopt the already widely applied All Patients Refined DRGs (APR DRGs) endorsed by MedPAC, but rather proposed to adopt a CMS-developed Consolidate Severity-Adjusted DRGs (CSA DRGs).

And, as regards the latter, we are concerned about the implications related to the subject of adjusting for case-mix "creep." While not specifically saying that it would impose an across-the-board behavior adjustment offset in response to or anticipation of case-mix increases stemming from improved documentation and coding, CMS nonetheless left an impression that it would include a behavioral adjustment offset when the severity adjustment is implemented. Rather than impose such an adjustment on all hospitals, we urge that such offsets be applied on a case-by-case basis. This will prevent all hospitals from being arbitrarily penalized for the practices of a relative few.

We are concerned about the potential unintended consequences and implications of such unproven and essentially untested payment changes on hospitals. Given obvious potential impact on hospitals' payments, we respectively urge CMS to postpone implementing both these proposals pending thorough analysis. Such analysis should include

running the proposed changes side-by-side with the current payment policies in order to better track and discern any unexpected patterns or impact.

This postponement is all the more essential in light of the newly proposed, but court-mandated, occupational mix adjustment to the area wage index.

Implementation of Proposed FY 2007 Occupational Mix Adjustment (as published in the Federal Register, May 17, 2006)

While we understand the unusual restraints stemming from the court-mandated order as regards the application of the occupational mix adjustment to 100 percent of the wage index, we strongly urge CMS to use its discretionary authority to insure that implementation is not unduly disruptive to selected individual hospitals. That could be addressed by the use of a multi-year transition or the use of corridors, as CMS has utilized in the past.

Obviously we are concerned about the implications of the court-mandated application of the occupational mix adjustment to 100 percent of the wage index beginning FY 2007. Previously, CMS applied the occupational mix adjustment using only 10 percent of the adjustment factor in calculating the wage index values.

To comply with the court's order, CMS is proposing to use the first three months (January 1, 2006 through March 31, 2006) of the survey data collected on the 2006 Medicare Wage Index Occupational Mix Survey and apply that adjustment to 100 percent of the FY 2007 wage index. Hospitals are required to submit this occupational mix data no later than June 1, 2006. Thus, while CMS will use new data to apply a 100 percent occupational mix adjustment factor, such adjustments will only be as accurate as the data reported. Considering the very short time frame to report the new data, make adjustments, and the fact that this is only the second time such data are being requested, accurate information and results could still pose a problem.

Value-Based Purchasing

CMS noted that the Act required it to develop a plan to implement value-based purchasing beginning with FY 2009. CMS went on to say that the plan must consider a number of issues, including an incentive methodology, and asked a number of questions.

Before addressing these incentive methodology questions, we wanted to raise a more fundamental question - "What is the goal of value-based purchasing?" Is it to improve quality of care? Or is it to reduce Medicare spending? We feel the goal should be to improve the overall quality of care. And, if in the process, Medicare savings are realized, then such savings should be considered an unexpected value, but one that does not take precedence over the primary goal.

The above perspective is what guides our responses to the incentive methodology questions that follow. Our recommendations follow the statement of the respective question posed by CMS:

1. "How should incentives be structured?" ***Hospitals should be rewarded for continued improvement over time.*** This approach is preferred over one that sets an absolute standard of performance. Use of the latter option could either discourage hospitals, especially small and rural hospitals, because it failed to reflect the hospital's unique situation and/or it failed to appropriately stimulate other hospitals.

2. "What level of incentive is needed?" ***We concur with the use of a 1 to 2 percent bonus incentive but feel strongly that penalties for "poor performance" would not be in keeping with the quality improvement spirit.*** And if such penalties are adopted, they should not, however, be determined based on only one year of performance. Rather, such a determination should consider a hospital's continued improvement over more than one year because one year may just be too short of an evaluation period to obtain a reliable performance determination.

3. "What should be the source of the incentives?" ***We encourage CMS to examine the possibilities of improving care coordination as an incentive funding source.*** In particular, CMS, as it noticed in the

proposal, would need to determine whether such an effort could produce measurable savings and whether some of the savings generated in one payment system could be used (as incentive payments) in another.

4. "What should the form of incentives be?" ***We believe, for simply practical purposes, that the incentive payments should be made on a periodic, lump sum, quarterly basis.*** First the logistics of making incentive payments on a per-service basis would, we believe, add an increased administrative burden on hospitals and could fracture a hospital's systemic effort to improve quality. Rather, a lump sum payment would serve to reward the entire hospital for its achievements. And setting up monthly lump sum payments would be inviting delays and complaints. It's better to take a little more time, i.e., every quarter, to get it right and on time.

5. "What should the timing of the incentives be in relation to performance?" ***(See #4 above.)***

6. "How should we develop composite scores?" ***We endorse the use of the highlighted composite scoring methodology currently being used for the Premier Hospital Quality Incentive Demonstration.*** We like this approach because it weighs individual measures by the volume of opportunities for the associated intervention by a particular hospitals; missing values for a particular aspect of care provided by an individual hospital would not prevent that hospital from being represented in a public report; and composite measures may easily accommodate the addition of individual measures.

In closing, we want to thank you for the opportunity to comment on the proposed FY 2007 IPPS rule. If enacted as proposed, this rule will have the largest impact on hospitals since the inception of the IPPS in 1983. Not only does the rule propose major changes to the DRG weight determination process but also proposes substantive severity of illness refinements. And if these changes were not enough, the rule, responding to a court mandate, also proposes to substantially revise the methodology for calculating the occupational mix adjustment of the hospital area wage index. Given these proposed changes we again urge CMS to defer implementation of the DRG related changes for at least a year in order to better assess the potential unintended consequences.

Sincerely,

Michael Rodgers
Senior Vice President, Public Policy and Advocacy

Submitter : **Mr. Glenn Hackbarth** **Date: 06/02/2006**

Organization : **Medicare Payment Advisory Commission**

Category : **Federal Government**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1488-P-148-Attach-1.DOC

#148

June 2, 2006

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

Re: file Codes CMS-1488-P IV.
Sections A. and B.

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on the two quality-related sections in CMS's proposed rule entitled *Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates*, Federal Register Vol. 71, No. 79, pages 23996-24472 (April 25, 2006). In this letter our comments are on the hospital quality data and value-based purchasing provisions of the proposed rule. Our comments on the rest of the proposed rule are forthcoming.

We applaud your ongoing efforts to improve the quality of care for Medicare beneficiaries by developing measures and collecting information on hospital quality, particularly given CMS's many competing priorities.

Specifically, we support your efforts to develop a plan to move forward on hospital pay for performance. Currently Medicare pays high- and low-quality providers the same. Medicare needs to change the incentives of the system and base a portion of provider payment on performance. We believe a sufficient number of accepted quality indicators are available to move ahead quickly on hospital pay for performance. We elaborate on these and other potential measures as well as other design issues in our comments on value based purchasing.

Hospital quality data
We support the expansion of measures outlined in this proposed rule. In addition we offer suggestions to improve the existing set.

CMS should set a date certain for including HCAHPS as a part of the required data set. We agree that HCAHPS will add an important dimension to the measure set. To help hospitals prepare, the final rule should establish a firm date upon which CMS will require

HCAHPS data in the set of measures that must be reported to CMS as a condition of receiving the full annual update. We suggest that CMS state that it intends to use information from fiscal year 2008 as a condition for receiving the full update in 2009. This will encourage hospitals to begin to collect the information beginning fiscal year 2007 and provide hospitals and CMS time to become familiar with collecting, reporting, and analyzing the information before it is linked with the annual update and value-based purchasing program.

Delete oxygenation assessment from the measure set. The Deficit Reduction Act (DRA) states that CMS has the ability to replace measures "where all hospitals are effectively in compliance." The scores on the oxygenation assessment measure for patients with pneumonia have reached such high levels that they no longer provide meaningful information upon which to distinguish hospitals. The average performance on this measure is 99 percent, thus virtually all hospitals are in compliance. Retiring this measure, while a modest step, would provide an important signal to hospitals that CMS is willing to reduce the burden of data collection as the set evolves.

To ensure data completeness, CMS should, in addition to attestation, audit data from a randomly chosen, small number of hospitals. The provisions in the proposed rule require hospitals to sign an attestation that the sample of claims submitted to qualify for the Reporting Hospital Quality Data for Annual Payment Update is a fair sample of all patients discharged from their facility. The Commission supports this requirement. CMS may also want to consider strategies to audit data.

Value-based purchasing

It is essential for the Medicare program to become a value-based purchaser. This section of the proposed rule identifies a number of important issues for creating such a program. As you know, the DRA asked the Commission to address many of the same design issues for home health agencies, and we hope to coordinate closely with you and your staff as we develop our report. Further, the Commission is working on strategies to measure physician and inpatient resource use and will continue to coordinate with your staff on those issues.

General design issues. The Commission strongly supports differentiating provider payment on the basis of quality. In March 2004 we recommended that Medicare do so for Medicare Advantage plans and for settings of care and physicians that treat beneficiaries with end stage renal disease. In March 2005 we recommended differentiating payment on the basis of quality performance for physicians, hospitals, and home health agencies. The Commission also developed criteria for determining which measures to use and design principles, and assessed a wide variety of measure sets. Our comments on this section are based on those discussions.

The goal of pay for performance should be to improve care for as many beneficiaries as possible by as much as possible. This has implications for a variety of design issues in a

value-based purchasing program. It is one reason that the Commission recommended that Medicare reward both improvement *and* attainment. Rewarding both will provide incentives for all providers to respond. By providing an incentive for providers in regions with low scores, it may also address some of the regional variation in quality performance.

To minimize major disruptions, the program should be funded initially by setting aside a small portion of base payments—1 percent or 2 percent. The Commission intends the program to be budget neutral, but the amount channeled into pay for performance should grow over time. It should be an expectation of the Medicare program that a portion of provider (in this case hospital) payment be based on the provider's performance on quality.

The measures. As the proposed rule notes, it is important to capture a broad set of services and thus a complete picture of the quality of care. The two sets contemplated by this proposed rule—the 10 current and 11 additional process measures in the Hospital Quality Alliance set and HCAHPS—are a good start. Together they provide information on patient perception of care and clinical effectiveness, two of the Institute of Medicine (IOM) goals for a quality health system. However, the program also needs information on safety, one of the other IOM goals. Improving patient safety can be encouraged by measuring the adverse outcomes of poor safety.

Linking the information mandated by the DRA on secondary diagnoses present on admission with safety indicators from administrative data could enhance CMS's ability to assess patient safety. To make measures of patient safety more useful, MedPAC recommended in March 2005 that CMS require hospitals to report this information on all admissions. This information could be used to help identify which conditions patients had when they entered the hospital and which ones may have been the result of unsafe care. One set of indicators to which this information could be linked is the Agency for Healthcare Research and Quality's patient safety indicators.

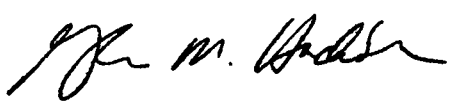
While reporting secondary diagnoses present on admission is a new responsibility for hospitals, it is information that could be used for many important purposes. This information could be helpful in adjusting for patient risk for quality outcome measures, and also in determining patient complexity for payment purposes. Further, many hospitals already collect the information because two large states—California and New York—require its collection. The National Uniform Billing Committee has included a field on the UB04 to accommodate this information.

From the proposed rule, it is unclear to us whether the agency intends to collect the information on all secondary diagnoses for all admissions. We believe this issue needs to be clarified in the final rule. As noted, the Commission believes this information is useful for a wide variety of functions and thus, CMS should collect all secondary diagnoses for all admissions.

Include measures of functions supported by the use of information technology in the value-based purchasing program. The Commission made this recommendation in March 2005. Adoption of clinical IT by providers has the potential to improve the quality, safety, and efficiency of health care. Because the benefits of IT result from its use for specific quality-enhancing functions, Medicare should incorporate measures of quality-enhancing functions supported by the use of information technology in any initiative to financially reward providers on the basis of quality. CMS should work with researchers, quality experts and hospitals to identify functions, such as medication reconciliation, that information technology supports and develop measures of their use.

Again, we look forward to continuing to work together to improve the Medicare program's ability to measure and reward quality and efficiency. If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director.

Sincerely,



Glenn M. Hackbarth, J.D.
Chairman

Submitter : **Date: 06/02/2006**

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1488-P-149-Attach-1.TXT

CMS-1488-P

June 2, 2006

#149

Response to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates: Reporting of
Hospital Quality Data for Annual Payment Update

This message is to express advocacy for a method by which hospitals, determined not to meet the RHQDAPU program requirements,
are able to appeal such determination.

We are supportive of a structured reconsideration process and agree with the proposed deadline of November 1, 2006
for FY 2007 RHQDAPU decisions, recognizing this allows 30 days from the public release of the decision to appeal.
We endorse reconsideration predicated on a written request specifically stating all reasons and factors why a hospital
believes it did meet the RHQDAPU program requirements. We concur with a time limit, maximum of 60 days, to be in receipt of
response from CMS regarding reconsideration.

Respectfully submitted,

Theresa J. Smiley

Theresa J. Smiley RN BSN
Novant Health
Corporate Clinical Improvement
2085 Frontis Plaza Blvd
Winston Salem, NC 27103
336.277.1063

Submitter : Mrs. Patricia Beatty **Date:** 06/02/2006

Organization : Saint Luke's East - Lee's Summit

Category : Individual

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

We are interested in providing feedback on the proposed Deficit Reduction
Action of 2005 which will reduce the Annual Payment Update (APU) to hospitals that fail to report the required measures of quality. If the proposed legislation goes through, it will have a significant financial impact on our hospital and we believe it is important that we provide feedback related to this important piece of legislation. Please find our comments below:

1. As proposed, the number of quality measures will increase from 10 to 21. This will require additional staff support to collect and transmit this additional information.
2. This proposed legislation requires hospitals to go back and abstract data from January 1, 2006. This is an alarming precedent to set and places an undue burden on a hospital to provide this additional data. In addition, our data will be publicly reported dating back before we had process improvement initiatives in place to address our performance.
3. In reviewing the hospital data, CMS plans to combine the samples for first quarter, second quarter and third quarter of 2005 into a single stratified sample to determine whether or not the 80-percent reliability level is met. We believe this is problematic because hospitals have not had an opportunity to appeal CMS Clinical Data Abstraction Center (CDAC) errors if the error did not result in the hospital failing for the given time period. As a result, a hospital may be negatively impacted by the decision to combine these three quarters into a single stratified sample as proposed. For example, a hospital could have errors (as abstracted by CMS) in their 1st and 2nd quarter report providing them with an 80% passing rate (which they could not appeal) and actually fail the third quarter which would result in failure of all 3 quarters based on the plan to combine the first three quarters as proposed).
4. The payment update for 2007 will be reduced by 2.0 percentage points for indicator performance that has a track record of poor reliability, especially working diagnosis of pneumonia. Some hospitals resort to answering working diagnosis for pneumonia as a yes for all pneumonia charts regardless of actual documentation, since the penalty is disproportionately more severe if the no answer is found to be incorrect. A couple of mismatches on the no to working diagnosis can drive the hospital to the brink of losing their APU.
5. Under the proposed timeline, January, February and March 2006 data will need to be abstracted and successfully submitted to CMS no later than July 31, 2006. With the CMS comment period deadline of June 12, 2006 and an anticipated response time of 60 days by CMS, the outcome may not be known until August 12, 2006. Hospitals will have to proactively submit data on the 21 indicators & in anticipation of the legislation going into effect. The proposed timelines as outlined are problematic.

Thank you for the opportunity to provide feedback on this important legislation. We believe it will have a negative impact on our organization and wanted CMS to consider the weaknesses and understand the implications. We look forward to your comments and feedback.

Submitter : Mr. Andrew Greenfield **Date:** 06/02/2006

Organization : Abiomed, Inc.

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1488-P-151-Attach-1.PDF

#151

22 Cherry Hill Drive
Danvers, MA 01923

June 2, 2006

Mr. Herb Kuhn
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments on CMS-1488-P, Changes to the Hospital Prospective Payment System for Fiscal Year 2007

Dear Mr. Kuhn,

ABIOMED welcomes the opportunity to provide the following comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule for changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 [CMS-1488-P], (hereinafter referred to as "proposed rule" or "NPRM").

ABIOMED, Inc. develops, manufactures and markets medical technology designed to restore, recover or replace the pumping function of the failing heart. Established in 1981, ABIOMED is committed to putting patients first by providing a range of therapeutic medical devices aimed at supporting patients through acute heart failure and if necessary, through the final stages of life. Currently, ABIOMED manufactures and sells the AB5000™ Circulatory Support System and the BVS® 5000 Biventricular Support System for temporary support of patients with reversible acute heart failure. These two devices are the only FDA-approved mechanical cardiac assist devices indicated for use in all forms of recoverable heart failure. More than 8,000 patients worldwide have been supported with ABIOMED devices, and all top five *U.S. News and World Report* ranked heart hospitals utilize ABIOMED recovery technology.

ABIOMED also manufacturers and markets the IMPELLA® RECOVER® technology under the CE Mark outside the US. This family of technology includes minimally invasive cardiovascular support systems designed for circulatory support in the cardiac cath lab for high risk percutaneous coronary intervention (PCI) patients and devices for more aggressive support intraoperatively following cardiotomy. ABIOMED recently received FDA approval to conduct clinical trials of the 2.5LP IMPELLA in the U.S.

The company's AbioCor® Implantable Replacement Heart is currently under review for designation as an HDE ("humanitarian device exemption") with the Food and Drug Administration but has not yet been approved for commercial distribution. If approved, the AbioCor would be the first totally implantable replacement organ brought to market.

Both the AB5000 and BVS5000 are reimbursed as "heart assist devices" under DRG 525 or DRG 103. In October 1, 2005, CMS announced a change in coding for external heart assist devices, such as the AB5000 or BVS5000, that assist patients through recovery of native heart function within a single hospital admission. This change allowed for the combined implant and explant of an extracorporeal ventricular assist device to map to DRG 103 instead of DRG 525. This put reimbursement for heart recovery with an external ventricular device on par with internal ventricular assist devices used for destination therapy and bridge-to-transplant, and heart transplantation. From a policy perspective, this was a solid acknowledgement that hospitals should be accurately reimbursed for treating extremely ill patients with failing heart function regardless of whether the failure is acute or chronic.

ABIOMED is wholly committed to providing technology that successfully recovers native heart function. This requires intervention in a timely, aggressive manner. Using a voluntary data registry, we reported last fall on a multi-center US experience for treating patients suffering from cardiogenic shock post myocardial infarction with AB5000 VAD technology.[1] Between October 2003 and July 2005, 50 patients were supported in 25 US centers and data was reviewed for demographics, patient management, and survival outcomes.

Preimplant conditions of these 50 patients included IABP 88%, mechanical ventilation 83%, pre-implant arrhythmia 71%, CPR 58%, vasopressors 83%, inotropes 90%, hyperbilirubinemia 50%, and hypercreatinemia 52%. Bi-Ventricular support was necessary in 48% of the patients. Hemodynamics were immediately stabilized after implantation of the AB5000 with significant improvements in cardiac index (1.7±0.5 to 2.6±0.5 L/min/m^2, $p<0.002$), systolic aortic pressure (77±15 to 112±16 mmHg, $p<0.0001$), central venous pressure (21±7 to 16±4 mmHg, $p=0.002$) and pulmonary arterial pressure (44±9 to 36±6 mmHg, $p=0.001$). The thirty day survival rate was 42% (n=21) for this patient population. Of the survivors 71% (n=15) recovered native heart function, 24% (n=5) were transplanted, and 5% (n=1) were transitioned to a destination device. The median support duration for recovery was 19 days (range 4-96 days).

For patients who are not implanted and explanted within the same admission, DRG 525 is available for procedures involving solely the "implant" or "replace and repair" of an external ventricular assist device.

Overall, ABIOMED supports a more accurate payment system and as a manufacturer of advanced medical technology, recognizes the complexity of establishing an accurate payment system that appropriately reflects changing technologies, an aging population and increasing strains on a publicly-funded health care system. The challenge before CMS is clearly daunting and ABIOMED supports their efforts to reshape the inpatient

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[1] Present in part by Anderson M, Acker M, Kasirajan V, et al. Mechanical circulatory support improves recovery outcomes in profound cardiogenic shock post acute myocardial infarction: a US multicenter study . *Am J Cardiol.* 2006;96:11H.

payment system to more accurately reflect provider economics and the realities of today's health care financing.

Our concern, however, is that CMS is attempting to accomplish too much, too fast, with too little understanding of the impact on today's much needed technology. Heart disease is the leading cause of death among both men and women. The American Heart Association reports that one in 3 Americans is living with some form of cardiovascular disease. Approximately 163,000 Americans die from sudden cardiac arrest *outside* the hospital setting each year and about two-thirds of all sudden cardiac deaths occur in individuals with no known heart disease.

Nearly 770,000 patients were discharged in 2003 with a primary diagnosis of acute myocardial infarction. Literature reports that 7-8% of them experience cardiogenic shock requiring advanced technology such as ABIOMED's available for immediate response. As the population ages, these heart failure patients will present with more secondary complications and co-morbities than ever before. It will be vitally important that patients have access to newer, innovative technology as the need arises.

While physicians will always be the best judge as to the appropriate clinical course to pursue, today's health economics necessitate that part of that decision making process does indeed include forethought to hospital and physician payment. Any measures to reshape the inpatient prospective payment system must, at a minimum, safeguard the clear and unbiased clinical decisions so important to the delivery of care. ABIOMED believes the CMS proposed rule for changes to impatient hospital payment for implementation in FY 2007 puts in jeopardy these decisions by disproportionately disadvantaging newer, innovative health technologies.

ABOIMED's comments are as follows:

"HSRV Weights"

CMS proposes to adopt MedPAC's recommendation that CMS replace its charge-based relative weight methodology with cost-based hospital-specific relative value (HSRV) weights because it is believed that the charge-based system has introduced "bias into the weights due to differential markups for ancillary services among DRGs." It is believed using cost-based relative weights will help reduce this bias and in some part, level the playing field among hospitals.

ABIOMED has three concerns with this approach. First, relying upon cost data will inherently disadvantage newer technologies such as heart assist devices designed for recovery because hospital cost data lags behind charge data. It is impossible to use data from FY 2004 and accurately reflect the utilization and benefit of newer technology. For example, ABIOMED heart assist devices, the most advanced of which was FDA approved in 2003, have successfully recovered Medicare patients under DRG 103 who have experienced acute heart failure, been supported through recovery to explant, and been discharged home without need for mechanical support. In FY 2004, 48 patients over the age of 65 benefited from support of this nature, whereas, within one year, this number had nearly doubled to 91 in FY 2005. The trend will only continue as the proven benefits of the technology become more fully rooted in clinical knowledge. Utilizing older cost data cannot capture this growth and utilization to establish accurate payment to hospitals.

Second, industry experts have identified technical flaws in the methodology CMS uses to calculate the cost-to-charge ratios that would be used in developing the HSRV weights. One involves the exclusion of data from a large volume of CMS hospitals from its analysis, which if included would result in different degrees of impact on new technology. Specifically to ABIOMED, utilizing modeling made available by Mr. Chris White, former MedPAC member and consultant to AdvaMed, ABIOMED's heart assist devices under DRG 525 would increase 2 percent according to CMS's approach, yet 11 percent with corrections for these technical errors.

And finally, we are concerned a cost-based system would be unreliable and perpetuate the common cost reporting errors and lack of timeliness that plagued hospitals prior to the change to a charge-based system in the early 1980s. Admittedly, because hospitals have full discretion in setting their charges they may not truly reflect actual costs and the reflection of resources, but neither are there safeguards and compliance within the reporting system to accurately report costs.

ABOIMED respectfully recommends that CMS retain for FY '07 a prospective payment system based on charge data because it will reflect the most current hospital expenditures for newer technology. ABIOMED is also concerned that the methodology proposed by CMS involves iterate steps and assumptions that are not transparent making it nearly impossible to determine the full impact of the proposed change to cost-based HSRV weights. Although we applaud an attempt to more accurately pay hospitals and eliminate variability among hospitals, the approach proposed needs further consideration and analysis before implementation.

"DRGs: Severity of Illness"

CMS proposes to adopt in FY 2008 (or earlier) a consolidated version of the 3M "all patient refined" (APR) DRG system to take into consideration severity of illness among patients within a DRG. CMS states that this refinement will be based on "complexity" defined as the relative volume and types of diagnostic, therapeutic, and bed services required fro the treatment of a particular illness. This, CMS proposes, would be referred to as consolidated severity of illness (SOI) DRGs and would increase the actual number of DRGs from 526 to 861 (and a decrease form the APR-DRG system of 1258).

In its proposed rule, CMS states the following in regard to the current DRG system.

> "The CMS DRG [referring to the current one] makes some DRG modifications difficult to accommodate. For example, high severity of illness diseases that occur in low volume are difficult to accommodate because the only choice is to form a separate base DRG with relatively few patients. Such an approach would lead to a proliferation of low-volume DRGs. Alternatively, these cases may be included in DRGs with other patients that are dissimilar clinically or in costs. [emphasis added] Requests for new base DRGs formed on the use of a specific technology may also be difficult to accommodate. Based DRGs formed based on the use of a specific technology would result in the payment weight for the DRG being dominated by the price set by the manufacturer for the technology."

Implicit in CMS's statement is a need to better refine the DRG system so that patients with variable degrees of illness will be accounted for and that hospitals will be

reimbursed based on these differences. To do so, CMS is proposing consolidated SOI DRGs that would stratify illnesses based on a formula that includes consideration of "patient volume" and "similarity of hospital charges across all four severity of illness subclasses and clinical similarity of the base APR DRGs."

ABIOMED supports CMS efforts to account for different patient conditions and degrees of illness; however, the restructuring of the DRG system is a vastly significant change from the current system and has an extremely deleterious impact on heart assist devices such as the ABIOMED AB5000 and BVS5000. This impact is primarily due to the regrouping of heart assist devices with procedures that represent far different technologies indicated for a completely different population of heart patients.

To determine the full impact of CMS proposed consolidated SOI DRGs, ABIOMED contracted with the Lewin Group, Falls Church, Virginia, to analyze the proposed rule to determine the mapping of DRG 103 and DRG 525 under the consolidated SOI DRG approach and its potential impact to reimbursement. [see attached Final Report]. From a review of 3M's APR DRG documentation, Lewin determined that heart assist devices were assigned to APR-DRG 161 ("Cardiac Defibrillators and Heart Assist Devices") along with several other cardiac procedures. It is this classification into a group of procedures ranging from cardiac defibrillators to total replacement hearts to IABP to ventricular assist devices that is most worrisome to ABIOMED.

Lewin's analysis stresses the significant negative impact to ventricular heart assist devices should the CMS proposed consolidated SOI DRG system be implemented as proposed. We summarize some of our concerns here.

Reimbursement for heart assist devices will be grossly underpaid under the proposed consolidated SOI DRG system. On average, under the consolidated SOI DRG system, the relative weight for heart assist device procedures would decline by approximately 34 percent for procedures now mapped to DRG 525 and 54% for recovery procedures now mapped to DRG 103. This significant reduction in reimbursement is due to simple arthmetic: relative weights are based on the average cost of all cases in the DRG and under the proposed grouping of consolidated SOI DRGs, heart assist devices would account for less than one percent of all cases in each of the four SOI DRGs.[2] Thus, although much more costly, their contribution to the "average" relative weight is negligible.

Moreover, the average charge for defibrillator cases and heart assist devices can differ between 25-299% depending upon the patient's SOI level. Resource intensity between the procedures are very different; e.g., the average length of stay for SOI Level 3 cardiac defibrillator patient is 6.7 days and for a heart assist device patient 14.5 days.

It is worth noting that this analysis would not apply to external ventricular assist devices that were recoded to DRG 103 effective October 1, 2005 because CMS's analysis (and thus the analysis by Lewin) was on 2004 MedPAR data. Thus, it is a safe assumption that these differences and the negative impact to the "recovery" reimbursement are grossly underestimated and could be far greater than can be determined at this time.

[2] Based on 2004 MedPAR data.

Grouping patients with failing hearts, many in bi-ventricular failure awaiting transplantation or with an acute, but life threatening condition such as viral myocarditis, with those receiving defibrillators for rhythm disorders is inappropriate. As noted in the multi-clinical trial described above, patients in need of ventricular assist devices have had multiple prior surgeries, advanced forms of mechanical support and often have multi-organ system failure due to a lack of adequate oxygenation and perfusion. Their situation requires immediate attention, instead of elective intervention as often is the case with cardiac defibrillators. Furthermore, ventricular assist devices are inserted in the operating room under anesthesia whereas defibrillators are placed by electrophysiology cardiologists generally without general anesthesia.

Because of these differences it is not surprising that 95% of the ventricular assist device cases would be assigned to SOI Level 3 or 4 under the proposed consolidated SOI DRG system. This creates the potential for frequent outlier payments (see comments below) and defeats CMS's stated goal of differentiating among patients within a DRG. Considering CMS is attempting to account for differences in patient sickness by proposing consolidated SOI DRGs, this grouping seems to be appositive with their goal.

And finally, this grouping would also include the total replacement heart, a technology that has been 25 years in the making and is earmarked for patients in biventricular failure who are too sick to benefit from heart transplantation but who have the potential for an extended life. Although in his letter dated April 26, 2006 from you to ABIOMED it was made clear that there is currently no Medicare coverage for the "total replacement heart" (ICD-9-CM codes 37.52 and 37.53), we raise the issue again in the context of CMS's proposed consolidated SOI DRGs. Of all procedures within this grouping, the one potentially most out of line with reimbursement.

ABIOMED respectfully recommends that CMS revisit the consolidated SOI DRG 207, 208, 209, and 204 and decouple ventricular assist devices and the total replacement heart from other procedures as proposed within those DRGs and consider implementation of one of the following.

a) Create a SOI DRG for ventricular assist devices and replacement hearts that would include external and internal heart assist devices that are FDA approved and indicated for destination therapy, bridge-to-transplant and recovery where recovery is defined as the implant and explant of an external heart assist device within the same hospital admission or the replacement and explant of a heart assist device within the same hospital admission. As the number of procedures this will alleviate CMS's concerns that low-volume DRGs are in essence, a mirror-imagine of what manufacturers want to charge for new technology. Additionally, CMS will have access to trends in ventricular assist devices through the newly established INTERMAC database (a joint CMS-FDA-NIH project) specifically aimed at better understanding the benefits, risks and utilization of ventricular assist devices.

b) Group heart assist devices with the proposed consolidated SOI DRG for heart transplantation. According to Lewin, the average length of stay for "recovery" patients was 46.1 days and the average cost was $742.265.[3] This is substantially higher than the average length of stay and charges for defibrillators (for example, SOI level 3,

[3] Based on MedPAR 2005 data. A total of 19 cases were analyzed.

6.7 days and $118,825); however, more in line with heart transplantation and implantable heart assist devices as shown here.

Procedure	Code	ALOS	Average Total Charge/Case	Average Standardize Charge/Case
Heart Transplant	37.5	41.1	$403,340	$286,334
Implantable Heart Assist Devices	37.66	47.2	$575,343	$433,576
Non-implantable Heart Assist Devices for AMI heart "recovery"	n/a at time of analysis	43.2	$378, 903 $405,350 (for bi-vad support)	$285,690 $267,050 (for bi-vad support)

Source: Lewin, "An Analysis of Medicare DRG Assignment for Heart Recovery Using External Heart Assist Devices," May 9, 2003, submitted as ABIOMED's official public comments to IPPS changes for FY 06.

Moreover, less than one year ago, CMS were persuaded to make a coding change to DRG 103 based on this data. Nothing has changed that would warrant splitting external heart assist devices from heart transplant reimbursement.

In addition, CMS states in the proposed rule that it "did not consolidate any of the pre-MDC DRGs that are DRGs to which cases are directly assigned on the basis of ICD-9-CM procedure codes." ABIOMED requests clarification as to whether this applies to other procedures within DRG 103, such as external heart assist devices for recovery. If so, ABIOMED seeks an explanation for why these procedures were handled differently than cardiac transplantation if all are currently reimbursed under DRG 103.

c) Establish separate consolidated SOI DRGs for cardiac procedures based on medical etiologies of rhythmic and vascular disorders versus pumping, valve or chamber dysfunction. To account for differences in length of stay, resource utilization, patient severity of illness, and immediacy in response, consideration should be given to distinguishing cardiac patients based on rhythmic and vascular disorders that require elective intervention generally by a cardiologist in a catheter lab from those patients with pumping, chamber, or valve disorders that require more aggressive technology performed in an operating room.

"Cost-Based Weight: Outlier Threshold"

In the proposed rule CMS acknowledges that it has limited statutory authority over the outlier payment system and that "we have not completed a detailed analysis of MedPAC's outlier recommendation because we do not have the authority to adopt such a change under current law." However, CMS goes on to say that they would "consider changes that would reduce or eliminate the effect of high-cost outliers on the DRG relative weight." By adopting the 3M proposed "all patient refined" DRG system with some modification for SOI, CMS is attempting to reduce outlier payments indirectly.

As stated in the above, utilizing 2004 MedPAR data, the Lewin Group determined that nearly 95 percent of all heart assist device procedures would be designated as SOI Level 3 or SOI Level 4 under the proposed consolidated SOI DRG system. This, coupled with anywhere from a 25 to 299 percent difference in reimbursement between heart assist devices and cardiac defibrillators, would most assuredly put heart assist devices into an outlier reimbursement category. This is directly at odds with what CMS

is attempting to accomplish by adopting the SOI DRG system. Instead of lowering the average outlier payment, this grouping could potentially increase it.

ABIOMED respectfully recommends that CMS adopt one of the three recommendations above to more accurate reimburse hospitals for heart assist devices, thus, eliminating the frequency of outlier cases that will most inevitably result from grouping these procedures with much less costly procedures such as cardiac defibrillators.

Requested coding change

ABIOMED uses this opportunity to respectfully request that CMS reconsider an earlier request that the reimbursement for external ventricular assist devices be modified to map the combined "repair and replace" (code 37.63) and "explant" (code 37.64) of a external heart assist device in a single admission to DRG 103. Your response dated April 26, 2006 to our original request leads us to believe we could better clarify our position and justification for requesting this change.

Although the number of procedures is small, the importance to improved patient outcomes is significant. Patients implanted with an external heart assist device who are transported to a tertiary hospital often undergo a second surgical procedure to "switch" the short-term external heart assist device to a more advanced, long-term device to give the heart adequate time to recover (see research herein indicating optimal recovery time is 19 days). This additional time may be necessary to stabilize clotting factors, restore nutritional balance, improve tenuous neurological conditions and wean the patient from respiratory support. The AB5000, a long-term external heart assist device, allows time for these improvements in patient outcomes and also allows the patient to ambulate, an important component of patient rehabilitation and recovery.

According to MedPAR 2004 data the average charges for combined "repair/replace" and "explant" were $375,561 and those for combined "implant" and "explant" were $371,211 (excluding one charge of $2M). Not surprisingly, these charges are very close. The resources, time, and personnel needed to surgically repair or replace the initial heart assist device to a second long-term device are comparable to the initial implant. Plus, the hospital course of these two populations of assisted patients is very similar. However, it is important to recognize that patients who are "switched" to a another device are given the advantage of a longer window of opportunity to recover their native heart function. This advantage results in additional use of resources that should be reflected in accurate payment.

Less than on year ago, CMS determined that the recovery approach ("implant" and "explant") utilizing an external assist device required a more accurate level of reimbursement. Similarly, patients who undergo a second procedure for placement of a long-term heart assist device utilize a comparable level of resources, have similar lengths of stay and according to MedPAR data, incur similar charges as patients who were implanted and explanted at the same hospital.

ABIOMED respectfully recommends that CMS revisit their review of this request and map a combined "repair/replace" (37.63) and "explant" (37.64) of an external heart assist device in a single admission to DRG 103.

In summary, ABIOMED supports CMS's efforts to change the inpatient prospective payment system to more accurately reflect costs as closely as possible and appreciates the efforts to implement the recommendations of the MedPAC 2005 Report to Congress. However, we believe CMS's proposed rule is problematic for several reasons. First, the use of cost-based weights inherently leads to the use of older data and lags behind charge-based data which disadvantages and misrepresents modern technology such as the AB5000 which has proven to be successful in the recovery of native heart function. While the impact of this approach would have a modest impact on the reimbursement of ABIOMED technology, it represents a wholesale change to the current system that is poorly understood.

Most importantly, ABIOMED is concerned about the proposed consolidation SOI DRG approach that would group ventricular heart assist devices with other procedures that involve much less aggressive technology and are intended for a much different patient population. ABIOMED does not support this approach and recommends alternatives to this grouping that improves on payment accuracy. Ultimately, patients in need of treatment for heart failure should be able to have access to technology that is fully recognized and reimbursed appropriately through reasonable and responsible changes to the payment system.

Please let us know if you have any questions regarding our comments or the Lewin Group report that we have attached. We request that it be made a part of our official public comment. We look forward to working with you and your staff to address these concerns and issues.

Sincerely,

Andrew Greenfield
Vice President
Abiomed, Inc.

Attachment.

The Lewin Group
3130 Fairview Park Dr.
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Falls Church, VA 22042

May 16, 2006

Gwen Mayes
Director of Reimbursement
Abiomed Inc.
22 Cherry Hill Road
Danvers, Massachusetts 01923

Dear Gwen:

As you requested, The Lewin Group reviewed the Centers for Medicare and Medicaid Services' (CMS) proposal to consider using Consolidated Severity-Adjusted Diagnosis Related Groups (DRGs). CMS recently published their proposed changes for the Inpatient Prospective Payment System (IPPS) for 2007, which discusses the potential use of consolidated severity-adjusted DRGs for fiscal year 2008.

This report identifies the Consolidated Severity-Adjusted DRG assignments for heart assist device procedures. The report also assesses whether the DRG assignments are appropriate for heart assist device procedures, based on hospital resource utilization for these patients. For these analyses, we used federal fiscal year 2004 hospital discharge data for all Medicare patients. Although 2005 data is currently available, CMS only provided the consolidated severity-adjusted DRGs on the 2004 data. Also, the 2004 data was used by CMS and 3M to develop the consolidated severity-adjusted DRGs.

1. Consolidated Severity-Adjusted DRG Assignment for Heart Assist Device Procedures

CMS used the All Patient Refined DRGs (APR-DRGs) developed by 3M as the basis for the consolidated severity-adjusted DRGs. CMS mapped each APR-DRG plus severity of illness level (SOI), which there are four SOI levels for each DRG, to a consolidated severity adjusted DRG. APR-DRG/SOI levels with low patient volumes (usually SOI level4) were often combined with others that were clinically similar.

We reviewed 3M's APR DRG documentation and found that all heart assist device procedures, except for removal of external heart assist device (37.64), are assigned to APR-DRG 161 (Cardiac Defibrillator and Heart Assist Device Implants). In order for a patient to be assigned to APR-DRG 161, they must have

a principal diagnosis of cardiovascular disease and one of the procedures listed in ***Figure 1*** below.

Figure 1
Procedures Included In APR-DRG 161
(Cardiac Defibrillator and Heart Assist Device Implants)

ICD9 Code	Description
00.51	Implant CRT defibrillator total system
37.52	Implant total replacement heart system
37.53	Replace or repair thoracic unit total replacement heart system
37.54	Replace or repair other total replacement heart system
37.62	Insert non-implantable heart assist device
37.63	Repair heart assist system
37.65	Implant external heart assist system
37.66	Insertion of implantable heart assist device
37.67	Implant cardiomyostimulation system
37.68	Insert percutaneous external heart assist system
37.94	Implant/replace cardiodefibrillator total system
00.52 & 00.54	Implant CRT defibrillator leads and pulse generator
37.95 & 37.96	Implant cardiodefibrillator leads and pulse generator
37.97 & 37.98	Replace cardiodefibrillator leads and pulse generator

Source: www.aprdrgassign.com

Under APR-DRG 161, heart assist device implant procedures are included in the same APR-DRG as cardiac defibrillator implant procedures. However, CMS proposes to separate patient cases that are assigned to APR-DRG 161 into four different consolidated severity-adjusted DRGs depending on the patient's SOI level. ***Figure 2*** shows CMS's proposed consolidated severity-adjusted DRG assignment for heart assist implant procedures.

Figure 2
Consolidated Severity-Adjusted DRG Assignment for Heart Assist Implant Procedures

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	APR-DRG	SOI Level	APR-DRG Description
204 1/	Cardiothoracic Procedures SOI 4	161	4	Cardiac Defibrillator & Heart Assist Implant SOI 4
207	Cardiac Defibrillator & Heart Assist Implant SOI 1	161	1	Cardiac Defibrillator & Heart Assist Implant SOI 1
208	Cardiac Defibrillator & Heart Assist Implant SOI 2	161	2	Cardiac Defibrillator & Heart Assist Implant SOI 2
209	Cardiac Defibrillator & Heart Assist Implant SOI 3	161	3	Cardiac Defibrillator & Heart Assist Implant SOI 3

1/ Consolidated severity-adjusted DRG 204 also includes APR-DRGs 160-major cardiothoracic repair of heart anomaly, 162/163-cardiac valve procedures, 165/166-CABG procedures, and 167-other cardiothoracic procedures. All with SOI level 4.
Source: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and FY 2007 Rates.

The SOI is defined by 3M as the extent of physiological decomposition or organ system loss of function [1]. The SOI subclasses used in the APR-DRGs are numbered from 1 to 4 indicating 1-minor, 2-moderate, 3-major and 4-extreme severity of illness. The SOI levels are dependent on the patient's underlying problems, so that patients with high SOI levels are usually characterized by multiple serious illnesses.

Under the APR-DRGs, each secondary diagnosis is assigned a SOI level of 1 to 4. The overall SOI assignment for the patient takes into consideration the SOI levels of all secondary diagnoses, the interaction between secondary diagnoses, patient age, principal diagnosis and the presence of certain operating room procedures. The process for determining the SOI level for a patient consists of the following three steps:

- the SOI level of each secondary diagnosis is determined;
- determine a base SOI level for the patient based on all secondary diagnoses; and
- final SOI level for the patient is determined by incorporating the impact of principal diagnosis, patient age, operating room procedure, multiple procedures, and combinations of categories of secondary diagnoses.

In order to determine how heart assist device procedures are distributed by SOI level, we analyzed the 2004 Medicare MedPAR database, which contains all inpatient Medicare discharges for federal fiscal year 2004 and was used by CMS to develop and evaluate the consolidated severity-adjusted DRGs. ***Figure 3*** shows that about 75 percent of heart assist procedures would be categorized as severity level 4 and 95 percent as severity level 3 or 4.

Figure 3
SOI Level Assignment for Heart Assist Device Procedures in FY 2004 [1/]

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	Medicare Cases in FFY 2004	Percent of Cases by SOI Level	DRG Relative Weight [2/]
207	Cardiac Defibrillator & Heart Assist Implant SOI 1	4	1%	3.8849
208	Cardiac Defibrillator & Heart Assist Implant SOI 2	18	4%	4.4273
209	Cardiac Defibrillator & Heart Assist Implant SOI 3	99	20%	5.4582
204	Cardiothoracic Procedures SOI 4	367	75%	9.3274
	All Heart Assist Implant Procedures	488	100%	n/a

1/ Includes implantable and non-implantable heart assist device procedures.
2/ DRG relative weights provided by CMS.
Source: Lewin Group analysis of the 2004 MedPAR database.

[1] 3M Health Information System, "All Patient Refined Diagnosis Related Groups (APR-DRGs), Methodology Overview", 2006

2. Consolidated Severity-Adjusted DRG Assignment for Removal of Heart Assist Device

Procedure code 37.64 (removal of external heart assist device) was not included in APR DRG 161, but was included in APR-DRG 173 (Other Vascular Procedures), which is consistent with the current CMS DRG assignment.

Under APR-DRG 173, the heart assist device removal procedure is included with 49 other vascular procedures [2]. Similar to APR DRG 161 above, CMS proposes to separate patient cases that are assigned to APR-DRG 173 into four different consolidated severity-adjusted DRGs depending on the patient's SOI level. ***Figure 4*** shows CMS's proposed consolidated severity-adjusted DRG assignment for heart assist device removal procedures.

Figure 4
Consolidated Severity-Adjusted DRG Assignment for Removal of Heart Assist Device

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	APR-DRG	SOI Level	APR-DRG Description
205 1/	Vascular Procedures SOI 4	173	4	Other Vascular Procedures SOI 4
234	Other Vascular Procedures SOI 1	173	1	Other Vascular Procedures SOI 1
235	Other Vascular Procedures SOI 2	173	2	Other Vascular Procedures SOI 2
236	Other Vascular Procedures SOI 3	173	3	Other Vascular Procedures SOI 3

1/ Consolidated severity-adjusted DRG 205 also includes APR-DRGs 169-major thoracic & Abdominal vascular procedures, SOI level 4.
Source: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and FY 2007 Rates.

In order to determine how heart assist device removal procedures are distributed by SOI level, we analyzed the 2004 Medicare MedPAR database. ***Figure 5*** shows that 99 percent of heart assist device removal procedures would be categorized as severity level 3 or 4.

[2] www.aprdrgassign.com, "3M APR DRG v23.0 Definitions Manual, Volume 1", page 211

Figure 5
SOI Level Assignment for Removal of Heart Assist Device in FY 2004 [1/]

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	Medicare Cases in FFY 2004	Percent of Cases by SOI Level	DRG Relative Weight [2/]
234	Other Vascular Procedures SOI 1	0	0%	1.5918
235	Other Vascular Procedures SOI 2	1	1%	2.0045
236	Other Vascular Procedures SOI 3	32	46%	3.1716
205	Vascular Procedures SOI 4	37	53%	6.7708
	All Removal of Heart Assist Devices	70	100%	n/a

1/ Includes implantable and non-implantable heart assist device procedures.
2/ DRG relative weights provided by CMS.
Source: Lewin Group analysis of the 2004 MedPAR database.

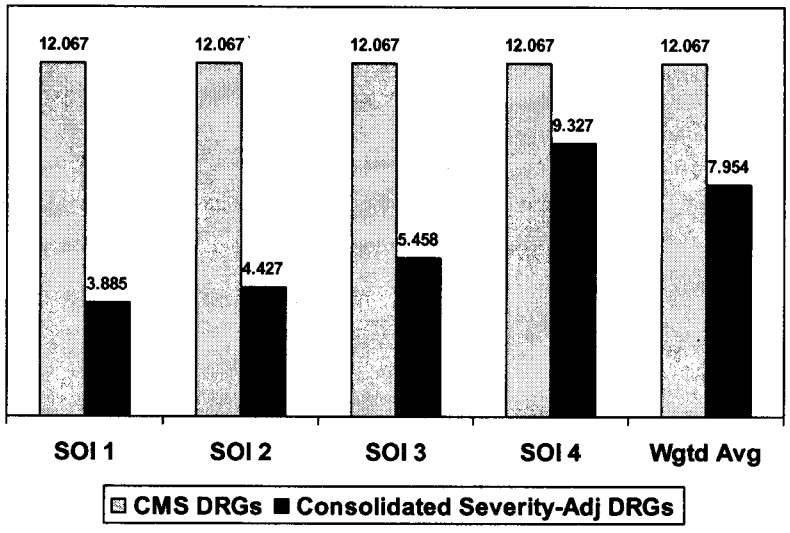
3. Impact on Medicare Payment Rates for Heart Assist Device Implant Procedures

Medicare payment for inpatient hospital services is based upon a hospital's base payment rate multiplied by the relative payment weight for the DRG assigned to the patient stay. CMS proposes to increase the Medicare base payment rate by 3.4 percent for 2007. The current DRG relative weight for non-implantable heart assist system procedures (DRG 525) for 2006 is 11.4282. The proposed DRG relative weight for 2007 for these procedures is 12.0673, which is a 5.6 percent increase. When the base payment rate increase is factored into the equation, hospitals will see an increase in Medicare payment for non-implantable heart assist device procedures of about nine percent (3.4% + 5.6%) for 2007.

The estimated relative payment weights that were computed by CMS for the consolidated severity-adjusted DRGs are significantly lower than the relative weights proposed under the CMS DRGs for 2007. As shown in ***Figure 6***, the consolidated severity-adjusted DRG relative weights are lower than the CMS DRG relative weights for each SOI level including SOI level 4.

As discussed above, the majority of non-implantable heart assist cases are assigned to higher severity DRGs, which would be paid using the higher relative weights. We accounted for this by computing a weighted average DRG relative weight using the number of non-implantable heart assist system procedure cases for each SOI level. We computed the weighted average relative weight under the consolidated severity-adjusted DRGs to be 7.954, which is about 34 percent lower than the CMS DRG weight for DRG 525 that is proposed by CMS for 2007.

Figure 6
Proposed DRG Relative Payment Weights for Non-Implantable Heart Assist Device Procedures



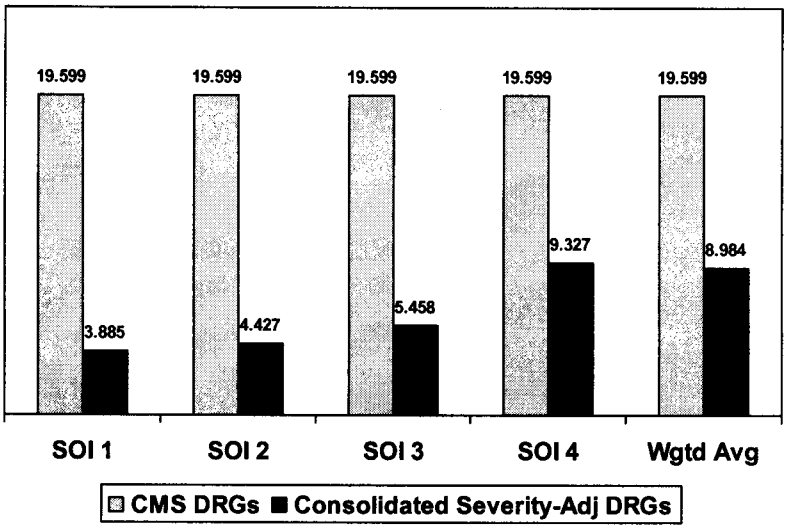
Weighted average DRG relative weight using the number of non-implantable heart assist system procedure cases for each SOI level.
Source: Lewin Group analysis of the 2004 MedPAR database.

The current DRG relative weight for implantable heart assist system procedures and heart recovery procedures (included in DRG 103) for 2006 is 18.5617. The proposed DRG relative weight for 2007 for these procedures is 19.599, which is a 5.6 percent increase. When the base payment rate increase is factored into the equation, hospitals will see an increase in Medicare payment for non-implantable heart assist device procedures of about nine percent (3.4% + 5.6%).

As shown in ***Figure 7,*** the consolidated severity-adjusted DRG relative weights are lower than the CMS DRG relative weights for each SOI level including SOI level 4. We computed a weighted average DRG relative weight using the number of implantable heart assist system procedure cases for each SOI level [3]. We computed the weighted average relative weight under the consolidated severity-adjusted DRGs to be 8.984, which is about 54 percent lower than the CMS DRG weight for DRG 103 that is proposed by CMS for 2007.

[3] The weighted average was based on implantable heart assist device implants and did not include heart recovery procedures because we used the 2004 data, which included only six heart recovery cases.

Figure 7
Proposed DRG Relative Payment Weights for Implantable Heart Assist Device Procedures for FY 2007 & 2008

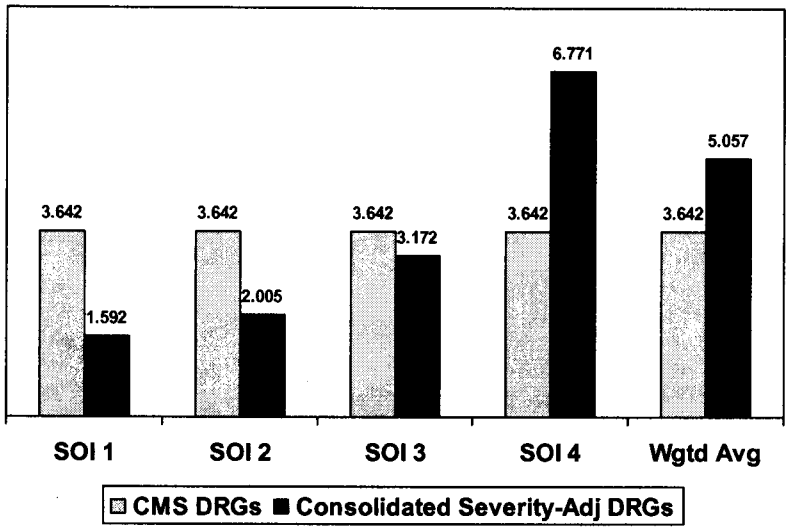


Weighted average DRG relative weight using the number of implantable heart assist system procedure cases for each SOI level.
Source: Lewin Group analysis of the 2004 MedPAR database.

The current DRG relative weight for a removal of heart assist system procedure (DRG 110) for 2006 is 3.8417. The proposed DRG relative weight for 2007 for this procedure is 3.642, which is a 5.2 percent reduction. When the Medicare base payment rate increase of 3.4 percent is factored into the equation, hospitals will see a net decrease in Medicare payment for removal of heart assist device procedures of about two percent (3.4% - 5.2%).

As shown in ***Figure 8,*** the consolidated severity-adjusted DRG relative weights are lower than the CMS DRG relative weights for each SOI level except SOI level 4, which is substantially higher. We computed a weighted average DRG relative weight using the number of implantable heart assist system procedure cases for each SOI level. Because most removal of heart assist system procedures are assigned to SOI level 3 or 4, the weighted average relative weight under the consolidated severity-adjusted DRGs is 5.057, which is about 39 percent higher than the CMS DRG weight for DRG 110 that is proposed by CMS for 2007.

Figure 8
Proposed DRG Relative Payment Weights for Removal of Heart Assist Device for FY 2007 & 2008



Weighted average DRG relative weight using the number of heart assist system removal procedures for each SOI level.
Source: Lewin Group analysis of the 2004 MedPAR database.

4. Comparison of Average Length of Stay and Charges Across Procedures within DRG (Cardiac Defibrillator & Heart Assist Implant)

The reason for the lower DRG relative weights for the heart assist device implant procedures is that CMS computes the relative weights based on the average cost of all cases in the DRG. Based on the 2004 MedPAR database, heart assist device procedures accounted for less than one percent of all cases in each of the four DRGs listed above (*Figure 9*).

Figure 9
ALOS and Average Charges for Cardiac Defibrillator and Heart Assist Cases in FY 2004

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	Total Cases in DRG	Heart Assist Device Cases in DRG	Percent Heart Assist Cases in DRG
207	Cardiac Defibrillator & Heart Assist Implant SOI 1	5,932	4	0.1%
208	Cardiac Defibrillator & Heart Assist Implant SOI 2	23,852	18	0.1%
209	Cardiac Defibrillator & Heart Assist Implant SOI 3	27,499	99	0.4%
204	Cardiothoracic Procedures SOI 4	23,077	367	1.6%
	Total	80,360	488	0.6%

Source: Lewin Group analysis of the 2004 MedPAR database.

However the resource intensity, as measured by average charges, for heart assist device cases is substantially higher than average charges for defibrillator cases. ***Figure 10*** shows that average charges for heart assist device cases are 60 percent higher for the SOI level 3 DRG and 94 percent higher for the SOI level 4 DRG, where the vast majority of the heart assist cases are assigned.

Figure 10
ALOS and Average Charges for Cardiac Defibrillator and Heart Assist Cases in FY 2004

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	ALOS Defib. Cases	ALOS Heart Assist Cases	Prcnt. Diff.	Average Charge Defibrillator Cases	Average Charge Heart Assist Cases	Prcnt. Diff.
207	Cardiac Defibrillator & Heart Assist Implant SOI 1	2.3	32.0	1,291%	$86,225	$344,271	299%
208	Cardiac Defibrillator & Heart Assist Implant SOI 2	3.7	11.3	205%	$97,647	$122,382	25%
209	Cardiac Defibrillator & Heart Assist Implant SOI 3	6.7	14.5	116%	$118,825	$189,933	60%
204	Cardiothoracic Procedures SOI 4	18.1	26.7	48%	$197,389	$382,612	94%

Includes implantable and non-implantable heart assist device procedures.
Source: Lewin Group analysis of the 2004 MedPAR database.

As described above, our analysis is based on 2004 data, which included very little data on heart recovery procedures (i.e., insertion and removal of external heart assist device during the same hospital stay). We analyzed the 2005 Medicare data and identified 19 heart recovery cases. The average length of stay for these cases was 46.1 days and the average charge was $742,265, which is also substantially higher than the average length of stay and charges for defibrillator cases.

One reason for the higher charges is that average length of stay is for heart assist device cases are substantially higher than for defibrillator cases. A second reason is that the cost of the heart assist device is much higher than the cost of defibrillators. (***would AdvaMed of Abiomed have data on this?***)

Since the heart assist cases account for less than one percent of the cases within each DRG, the average cost computed by CMS is heavily weighted toward the defibrillator cases in these DRGs. When CMS computes the DRG relative weights they use an average cost for the DRG that is nearly equal to the average defibrillator patient cost and the resulting Medicare payment for all procedures in the DRG is based on this average cost. Since the Medicare payment is based on this average cost, and the cost of heart assist device procedures is substantially higher than the average, then Medicare payment for heart assist device implant procedures will be substantially below its cost.

5. Comparison of Average Length of Stay and Charges Across Procedures within DRG (Other Vascular Procedures)

Based on 2004 Medicare hospital discharge data, average length of stay and average charges for heart assist device removal cases are similar to the 49 other vascular procedures included in those DRGs. ***Figure 11*** shows that average charges for heart assist device removal cases are less than eight percent different than the average charge for other vascular procedures included in the DRGs. This indicates that heart assist device removal procedures may be appropriate placed in regards to hospital's resources required for the procedure.

Figure 11
ALOS and Average Charges for Other Vascular Procedures and Heart Assist Device Removal Cases in FY 2004

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	ALOS Other Vascular Procedures	ALOS Heart Assist Device Removals	Prcnt. Diff.	Average Charge Other Vascular Procedures	Average Charge Heart Assist Device Removals	Prcnt. Diff.
234	Other Vascular Procedures SOI 1	2.9	n/a	n/a	$31,166	n/a	n/a
235	Other Vascular Procedures SOI 2	4.9	4.0	-18%	$38,449	$39,125	2%
236	Other Vascular Procedures SOI 3	10.6	9.7	-9%	$61,041	$65,093	7%
205	Vascular Procedures SOI 4	18.7	16.0	-14%	$126,927	$136,604	8%

Includes implantable and non-implantable heart assist device procedures.
Source: Lewin Group analysis of the 2004 MedPAR database.

6. Conclusion

Under the current CMS DRGs, most non-implantable heart assist device procedures are assigned to their own DRG, which is 525 (other heart assist system implants). Implantable heart assist devices are assigned to the same DRG as heart transplant cases (DRG 103). Also, the implant and removal of an external heart assist device during the same stay (heart recovery) is also assigned to CMS DRG 103. Heart assist device removal procedures are included in CMS DRG 110 (major cardiovascular procedures).

Under CMS's proposed consolidated severity-adjusted DRG, heart assist device implant procedures are included in the same DRG as cardiac defibrillator implant procedures. However, CMS proposes to separate these procedures into different consolidated severity-adjusted DRGs depending on the patient's SOI level.

We have drawn the following conclusions from the above analyses on the assignment of heart assist device procedures in these consolidated severity-adjusted DRGs:

- Heart assist device implant procedures should not be included in the same DRGs as cardiac defibrillator cases because the resource intensity between these types of procedures is very different;

- Medicare payments for heart assist device implant procedures would be dramatically reduced under the consolidated severity-adjusted DRGs;

- Average length of stay and average charges for implantable heart assist cases and heart recovery cases were extraordinarily higher than cardiac defibrillator cases and Medicare payments for these procedures could be reduced by more than 50 percent under the proposed consolidated severity-adjusted DRGs;

- Other non-implantable heart assist device procedures should be assigned their own consolidated severity-adjusted DRG because the resource intensity is very different from cardiac defibrillator procedures. Since about 93 percent of all non-implantable heart assist cases are assigned to severity levels 3 or 4, CMS could combine all non-implantable heart assist procedures into one or two DRGs.

- Finally, removing heart assist device procedures from the consolidated severity-adjusted DRGs 204, 207, 208 and 209 would have little impact on the relative weights for these DRGs since these procedures represent less than one percent of cases in each DRG (***Figure 12***).

Figure 12
ALOS and Average Charges For Consolidated Severity-Adjusted DRGs by Procedure in FY 2004

	Description	Number of Discharges	ALOS	Average Total Charges
DRG 207 - Cardiac Defibrillator & Heart Assist Implant SOI 1				
	Total DRG	5,932	2.3	$86,399
	All Defibrillator Implants	5,928	2.3	$86,225
	All Heart Assist System Implants	4	32.0	$344,271
DRG 208 - Cardiac Defibrillator & Heart Assist Implant SOI 2				
	Total DRG	23,852	3.7	$97,665
	All Defibrillator Implants	23,834	3.7	$97,647
	All Heart Assist System Implants	18	11.3	$122,582
DRG 209 - Cardiac Defibrillator & Heart Assist Implant SOI 3				
	Total DRG	27,499	6.7	$119,081
	All Defibrillator Implants	27,400	6.7	$118,825
	All Heart Assist System Implants	99	14.5	$189,933
DRG 204 - Cardiothoracic Procedures SOI 4				
	Total DRG	23,077	18.9	$187,932
	All Defibrillator Implants and Other Procedures	22,710	18.8	$184,786
	All Heart Assist System Implants	367	26.7	$382,612

Source: Lewin Group analysis of the 2004 MedPAR database.

Submitter : sameer oza **Date:** 06/03/2006

Organization : heart rhythm society

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 200 bed hospital located in Boulder, CO, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

SAMEER OZA, MD

Submitter : Mr. Thane Forthman **Date:** 06/03/2006

Organization : The Delta Group, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

Please refer to the attached WORD document.

CMS-1488-P-153-Attach-1.DOC

#153

June 5, 2006

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

Re: CMS-1488-P (Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates)

Dear Administrator McClellan:

The Delta Group is grateful for the opportunity to submit comments on the proposed rule regarding Medicare's inpatient hospital payment system. The Delta Group is healthcare information services company that profiles the clinical and financial performance of nearly 200 client hospitals. As part of our information services, we adjust the CMS MedPAR file for severity of illness in order to make valid comparisons among hospitals. Consequently, we have extensive knowledge of and experience with the 3M APR-DRGs, Yale R-DRGs, HSS APS-DRGs, and MedStat's Disease Staging and Scale.

While we are not paid by Medicare under the inpatient hospital prospective payment system (IPPS), we assist customers that are paid under this system. In this capacity, we have identified a number of concerns with the proposed rule, particularly related to the proposed changes to the Diagnosis Related Group (DRG) classification system. Foremost among these concerns is the need for transparency with regard to any changes to the DRG classification system because the lack of such transparency has the potential to cripple our ability to continue to assist our customers. We also think that CMS should not rush into this change in the upcoming fiscal year and that it should consider the complexity of any revision and the impacts on hospital coding and billing. These concerns are discussed below.

A. Transparency

Currently, we are able to access the complete DRG classification methodology, which CMS makes available equally to all members of the public. Complete and timely access to this methodology is crucial to our business since DRG severity adjustment is central to our processing of comparative hospital data. It is important that as CMS changes the DRG system, vendors such as us retain access to the underlying methodology at a level equivalent to what we experience today. There seems to be no

guarantee that this would remain the case under the proposed move to All Patient Refined Diagnosis Related Group (APR-DRG) classification system. As you know, the APR-DRG system is a proprietary system and nothing in the proposed rule provides us with any comfort that if the agency were to move to the APR-DRG system the same level of detail that is currently available would continue to be available. Indeed, the proposed rule offers a website for more detail on APR-DRGs, but that site contains a very limited amount of disclosure about the methodology, a level that is insufficient for our business purposes. Our concern is that the vendor whose proprietary system CMS ultimately might use would have a significant advantage over other vendors in our line of business unless CMS were to insure that all interested parties were able to get access to source code, comprehensive system and user documentation, test data and quality support from the owner of the methodology at costs similar to what the industry now pays relative to the DRG system and well enough in advance of implementation (10-12 months) to be able to support our clients effectively.

Given the above issues, we strongly urge CMS, irrespective of the revision of the DRG system adopted by the agency, to ensure that as much detail about the new system is made available as CMS currently makes available under the existing DRG system. We also ask that details regarding the new system become available as soon as possible so that the impact of this system on hospital data processing, billing and management systems can be fully evaluated. We also ask that Medicare continue to make the DRG update process totally transparent. We need the same level of dialogue with CMS regarding DRG changes as has existed since the advent of the inpatient PPS.

B. Need for Time to Adapt to DRG Change

According to the proposed rule, CMS might move to the APR-DRGs as soon as October 1, 2006. Based on our experience in working with hospitals, we believe this would be an unrealistic time frame for such a dramatic change to the inpatient hospital payment system. Hospitals would not have time to effectively plan for and implement this system. Moreover, it would be difficult for us and other data vendors to provide the services we currently do if the use of APR-DRGs were finalized two months before the start of the fiscal year. Quite simply, it is highly unlikely that all necessary actions could be accomplished by October 1 of this year and we therefore recommend that CMS not change the classification system in fiscal year 2007.

C. Considering Other Methodologies

While the proposed rule discusses only APR-DRGs, there are other classification systems that could be used but do not seem to have been considered by CMS. These systems include APS-DRGs, R-DRGs, and S-DRGs These systems are built on top of the current CMS DRG system and achieve similar statistical performance while introducing less disruption to the coding and billing processes required by the adoption of the APR-DRGs. We ask that CMS address other alternatives to the APR-DRGs and allow the public the opportunity to comment on a DRG classification system change before any such change is adopted.

D. Minimizing Complexity and Burden

Obviously, a change to the DRG system will be a complex endeavor that will be burdensome for hospitals. However, there seem to be strategies for making this change less complex and less burdensome to hospitals. For example, we suggest that CMS look toward a system that uses a similar coding framework as is currently being used. Otherwise, greater complexity will decrease coder productivity and lengthen revenue cycles. As an industry we are already facing changes required by UB-04, ICD-10 and the quality provisions of the Deficit Reduction Act. There is only so much change that any industry can withstand. If we could streamline and coordinate these changes there would be a positive overall impact on healthcare management and the associated expense of this process.

Again, The Delta Group appreciates the opportunity to comment on the proposed rule. We hope that the agency will carefully consider these comments as it moves forward regarding the DRG system. Thank you for your consideration.

Sincerely,

M. Thane Forthman
Managing Principal

Submitter : Dr. Kevin Vaska **Date:** 06/04/2006

Organization : USD School of Medicine

Category : Physician

Issue Areas/Comments

MedPac Update Recommendation

MedPac Update Recommendation

As an independent, cardiologist caught between a non-profit community hospital (owns cardiologists) and a heart hospital associated with another non-profit community hospital (cardiologist owners), I live the daily experience of poor patient cardiac care, cardiovascular decisions based on financial incentive, waste of medical resources and monies, greed, power, control, and what I consider to be fruadulent behavior. Thus, we are the minority of cardiologists who are neither owned by a hospital, or own a hospital! I wholeheartedly support your recommendations regarding updating inpatient DRG payments based, in part, on cost (rather than charges) and severity adjustments. Both systems waste an enormous amount of taxpayer money on fraudulent advertising, unnecessary expansion of services and space, unnecessary procedures and protocols designed to maximize profit, physician salaries that are way above fair market value, profit-sharing schemes, bad administrative oversight, continued disconnect of healthcare prices and product to offset their extensive competition, unnecessary upper management (one system has 30 vice-presidents of something!), continued denial or transfer of care of uninsured or underinsured patients, and etc. etc. Where is the oversight and enforcement of these antitrust behaviors?

I believe a 'correction' of inpatient hospital cardiac revenues will force both systems to re-evaluate unnecessary expenditures that waste precious money and resources on futile causes, and leave the individual taxpayer unprotected. Maybe, this will cause them to re-evalute the wisdom of the corporate practice of medicine, or the concept of physician-hospital ownership.

Ironically, I was encouraged to write this comment by a medical device manufacturer, and to opine against your recommendations! Although I would consider myself a fiscal conservative, I find myself drifting toward a more populist (or socialist) solution to the amount of greed, power, and control I see in healthcare practices. I long for a system of universal healthcare for all, and a return to fairness and justice for all taxpayers (and patients).

Please continue your worthwhile efforts! Please continue to be generous on the support of our future physicians through GME reform, and remember, our residents are not the problem when we discuss CMS solvency!

Sincerely,

Kevin Vaska MD

Submitter : **Date: 06/05/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Shifting payments away from surgical procedures which are notoriously expensive to staff, supply, and perform will hurt the people who need the procedure most - the patient. Surgical procedures require and immense amount of Post Graduate Medical Education to be licensed to perform, increased costs of technology, substantial time commitments, and inherent risks. Any move to lessen reimbursement for such proven procedures (Drug eluting stents, ICD's etc), should be adamantly opposed. These are necessary services and vital to a patients survival, well being, and outcome. Failure to financially protect our ability to provide these services is damaging to the entire community that we serve - ultimately reducing the quality of care across our country. Cutting reimbursement results in limiting our ability to preform these essential services - who will spend the extra 3-4 years in training cardiology, going deeper into debt, to make 30% less than cardiologists make in FY 2006? There is already a massive shortage of physicians, and especially cardiologists predicted - why exacerbate this shortage by cutting funding to one of the most crucial services hospitals can provide? America has an astronomical incidence of heart disease - and these proposed rules promote an environment where we have less cardiologist available to treat these patients. I strongly urge you to NOT cut any funding to cardiology services, or any surgical service.

Submitter : **Dr. Michael Springer** **Date: 06/05/2006**

Organization : **Dr. Michael Springer**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 600 bed hospital located in Louisville, KY I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

Michael Springer MD

Submitter : **Mrs. Margaret Springer** **Date: 06/05/2006**

Organization : **Mrs. Margaret Springer**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

The propsed changes to hospital reimbursements will make it difficult for hospitals to provide needed care to Medicare beneficiaries. Not long ago, hospitals in our area were "rationing" biventricular implantable defibrillators. Some patients who would have benefited from these devices didn't get them I do not want to see that happen again. It is my understanding that the methodology used to compute the proposed changes was flawed. Please defer these changes for a year or as long as it takes to get this right.

Sincerely,

Margaret Springer

Submitter : **Date: 06/05/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

Drug eluting stents have been a major advance in cardiogy. angioplasty results now mirror surgical results without the associated morbidity and mortality.However, hospitals already are even to losing money on drug eluting stents as is in multivessel cases. A further 30% plus cut in hospital reimbursement will force many patients to have bypass instead of multivessel angioplasty - all because of this change !!! If you don't like specialty hospitals - just ban them. Don't hurt everyone else and the patients we are trying to help.

Submitter : Dr. Richard Mathe **Date:** 06/05/2006

Organization : South Denver Cardiology Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am highly concerned about the proposed reduction in HOSPITAL RE-IMBURSEMENT for CARDIOLOGY DEVICE THERAPY beginning in 2007. Should this proposal come to fruition, there will be a clear-cut impact on delivery of care for a disease which remains the LEADING CAUSE OF DEATH in both men and women in this country. In the past decade practioners of care in cardiology have seen a remarkable improvement in outcomes, particularly in the care of acute MI (heart attack) and congestive heart failure/left ventricular dysfuncton, which can be attributed to device therapy in no small measure and which can only be delivered (at this time) in the hospital setting. Continued broad access to these device treatments is imperative to continue the gains we have seen.
I stongly urge you to cease the proposed reduction.
Sincerely,
Richard Mathe, MD

Submitter : **Date: 06/05/2006**

Organization :

Category : **Hospital**

Issue Areas/Comments

Excluded Hospitals Rate of Increase

Excluded Hospitals Rate of Increase

Expanding the 10 quality indicators to 21 is a good idea in the best interest of patient care. Increasing the penalty to 2% for nonparticipating hospitals is also understandable. However, based on the short notice and intense planning and work required for hospitals to report double the amount of indicators, it is unreasonable to ask that this information collection go back to January 1, 2006. A more realistic expectation would be that the data collection of these new indicators begin on July 1, 2006. For hospitals not already collecting these additional SIP indicators, it would cause great hardship to backtrack and collect this data from the first of the year.

Submitter : Mr. Rick Mace **Date:** 06/05/2006

Organization : Kettering Medical Center

Category : Hospital

Issue Areas/Comments

Impact Analysis

Impact Analysis

While we understand and appreciate the attempt to better match payments and costs, but the negative financial impact to hospitals of all sizes that provide heart rhythm services will be devastating. We predict that small programs will have to close, and that many hospitals will have to significantly reduce their level of service, or close their heart rhythm programs altogether. The cost data that CMS has evaluated does not fully cover the cost to hospitals of the devices that are used. Most hospitals were losing money especially on CMS patients prior to the proposed changes.

We believe that the proposed changes are "too much, too soon and too fast". We are very involved in quality initiatives, those proposed and initiated by CMS and other governmental organizations, as well as many internal initiatives which we are committed to because of our dedication to mission and patient care. However, we are challenged to figure out how we are going to meet the resource demands to continue to support quality improvement initiatives and provide the necessary care to the patients that we serve in our community.

About a year ago, CMS expanded (with good clinical documentation) the indications for cardiac defibrillators that are used to prevent sudden cardiac death, the nation's number one cause of mortality. While these changes allowed for more patients to receive the technology, the cost of the cardiac defibrillator devices have never been and are not now totally covered by the DRG reimbursement methodology. Hospitals are in a "catch 22" situation because we have no control over the vendors who develop, produce, and sell these products to us, and the indications for these devices (to save human life) are expanded and necessary, thus for most CMS patients we lose money doing the right thing.

Submitter : Dr. Martha Radford **Date:** 06/05/2006

Organization : New York University Hospitals Center

Category : Physician

Issue Areas/Comments

Hospital Market Basket Proxy

Hospital Market Basket Proxy

For the provider community the proposed rules will require a significant increase in resources for quality data management and reporting. There are two aspects: 1. Submission of quality data for the SIP measures requires abstraction of a considerable number of records. The sample size is onerous for a full-service acute care hospital: we estimate 150-200 records per quarter for the two hospitals in our system which will report these measures, and we estimate that we will require an additional 0.4 FTE to complete this requirement. The CMS-JCAHO sample size is based on adequate separate samples for each surgical specialty. Since the quality reporting will be a single institutional rate, we respectfully suggest that the sample size be calculated using the entire organization's activity rather than each specialty. If hospitals want bigger samples to enable specialty drill-down, that is a hospital decision. (The sample sizes for the other three modules [AMI, heart failure, pneumonia] are also probably unnecessarily large for stable estimates of performance.) 2. The requirement to retrospectively submit data from January 2006 discharges is also onerous, and does not serve quality improvement. For our hospitals, it will mean double data abstraction, since we are already abstracting a 'higher bar' version of these measures. We respectfully suggest that the new measures be submitted beginning with July 2006 discharges. Thank you for your kind attention. Please do not hesitate to contact me if I can provide any further help or clarification. Martha J. Radford, MD, Chief of Clinical Quality, New York University Hospitals Center, 550 First Avenue, GBH C-120, New York, NY 10016; 212-263-8199; Fax 212-263-0096; martha.radford@nyumc.org

Submitter : Ms. Jodi Raus **Date:** 06/05/2006

Organization : AGA Medical Corporation

Category : Device Industry

Issue Areas/Comments

DRG Weights

DRG Weights

The current proposal to modify the DRGs is flawed and should be rejected until the data and methodology are corrected. The most appropriate course of action for CMS would be to return to the current charge-based methodology for the coming fiscal year and work with stakeholders to improve hospital cost reporting processes before any transition to cost-based weights.

Submitter : **Dr. Christopher Fellows** **Date: 06/05/2006**

Organization : **Virginia Mason Medical Center**

Category : **Physician**

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 350 bed hospital located in Seattle, Wa. I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,
Christopher L. Fellows, MD, FACC, FHRS

Submitter : **Mrs. Shaunda Calkins** **Date: 06/05/2006**

Organization : **Mary Greeley MEdical Center**

Category : **Nurse**

Issue Areas/Comments

Impact Analysis

Impact Analysis

I am writing as the Director of Cardiology Services here at Mary Greeley Medical Center. I understand that the Proposed Changes to the Hospital Inpatient PPS for Fiscal Year 2007 will dramatically impact payment for cardiac patients receiving stents, pacemakers and ICD implants. The existing proposal will negatively impact cardiac programs across the country and may potentially limit patient access to leading edge technology because hospitals may not be able to adequately recover their acquisition costs. Please consider delaying the implementation of any changes to cardiac services reimbursement until such time as accurate and appropriate information regarding costs to treat and manage patients with cardiovascular diseases can be compiled. Thank you for allowing me to comment on this proposed change.

Shaunda Calkins, RN, BSN, MHA
Director of Cardiology Services
Mary Greeley Medical Center
1111 Duff Avenue
Ames, Iowa 50010

Submitter : Dr. Bradley Titus **Date:** 06/05/2006

Organization : Northwest Cardiovascular Institute

Category : Physician

Issue Areas/Comments

Cost-Based Weights: Outlier Threshold

Cost-Based Weights: Outlier Threshold

To whom it may concern,
As a practicing interventional cardiologist who maintains privileges at several of our local hospitals to perform drug-eluting coronary stents and other cardiac invasive procedures, I am writing to deter you from implementing the proposed cost-based DRG weighting for inpatient cardiac procedures. An estimated reduction in hospital reimbursement of 30% for 2007 is simply unrealistic and clearly indicates major flaws in the assumptions that are being used to formulate this new scheme. Cath lab budgets are already tight in the hospitals in which I work and many cut-backs have already occurred that I believe are detrimental to patient care. The severity of the proposed cuts will have an enormous adverse impact on the care we will be able to provide to the heart patients of our country. Please consider delaying these proposals until further analysis can be performed and better assumptions can be utilized. Thank you for your consideration.
Bradley G. Titus, MD
Portland, Oregon

Submitter : **Ms. Beth Anderson** **Date: 06/05/2006**

Organization : **Saint Luke's Hospital of Garnett**

Category : **Nurse**

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

We are interested in providing feedback on the proposed Deficit Reduction
Action of 2005 which will reduce the Annual Payment Update (APU) to hospitals that fail to report the required measures of quality. If the proposed legislation goes through, it will have a significant financial impact on our hospital and we believe it is important that we provide feedback related to this important piece of legislation. Please find our comments below:

1. As proposed, the number of quality measures will increase from 10 to 21. This will require additional staff support to collect and transmit this additional information.
2. This proposed legislation requires hospitals to go back and abstract data from January 1, 2006. This is an alarming precedent to set and places an undue burden on a hospital to provide this additional data. In addition, our data will be publicly reported dating back before we had process improvement initiatives in place to address our performance.
3. In reviewing the hospital data, CMS plans to combine the samples for first quarter, second quarter and third quarter of 2005 into a single stratified sample to determine whether or not the 80-percent reliability level is met. We believe this is problematic because hospitals have not had an opportunity to appeal CMS Clinical Data Abstraction Center (CDAC) errors if the error did not result in the hospital failing for the given time period. As a result, a hospital may be negatively impacted by the decision to combine these three quarters into a single stratified sample as proposed. For example, a hospital could have errors (as abstracted by CMS) in their 1st and 2nd quarter report providing them with an 80% passing rate (which they could not appeal) and actually fail the third quarter which would result in failure of all 3 quarters based on the plan to combine the first three quarters as proposed).
4. The payment update for 2007 will be reduced by 2.0 percentage points for indicator performance that has a track record of poor reliability, especially working diagnosis of pneumonia. Some hospitals resort to answering working diagnosis for pneumonia as a yes for all pneumonia charts regardless of actual documentation, since the penalty is disproportionately more severe if the no answer is found to be incorrect. A couple of mismatches on the no to working diagnosis can drive the hospital to the brink of losing their APU.
5. Under the proposed timeline, January, February and March 2006 data will need to be abstracted and successfully submitted to CMS no later than July 31, 2006. With the CMS comment period deadline of June 12, 2006 and an anticipated response time of 60 days by CMS, the outcome may not be known until August 12, 2006. Hospitals will have to proactively submit data on the 21 indicators & in anticipation of the legislation going into effect. The proposed timelines as outlined are problematic.

Thank you for the opportunity to provide feedback on this important legislation. We believe it will have a negative impact on our organization and wanted CMS to consider the weaknesses and understand the implications. We look forward to your comments and feedback.

Submitter : Dr. Charles Love **Date:** 06/05/2006

Organization : OSU Division of Cardiovascular Medicine

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am writing concerning the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. The severe cuts planned will significantly impact our hospital's ability to provide the necessary care to Medicare, as well as other patients. These cuts will go to the point that the cost of the device (ICD or Pacemaker) to the hospital will be in excess of the payment being made. The hosptial will end up with a loss before accounting for any other expenses related to the patient's care in some cases. This is not acceptable, nor the intent of how this payment system was designed to operate. I urge you to reconsider the proposed cuts to this area of healthcare.

Sincrely,
Charles J. Love, MD FACC FAHA FHRS
Charles.Love@osumc.edu

Submitter : Mr. Eugene Chinn **Date:** 06/05/2006

Organization : GME Solutions LLC

Category : Individual

Issue Areas/Comments

FTE Resident Count and Documentation

FTE Resident Count and Documentation

See Attachment

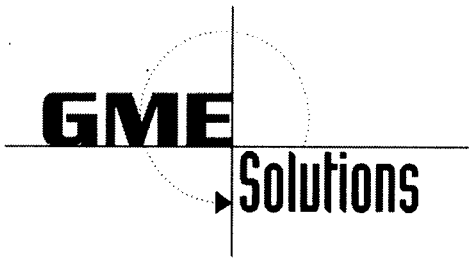
GENERAL

GENERAL

See Attachment

CMS-1488-P-169-Attach-1.DOC

#169



June 5, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS -1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Comments to Proposed Rule for 2007 IPPS

We appreciate your consideration of two issues under Section H for **Direct Graduate Medical Education**.

FTE Resident Count and Documentation

In order for hospitals and intermediaries to arrive at proper GME payment claims and determinations, better guidance directives and reporting systems are needed. As the Proposed Rules point out, CMS has continued to receive questions regarding proper documentation, even though the current policies have been in place since 1985. When constant clarification of the most basic rules is necessary, something is amiss. Currently, the GME rules for calculating payment are among the most complex. Medicare's cost report instructions, rules, and reporting system try to apply payment policy correctly, but every rule is unique and does not follow a pattern. Consequently, errors are made by both hospitals and intermediaries.

To achieve cost-effective compliance, payment policy makers should periodically evaluate the rules to determine operational efficiency and effectiveness. Understandably, this has not occurred due to the many different priorities CMS staff must adhere to. However, during the last 20 years, new payment rules have been added and are distinctive for each payment calculation. As a result, the rules have become increasingly more complex, because they are numerous and are different. The bottom line is: without better guidance directives and reporting systems, hospitals and intermediaries will continue to make errors. And these errors are costly to both Medicare and the hospitals as issues are appealed to several levels.

Cost effectiveness should include both the costs of CMS and its contractors when determining payment to providers for the care of Medicare beneficiaries. Often policy staff focuses on "payment benefit" and not on "operational costs". Yet, CMS operational costs are $5 billion a year.

If the goal is to have a cost-effective method that eliminates hospital/intermediary disagreements and appeals, then clearer and more straightforward methods are needed. Medicare must train and guide hospitals and intermediaries on the spirit and intent of the law. That is, the law provides payment to be based on rules of non-government organizations such as the American Council of Graduate Medical Education (ACGME) and American Board of Medical Specialties (ABMS). However, their criteria are not enforced rigidly and do not have the force of law. Unfortunately, this anomaly is a difficult concept for auditors to grasp when they only look for black and white determinations and have difficulty with gray issues. Yet, policy cannot cover every situation. Therefore, policy is written to be flexible to address situations not contemplated. Conversely, financial auditors will not allow a situation unless it is specifically addressed in regulation or other directives.

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This letter will focus on two aspects of the proposed rule, the resident FTE reporting system and documents needed to validate reported data.

General observations by a former colleague

I share my observations with you as a former colleague and one who has been enlightened by working in the hospital setting. For the last eleven years, I have advised major academic teaching hospitals across the nation about Medicare GME payment (1995 to 2006). Prior to 1995, I was in charge of Medicare institutional reimbursement in the San Francisco Medicare Regional Office for 20 years (1975 to 1995). During my time with Medicare, I led the regional implementation of the IPPS system, represented Medicare in reimbursement litigation and was a standing member of the national Audit and Reimbursement Technical Advisory Group (TAG). Before my time spent with Medicare, I spent five years as a supervisory auditor with the General Accounting Office (now called the Government Accountability Office) and four years with the U.S. Air Force Judge Advocate General's Office.

At its most basic level, one of the Regional Office's main functions is to ensure that Medicare intermediary auditors correctly paid hospitals. As such, an underpayment is equally as bad as an overpayment. When I was in Medicare I shared in the responsibility to insure that hospitals received correct payment. However, my perception was that the intermediaries' determinations potentially overpaid hospitals. After eleven years on the hospital side, I have seen first-hand that the intermediaries often underpay hospitals. In either case, intermediaries do not clearly articulate their reason for making an overpayment or underpayment determination as required by Medicare directives. Specifically, regarding GME payment issues, poor payment determinations appear to be the result of the intermediaries' lack of knowledge and incorrect perceptions about GME rules. Also, auditors and their supervisors do not appear to be well trained on reasonable cost principles. Granted, it is understandable that some knowledge gap may exist on reasonable cost principles since cost reimbursement has not been a determining factor for most acute hospitals for over 20 years. However, intermediary auditors apply a financial statement audit approach when they should be applying a program compliance approach. The financial audit approach is "I have no knowledge but will accept your costs with a paid invoice." Likewise, the intermediary auditors' approach is "I have no GME knowledge so unless you prove it to my satisfaction, or I will not allow payment." This "prove it" attitude generally results in unnecessary documentation disputes between the intermediary and hospitals. Medicare contracts with intermediaries with the expectation that such intermediaries also have "program review" knowledge. Under such a contract, there should be a reasonable expectation for the intermediary to be knowledgeable about the resident training process, such as differences between accreditation and certification. Further, said intermediary should also know about the differences between sponsoring and participating hospitals.

To remedy the fact that intermediaries are not well versed in many of the basic principles required for GME audit work, there is a need for Medicare GME payment specialists. Currently, the intermediary's junior and senior auditors may have little experience about GME payment rules. Auditors that are generalists do not understand the nuances of different types of teaching hospitals and try to apply the same to standard to all teaching hospitals. For example, in some states there is only one major academic teaching hospital with a different junior auditor assigned every year. Even in larger states, such as California, Illinois, Michigan, New York and Massachusetts where there are many major academic teaching hospitals, the auditors 'documentation requirements are inconsistent from year to year.

That is not to say the hospitals are necessarily knowledgeable about the nuances of Medicare GME payment rules, either. However, hospitals submit to intermediary decisions. Hospitals also must contend with inconsistency from different auditors every year. These inconsistencies even occur among different audit groups within the same intermediary office. As such, it should not be surprising that different intermediaries are not consistent in applying GME rules. During my time with Medicare, consistent application of the rules was important as Medicare is a national program and that visibility coupled with the scope of the program made consistency a priority.

During my 29 years of government service, the approach was to always to follow the spirit and intent of the law. However, Medicare regulations to implement the law often are established without full understanding of hospital operations and teaching programs. In turn, auditors trying apply the Medicare regulations and other directives are even less knowledgeable than government policy makers.

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While auditors review hospital documents, they have little knowledge about the hospital requirements and process for maintaining records. Having worked on the hospital side for eleven years, I hope to help inform you on the importance of issuing policies that follow the spirit and intent of the law. Hopefully, the policies will provide more direction to intermediary auditors for consistent application of GME payment rules.

Policy and Operations should be Cost-Effective

A cost effective method is needed to apply regulatory policy. True cost-effectiveness occurs when all involved parties benefit. Making policy and applying policy require different levels of knowledge and skill. Applying policy requires knowledge of hospital operations, financial and auditing standards. In general, policy making is separate from describing operational steps to comply with policy.

Yet, CMS comments appear to show frustration at having to clarify policies that have been in effect for 20 years. However, this apparent frustration assumes that hospital and intermediary staff are as knowledgeable as the GME policy specialists. Yet, many of the current hospital and intermediary staff were children twenty years ago and others may not have worked in teaching hospitals at that time. Further, the DGME and IME methods for calculating Medicare payments have gone from simple to incredibly complex. The nuances and explanation of calculation methods appear piece meal in periodic federal registers. Without a directive that comprehensively explains reporting details, questions will continue and mistakes will be made by both hospital and intermediary staff in applying policy. The timing is right to provide an extensive guidance system which will help educate both the intermediaries and hospitals alike on the nuances of the Medicare GME payment system.

One mechanism that could be, and probably should be, used to comprehensively address payment rules and the proper application of such rules is the Provider Reimbursement Manual (PRM). Rather than attempting to track the changes to policy by issuing multiple revisions through federal registers, it would be more productive and effective to revise the PRM which has not been updated in years. That way, a single source could be referenced as a guide for payment rules rather trying to tie together multiple entries in different publications for that same guidance.

Clearly, the complex nature of GME must be recognized. In a given year, about 1100 hospitals train 100,000 residents in 8,000 ACGME accredited programs. In addition, hospitals also train osteopathic, dental, podiatry and residents in non-ACGME accredited programs that are eligible for GME payments. ACGME recently limited a resident's duty hours to an average of 80 hours per week. Such duty is more than double the typical 40 hour work week and since the 80 hours is an average, some weeks will be longer than others. In the past, some residents worked 120-hour weeks.

Medicare recognized residents in different specialties and subspecialties have different and extraordinary duty hours. To provide flexibility, Medicare's initial policy was to limit a resident count to one FTE regardless of the duty hours. Further, Medicare regulations provide that standard industry reporting practices are acceptable and changes will not be required for Medicare payment determination. Yet, intermediary auditors often will not allow a part of a FTE without documentation that meets their individual satisfaction.

Resident FTE Count Report

A cost-effective approach to accurately count Resident FTEs would be to modify the Medicare IRIS (Interns and Resident Information System) reporting system. As currently established, the IRIS does not meet the regulatory provision to report all of the training locations for an individual resident. Central Office's initial method closely met the regulatory provision by comparing all IRIS data nationwide. However, Medicare diluted the process when it transferred the IRIS process of comparing teaching hospitals nationwide to a local comparison of teaching hospitals served by an intermediary. We believe Medicare understood the transfer had limitations, but it was an acceptable and cost-effective risk factor. Intermediaries, however, commonly interpret software limitations as the need for the hospitals to produce additional documentation beyond what is normally maintained by the hospital. Intermediaries required such documents even though such mandated requests are prohibited by regulation and Government Auditing Standards. Without such documents, intermediaries did not make payments that should have been Medicare's proper share of the Hospital training residents.

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To obtain a more cost-effective reporting process, a more specific reporting system by sponsoring entities is needed. Further, a dedicated intermediary or specific intermediary staff needs to be trained to make correct Medicare GME payment determinations.

While it is a regulatory requirement to report every training location for each resident, it has never been requested or placed in practice because Medicare only required the IRIS report for each hospital. The IRIS requires that each hospital report the time that a resident trains at the hospital but does not provide a total listing for an individual resident. To determine whether or not different hospitals reported the same time for a resident, the Intermediary runs a comparative check or "Overlap Report" among all IRIS databases for hospitals that it serves. Unfortunately, the IRIS software does not identify the exact duplicate dates among the hospitals but rather only a range of reported assignment dates wherein the exact duplicate days exist. For example, Hospital A may report a resident trained from Jan 1 to July 1 and Hospital B may report the same resident trained from July 1 to December 31. This one-day overlap will result in the proposed disallowance of 182 days for both Hospital A and B.

Then, the intermediary validates the resident FTE count from each reporting hospital's documentation which may conflict with another hospital. A properly trained auditor would refer to the "source document" (sponsoring institution) rather than from conflicting hospital records. However, intermediary auditors do not seek the correct payment; rather, the easier task is to disallow the claim because the hospital records are insufficient according to the individual auditor.

In practice, neither the intermediary nor the hospitals have followed the regulatory requirement to report all training locations of a resident. This occurs because the sponsoring hospital is the only institution involved that can perform the task and because of IRIS requirements. Specifically, a participating hospital only knows about the period in which the resident is training at its location but cannot attest to where the resident is training elsewhere. Intermediary auditors have not performed this analysis because of the IRIS requirements and because they are told to only accept the reporting hospitals' documents and not the "source documents".

We recommend CMS clarify that hospitals must obtain a report from the entity sponsoring the training program that lists each resident's training location.

Documentation

Medicare requires hospitals to report specific data elements, and intermediary auditors are instructed to validate the reported data. The intermediary's test to determine that the count by all teaching hospitals does not exceed one FTE (1.0) per resident is just to identify duplicate assignments. A comprehensive listing that tallies the FTE count for an individual resident has never been presented during our work with various clients. This often goes against the Medicare cost principle to ensure Medicare pays its fair share of the training costs and to not burden others with Medicare's share. (42 CFR 413.5(a))

After the Overlap Report is run, the auditor selects a sample to validate reported data. In many cases, the auditor only accepts rotation schedules or requires contemporaneous documentation. This standard of proof is beyond Medicare regulations, directives and Government Auditing Standards (GAS). (42 CFR 413.20(a), Medicare Financial Management Manual 100-6, Chapter 8, and GAS) The intermediary's level of acceptable documents has been increasingly stringent and has gotten to the point of being tantamount to "proof beyond reasonable doubt". Such standard of proof is applied for criminal cases whereas the GAS standard of proof is that of a reasonable person. Clearly, intermediaries have not provided sufficient training to auditors on this matter and have not performed adequate supervisory review. When such disallowances occur, hospitals will appeal the disallowances, resulting in the expenditure of additional time and resources.

The auditors' approach ignores Medicare's directive that the intermediary's primary objective is to make a correct settlement. Using the GAS standard of proof of a reasonable person, one would conclude that if the auditor determined the following: 1) a resident was enrolled full-time in an approved program, 2) a rotation schedule showed that the resident trained in clinical settings at Hospital A for 75 percent of a given period, and 3) the document did not show that the resident trained in research in the hospital complex for the other 25 percent of the time, the result would be the intermediary disallowance of only the 25 percent portion. However, instances have occurred when the entire resident claim is disallowed

because the submitted documentation does not meet the intermediary's individual discretionary auditing standard. Standard industry reporting practice for most subspecialties is that the rotation schedule only shows assignments in clinical settings. The auditor's determination ignores the Medicare regulation which states "Changes in these practices and system will not be required in order to determine costs payable". (42 CFR 413.20(a) The auditor, however, will not allow this time unless the hospital generates documentation to his satisfaction. Another example, it is standard industry practice for rotation schedules not to show a resident's assignment to continuity clinic. Normally, training in continuity clinics are assigned for half a day per week. Some intermediary auditors will deduct this time which results in an aggregate calculation of less than one FTE for that resident for the year.

Under the reasonable cost method, Medicare would pay its full share of the hospital's total cost of training, not 75 percent under the resident FTE count method (as per the example cited above). Congressional change to the APRA method was done to control payment based on a hospital's 1984 training costs, but it did not change the type of allowed and/or amount of training. .

Briefly, we have encountered auditors that:

- Disallowed all resident FTE time because the training was beyond the Initial Residency Period (IRP) instead of weighting DGME
- Disallowed resident FTEs because they were training in unaccredited combination programs that are listed in the ACGME Green Book and with established IRP
- Disallowed resident FTEs when the hospital did not have a state medical license for the resident(s) in question (state rules vary). Medicare does require this to be a reported data element.
- Disallowed resident FTEs training in hospital inpatient and outpatient locations because it considered an excluded psychiatric unit to be a TEFRA unit, even though Medicare has designated it as an excluded unit.
- Disallowed foreign resident FTEs because the hospital cannot produce an ECFMG Certificate, but the hospital provided documents to show the resident passed Parts I and II of the USMLE. For example, a resident with a full state medical license must satisfy the prerequisite of passing Parts I and Ii before passing Part III of the USMLE to obtain a medical license.

Hospitals are equally frustrated when some intermediaries are not consistent with the application of policy and operational methods, even in instances where auditors are from the same intermediary office.

Resident Time Spent in Nonpatient Care Activities as Part of Approved Residency Programs

The definition that didactic activities are non-patient care activities is not supported by citing 42 CFR § 413.9 Cost Related to Patient Care. Further, the statement that it clarifies long standing policy is contrary to your 9/24/99 letter that stated "HCFA interprets the phrase "patient care activities" broadly. We are unaware of any Medicare directive that distinguishes patient care activity in a hospital and non-hospital site. Finally, didactic activities are unusual in non-hospital sites referred to in the regulations as free-standing clinics, nursing homes and physician offices. The extent of such activity should be measured to determine if clarification is warranted. To avoid challenges, a definition of "patient care activities" for non-hospital locations should be promulgated under the Administrative Procedures Act (APA).

We agree that the regulations 42 CFR §413.9 "Cost Related to Patient Care" would be the basis for determining patient care activities. This regulation covers an institution's operating costs to render patient care and includes costs other than direct patient care such as accounting, legal and systems. The Provider Reimbursement Manual Chapter 21 provides more explanation about "Cost Related to Patient Care." Specifically, §2120 entitled Reimbursement for Costs of Interns and Residents elaborates which costs in approved programs are allowable costs. Under the cost method, there is no distinction between training types or training location. Therefore, Medicare allowed costs of residents when they trained in didactic activities in non-hospital locations.

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Your 9/24/99 letter stated that "patient care activities"...include any patient care oriented activities that are part of the residency program. ... this can include resident participation in 1) the direct delivery of patient care, such as clinical rounds, discussions, and conferences, and 2) scholarly activities, such as educational seminars, classroom lectures, research conferences, patient care related research as part of the residency program, and presentations of papers and research results to fellow residents, medical student, and faculty. Conversely, the clarification of policy regarding this issue in the proposed rule is not clear.

If new policy is to narrow the definition of patient care activities of residents training in non-hospital locations, then the agency must not circumvent the APA by using the unpersuasive term of "clarifying longstanding policy."

It is important for the hospital and intermediary staff to know the basics of GME payment in order to properly claim FTEs and make payment determinations. Thus, I have attached an appendix that outlines some of the major events that have had a great effect on GME payments. These are fundamental points that intermediary auditors need to know and apply. By disallowing resident FTEs because the hospital did not provide documents to support the data elements listed in the regulation, unnecessary costs are incurred by both Medicare and the Hospital in appeal cases.

We hope this information provides you with a better picture of the issues both the hospital and intermediary address during an audit. Thorough and effective review of the current policy would result in a more cost-effective operation, to the benefit of all parties involved.

Sincerely,

Eugene L. Chinn
Senior Principal

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APPENDIX

Reasonable Cost Principles (1965 to 1985)
Congressional committees decided that Medicare should share in the Hospital's resident training costs because "Educational activities enhance the quality of care in an institution." (S. Rep. No. 404, 89th Cong., 1st Sess. 36 (1965); H.R. Rep. No. 213, 89th Cong, 1st Sess. 32 (1965))

Reasonable cost means costs related to patient care actually incurred. (42 CFR 413.9)

Cost related to patient care includes the hospital's total costs for training residents (PRM §2120)

Medicare paid a share of the hospital's total costs for training residents. The payment method was based on costs regardless of where the resident was training.

Congress First Control of GME and IME Payments
In 1985, Congress established controls for the amount of Medicare direct GME payment for training residents. A per resident amount was based on an individual hospital's 1984 total training costs divided by resident FTEs. This 1984 average per-resident amount (APRA) was increased by an annual inflationary index. In this manner, the law controlled Medicare payment to Hospitals regardless of the Hospital's costs. There were no changes to the training cost categories since the law limited payment. A significant change was that payment was based on where the resident was training but not on costs.

In 1984, Congress provided an indirect or IME payment for teaching hospitals. This payment recognized that the DRG method did not account for the extra costs of teaching hospitals. Initially, the IME amount was determined by multiplying the DRG payments times a payment factor 11.50 percent for every ten percent increase in the resident FTE/bed ratio.

Resident FTE Count (1989 for DGME and 1990 for IME)
Medicare refined the resident FTE count method at this time. It is important to note that Medicare recognized that residents do not work a standard 40 hour week and that the work week varied among different programs. For ease, the criterion was no more than 1.0 FTE per resident was allowed for payment. Therefore a resident working 60 hours a week and another resident working 120 hours per week were each counted as one FTE. Medicare further recognized that the count method should not require hospitals to establish a time clock or bookkeeping method to track resident time. Rather, Medicare believed that individual teaching hospital's current record keeping systems were sufficient. (FR dated 9/29/89) In fact, the regulations prohibit Medicare from requiring a hospital to change practices and systems to make Medicare payments. (42 CFR 413.20(a))

Again, Medicare reiterated that this resident FTE count method did not change the types of training previously allowed but it did reduce the DGME payment for training beyond the initial residency period.

The next year, Medicare decided that the resident FTE count method should be consistent with the DGME method, with some differences.

Congress Second Control of DGME and IME Payment
The Balanced Budget Act of 1997 imposed several limits on DGME and IME. Limits on the number of FTEs and rolling average impacted both DGME and IME payments. Also, Congress limited IME by imposing the lower of the current year or prior year resident FTE to bed ratio and reduced the payment factor that was initially 11.5% with a gradual reduction to 5.5%. Congress did not further change the types of training allowed under the cost reimbursement system.

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Submitter : Mr. Kyle Kramer **Date:** 06/05/2006

Organization : American College of Cardiovascular Administrators

Category : Health Care Professional or Association

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

Comments from the American College of Cardiovascular Administrators are contained in the attached document.

DRG Weights

DRG Weights

Comments from the American College of Cardiovascular Administrators are contained in the attached letter.

DRGs: MCVs and Defibrillators

DRGs: MCVs and Defibrillators

Comments from the American College of Cardiovascular Administrators are contained in the attached letter. In brief, the proposed IPPS will cause hospitals to be inadequately reimbursed for expensive technolgies such as implantable devices - such as drug-eluting stents, pacemakers, defibrillators, bi-ventricular pacemakers, and bi-ventricular defibrillators.

DRGs: Severity of Illness

DRGs: Severity of Illness

Comments from the American College of Cardiovascular Administrators are contained in the attached document.

GENERAL

GENERAL

To Whom it May Concern:

Attached please find comments on CMS Docket 1488P from the American College of Cardiovascular Administrators, a specialty group of the American Academy of Medical Administrators.

Sincerely,

R. Kyle Kramer

CMS-1488-P-170-Attach-1.PDF

#170

American Academy of Medical Administrators

Developing Excellence in Healthcare and Leadership

701 Lee Street • Suite 600 • Des Plaines, IL 60016-4516
Phone: (847) 759-8601 • Fax: (847) 759-8602 • email: info@aameda.org • www.aameda.org

AMERICAN COLLEGE OF CARDIOVASCULAR ADMINISTRATORS

June 1, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
Docket Number: CMS –1488-P

Dear Dr. McClellan:

The American College of Cardiovascular Administrators appreciates the opportunity to submit comments related to the proposed 2007 Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Prospective Payment System (IPPS), released on April 12, 2006 and published in the *Federal Register* on April 25, 2006. Our comments are submitted on behalf of all cardiovascular programs and administrative professionals across the United States.

The American College of Cardiovascular Administrators (ACCA) is a specialty group of the American Academy of Medical Administrators (AAMA), which is comprised of over 2,500 members representing all sectors of the healthcare administrative field. Specifically, the ACCA/AAMA is a nonprofit professional society of individuals involved in the administration of cardiovascular and other specialty services at hospitals and clinics across the United States whose purpose is to develop and refine concepts and practices in the field of cardiovascular and other specialty healthcare administration and to promote the advancement of its members in knowledge, professional development, and personal achievements through continuing education, research, and advocacy in healthcare management. Our members are the primary personnel responsible for the implementation and management of issues – technology and otherwise – impacting cardiovascular programs across the country.

We appreciate the considerable effort you and your staff members have put into the development and improvement of the inpatient prospective payment system (IPPS) and specifically recognize the need to continually evolve the payment system to reflect the current landscape within the field of medical services. We further recognize the significant complexities associated with gathering reasonably accurate cost data – data that should serve as the foundation of payment systems such as the proposed IPPS.

Origins of the Proposal

CMS is proposing to make the most significant changes to the hospital inpatient payment system since the late 1980s. The proposed changes appear to have their roots in the Medicare Payment Advisory Commission's (MedPAC) 2005 Report to Congress on Medicare payments for a certain subset of "specialty" hospitals. The MedPAC report raised concerns that the specialty hospitals were selecting the most profitable cases in their area and leaving the other acute care hospitals with less profitable services. Rather than addressing this issue of specialty hospitals in independent fashion, MedPAC recommended changing the payments for ALL acute care hospitals to reduce the incentives in the overall inpatient payment system that fueled the growth of specialty hospital facilities.

CMS should certainly weigh the issues and concerns raised in the MedPAC report when considering policy changes. However, the proposed changes to the inpatient payment system are the equivalent of throwing the baby out with the bath water. Efforts to address issues identified in the MedPAC report should begin and end with the specialty hospital subset and should not occur in conjunction with payment systems at large for all other hospital facilities.

Issues with the proposed IPPS

Setting aside the issues associated with specialty hospitals, ACCA notes two major areas of concern with the proposed IPPS. First, the proposal incorporates an estimated "cost-based" system, rather than a charge-based system for determining the payment weights for each patient category in 2007. Second, the proposal endeavors to change the method of identifying the variation in patients' severity of illness that would be implemented in 2008, or potentially 2007. Each change is significant and in previous years would be considered a major modification to the payment system. Proposing both changes in a single regulation, with implementation in 2007, is unprecedented.

Estimated, not Actual, Costs

CMS proposes to base payments on "costs". In many senses, this is a positive move and is consistent with how private insurers handle costs associated with technology. However, the primary difference between CMS's proposed methodology and the private insurers is the timing of cost data. Private insurers are utilizing data in real-time and are paying actual invoice costs for technology used in the care of patients. In CMS's proposal, the "cost" for a particular category of patients is not an approximation of the actual price the hospital pays for the items and services required to treat patients, rather it is a rough approximation of costs. To calculate the cost estimates for Fiscal Year 2007 payments, CMS proposes to utilize hospital claims data from Fiscal Year 2005 and hospital cost reports from Fiscal Year 2003. The cost reports provide the actual costs and the actual charges for all patients (non-Medicare and Medicare patients). The use of any data from Fiscal Year 2003 fails to account for current technology costs – namely drug-eluting stents and bi-ventricular pacemakers/defibrillators, mainstays in the cardiac care landscape. As such, the estimates on cost that CMS will use to put forth its rates in 2007 will necessarily be incorrect and will inadequately compensate hospitals for the care of Medicare patients.

It is widely known that hospitals across the country do not use a uniform approach to mark-up strategies for technology. Higher cost technologies, such as those used in the treatment of cardiac patients, are

often marked up a lower rate than lower cost items. This leads to an inappropriate reflection of cost when attempting to apply derived averages. The following table demonstrates this principle and points out that high-cost technology such as defibrillators and drug-eluting stents would be unfairly accounted for in the proposed reimbursement methodology, causing hospitals to lose substantially with these technologies. This example also highlights why cost reports were never intended to be utilized for the sake of developing accurate procedure specific payment rates.

Impact of Assuming Uniform Mark-up in Estimating Costs

	Acquisition Cost	Actual Hospital Mark-Up	Charges After Mark-Up	CMS Derived Average Mark-Up	CMS Estimated Costs Based on Avg Mark-up	Delta Between CMS to Actual
Dual Chamber ICD	$ 20,000	200%	$ 40,000	267%	$ 14,998	$ 5,002
Bi-Ventricular ICD	$ 28,000	200%	$ 56,000	267%	$ 20,997	$ 7,003
Drug-Eluting Stent	$ 2,500	200%	$ 5,000	267%	$ 1,875	$ 625
Other supplies	$ 8	400%	$ 32	267%	$ 12	$ (4)

Gross Impact on Cardiac Care

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by approximately 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.

These proposed reductions to cardiac services are severe and are not rooted in any type of realistic mechanism for assessing costs to provide treatment. While it is appropriate to pursue a better understanding of actual costs to treat cardiac patients, any such efforts must be made with the intention of producing accurate information – the end result may well be an alteration in the existing infrastructure for cardiac services reimbursement. However, the existing proposal simply cannot be implemented in its current form, as the impact for cardiac programs across the country will be grave and may potentially limit patient access to leading edge technology (because hospitals will not be able to adequately recover their acquisition costs). This is clearly not what CMS intends to achieve with this proposal. As such, delaying the implementation of any changes to cardiac services reimbursement until such time as accurate and appropriate information regarding costs to treat and manage patients with cardiovascular diseases can be compiled is the only prudent approach that can be taken.

Summary

Again, ACCA/AAMA appreciates the opportunity to provide our commentary on the 2007 CMS IPPS proposal. ACCA/AAMA remains fully supportive of prospective payment for hospital inpatient services, and commends CMS for its ongoing efforts to ensure adequate reimbursement for all clinical services. Moreover, we recognize the extremely complex issues involved in establishing appropriate

reimbursement for procedures performed in the inpatient setting. As such, ACCA/AAMA remains committed to working with CMS and other affected parties to ensure that hospitals remain able to provide access to high quality cardiovascular care involving cutting-edge technologies in all settings of care. Finally, ACCA/AAMA supports CMS's efforts to ensure that Medicare beneficiaries have continued access to high quality, efficient, and effective cardiovascular services.

Sincerely,

Marilyn M. Henry

Marilyn M. Henry, FAAMA, FACCA
President
American College of Cardiovascular Administrators

the American College of Cardiovascular Administrators
is a specialty group of the
American Academy of Medical Administrators

Xc: Renee Schleicher, CAE
ACCA/AAMA Board of Directors

Submitter : Mr. John Gaspelin **Date:** 06/05/2006

Organization : Orlando Regional Healtcare

Category : Hospital

Issue Areas/Comments

HSRV Weights

HSRV Weights

Changing the DRG weighting system is a major change to the IPPS reimbursement system. The HSRV weighting system is at best very confusing, and the accuracy of determining cost of a DRG by provider is questionable. We do not believe the development method provides a true cost based DRG weighting system. We did an impact analysis of the changing weights under the HSRVcc system and the Consolidated Severity Adjusted DRGs and came up with diverging results. Under the HSRVcc weighting system our hospital was negatively impacted by over 4 million dollars, and under the Severity adjusted weights our hospital was positively impacted by over 2 million dollars. Based on this we feel the HSRVcc weighting system will shift reimbursement by provider inaccurately. With the ultimate goal of getting to a severity adjusted DRG system we do not feel this system should be implemented in 2007 as an interim step to get the severity adjusted DRGs. We also feel there is not adequate time to implement severity adjusted DRGs for FY 2007. To implement a severity adjusted DRG system a great deal of time will be needed for providers, system vendors and FI s to develop the appropriate software systems. A minimum of one year should be allowed for the development of software systems to handle these changes. If proper time is not allowed claims will be mishandled increasing the administrative costs for providers and CMS.

Submitter : **Dr. Warren Jackman** **Date: 06/05/2006**

Organization : **University of Oklahoma HSC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 5, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850.

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

I am a practicing cardiologist in a group academic practice. My practice is devoted entirely to treating heart rhythm disorders (arrhythmias). The members of our practice implant medical devices and perform other cardiac procedures on a significant number of Medicare beneficiaries in the inpatient setting. Because inpatient procedures are a key component of delivering appropriate cardiac care, I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to change the way Medicare pays for inpatient services.

The new DRG weights proposed by CMS result in a dramatic reduction in hospital payments for cardiology procedures. These payment changes, if finalized, would have a severe financial impact on the hospital where I perform these procedures because the proposed payment levels are significantly less than my hospital s actual cost to deliver these services. From what I have learned, these insufficient payment levels are largely the result of Medicare errors in calculation and questionable data.

The obvious costs constraints resulting from these reductions in hospital payment will limit patient access to cardiac care, which treats the number one killer in America today - heart disease. As hospitals ask physicians to scale back their number of procedures, due to financial uncertainties, patient access will surely be impacted.

I respectfully request that CMS return to the current charge-based methodology for the coming fiscal year and work with stakeholders to improve hospital cost reporting processes before any transition to cost-based weights.

Thank you for your consideration.

Sincerely,

Warren M . Jackman, M.D.
University of Oklahoma Health Sciences Center
Professor of Medicine, Cardiology
George Lynn Cross Research Professor
Director, Clinical Electrophysiology
Clinical Director, Cardiac Arrhythmia Research Institute

Submitter : **Mrs. Rosamond Richards** **Date: 06/05/2006**

Organization : **Sentara Healthcare**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

I am writing to make four major points about the possible change this year to the APRDRG system 10/1/06, and to give a suggestion: 1) The time frame is too short for hospitals to adequately teach their coders the APRDRG methodology by 10/1/06; 2) it will be impossible for information technology departments to complete the massive changes necessary for such an event; 3) the APRDRG algorithms must be in the public domain, or any other algorithm chosen over the DRG methodology must be in the public domain. Anything else is unfair to other vendors and to their customers. 4) (whatever the decision is regarding implementation of the APRDRG system, do not split the implementation - either do it all at once or postpone it until 10/01/07). My suggestion is that the implementation date for switching to APRDRGs be moved to Jan 1, 2007 at the earliest. This allows three quarters under the new system, and avoids a crippling blow to hospitals. Rosamond B Richards, RHIA, CPHQ, Director, Clinical Coding, Sentara Healthcare.

Submitter : **Ms. Adda Alexander** **Date: 06/05/2006**

Organization : **Arizona Hospital and Healthcare Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Retroactive collection of data is cost prohibitive. This data is not electronically collected thus requiring chart abstraction (on charts that have already been abstracted). The data collection should start when the project is implemented, on or after July first.

Submitter : Mr. Jerome Rivet

Date: 06/05/2006

Organization : Covenant HealthCare

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

CMS-1488-P-175-Attach-1.PDF

#175

COVENANT HealthCare

June 6, 2006

Mark McClellan, M.D., Ph.D, Administrator

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention:CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: FY 2007 Medicare Inpatient Prospective Payment System Proposed Rule CMS-1488-P

Dear Dr. McClellan:

Thank you for the opportunity to comment to Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule to update the Inpatient Prospective System for FY 2007.

CMS is proposing the most significant change to the DRG relative weight calculation since the beginning of the PPS. **The revised DRG weights will result in a significant redistribution of Medicare inpatient payments among hospitals.** Although on a statewide basis, the FY2007 CMI changes will have a minimal impact, Covenant HealthCare is anticipating a significant decrease in our DRG relative weights. **We strongly urge CMS to delay implementing the revised relative weighting system.**

- The proposed DRG weights are based on a change in DRG weights based on charges to weights based on hospital-specific cost.
- The methodology assumes a consistent cost-to-charge ratio between ancillary departments, which is not the case. High cost surgical implants, such are cardiac devices, typically have a significantly lower mark-up than lower cost items. This assumption artificially decreases the relative weights when charges are converted to cost using the same ratio for all departments. This results in an inappropriate reduction in relative weights for implant cases.

In the proposed rule, the IME payment adjustment multiplier is reduced from 1.35 to 1.32. We suggest that the CMS maintain IME payments at the current levels. Further payment reductions will jeoprodize teaching programs and the adequate supply of future physicians.

Again, we appreciate this opportunity to comment to CMS on regarding the FY 2007 Medicare Inpatient Prospective Payment System Proposed Rule and urge you to please take them into consideration. If you have any questions regarding this comment, please contact me at jrivet@chs-mi.com or (989) 583-4847.

Sincerely,

Jerome A. Rivet
Reimbursement Administrator
515 N. Michigan Ave
Saginaw, MI. 48602

Submitter : Mr. Tim Barnett **Date:** 06/05/2006

Organization : Yavapai Regional Medical Center

Category : Hospital

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Hospital Quality Data: We understand the ramifications of the DRA of 2005. We would request that the reporting of these new quality measures should take affect on or after July 1, 2006 and not be retroactive to January 1, 2006, as this would be costly in both time and resources. Thank you for your consideration.

Submitter : **Mr. Robert Seifert** **Date: 06/05/2006**

Organization : **Abbott Vascular**

Category : **Other Technician**

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

These proposed CMS changes in reimbursements that are proposed will hurt the already ailing hospital systems in the US. It will increase prices for patients and lower the availability for much needed cardiac services in the US. Also, technology advancements will suffer and ultimately reduce the amount of patients that receive already proven treatments and technologies. Cardiac conditions are the #1 problem in US health issues and should not be cut.

Submitter : **Dr. Brian Goodell** **Date: 06/05/2006**

Organization : **St. Luke's Hospital**

Category : **Hospital**

Issue Areas/Comments

DRGs: Spinal Fusion

DRGs: Spinal Fusion

June 5, 2006

To Whom It May Concern:

On behalf of St. Luke's Hospital, I am posting comments to CMS to support the application for docet number CMS-1488-P DRGs: Spinal Fusion.

St. Luke's provides healthcare services to the San Francisco community and its physicians. For several months now, we have been performing X STOP surgical procedures and it has been well received. We believe the device is safe and effective according to the FDA indiciations for use. We urge that CMS approve the Add-On application as the financial piece is importnat in the decision making process in adoption of new technologies.

We appreciate your consideration. Thank you in advance for your support.

Sincerely,
Brian Goodell, M.D.
Interm Chief Administrative Officer
St. Luke's Hospital
San Francisco, CA

CMS-1488-P-178-Attach-1.PDF

#178

St. Luke's Hospital
A Sutter Health Affiliate

3555 Cesar Chavez St.
San Francisco, CA 94110
(415) 647-8600

June 5, 2006

To Whom It May Concern:

On behalf of St. Luke's Hospital, I am posting comments to CMS to support the application for docket number CMS-1488-P DRGs: Spinal Fusion.

St. Luke's provides healthcare services to the San Francisco community and its physicians. For several months now, we have been performing X STOP surgical procedures and it has been well received. We believe the device is safe and effective according to the FDA indications for use. We urge that CMS approve the Add-On application as the financial piece is important in the decision making process in adoption of new technologies.

We appreciate your consideration. Thank you in advance for your support.

Sincerely,

Brian Goodell, M.D.
Interim Chief Administrative Officer
St. Luke's Hospital
San Francisco, CA

Submitter : Dr. Norman Lepor **Date:** 06/06/2006

Organization : Westside Medical Associates of Los Angeels

Category : Physician

Issue Areas/Comments

Update Factors

Update Factors

On April 12, 2006, CMS released its proposed hospital inpatient payment rule for FY07. The rule recommends significant changes to the DRG methodology that move funds away from cardiology services, including proven, cost-effective therapies like implantable cardioverter defibrillators (ICDs) and drug eluting stents, and into other hospital services.

Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights.
The reduction of payments in cardiology could reduce patient access to interventional procedures.
The most appropriate course of action for CMS would be to return to the current charge-based methodology for the coming fiscal year and work with stakeholders to improve hospital cost reporting processes before any transition to cost-based weights

Submitter : **Dr. Daniel Lustgarten** **Date: 06/06/2006**

Organization : **Fletcher Allen Health Care/University of Vermont**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 400 bed hospital located in Burlington, VT: I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

Daniel L. Lustgarten, MD, PhD

Submitter : Mr. **Date:** 06/06/2006

Organization : Mr.

Category : Other Health Care Professional

Issue Areas/Comments

DRGs: Carotid Artery Stents

DRGs: Carotid Artery Stents

Technology today allows each of us to live a more productive life. This is no different in what is offered in health care. Please review these proposed changes carefully not to penalize a Non-Profit facility that is providing these services to all populations.

DRGs: MCVs and Defibrillators

DRGs: MCVs and Defibrillators

Technology today has proven to be a factor in all of our lives. The population that requires assistance from these implantable devices should not be penalized over the population that require medication to correct heart rates, or other related issues. Please review carefully and do not penalize facilities that are Non-Profit and providing care and technology to all populations.

Submitter : **Mr. Leslie Reed** **Date: 06/06/2006**

Organization : **Wright Memorial Hospital**

Category : **Hospital**

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

We are interested in providing feedback on the proposed Deficit Reduction
Action of 2005 which will reduce the Annual Payment Update (APU) to hospitals that fail to report the required measures of quality. If the proposed legislation goes through, it will have a significant financial impact on our hospital and we believe it is important that we provide feedback related to this important piece of legislation. Please find our comments below:

1. As proposed, the number of quality measures will increase from 10 to 21. This will require additional staff support to collect and transmit this additional information.
2. This proposed legislation requires hospitals to go back and abstract data from January 1, 2006. This is an alarming precedent to set and places an undue burden on a hospital to provide this additional data. In addition, our data will be publicly reported dating back before we had process improvement initiatives in place to address our performance.
3. In reviewing the hospital data, CMS plans to combine the samples for first quarter, second quarter and third quarter of 2005 into a single stratified sample to determine whether or not the 80-percent reliability level is met. We believe this is problematic because hospitals have not had an opportunity to appeal CMS Clinical Data Abstraction Center (CDAC) errors if the error did not result in the hospital failing for the given time period. As a result, a hospital may be negatively impacted by the decision to combine these three quarters into a single stratified sample as proposed. For example, a hospital could have errors (as abstracted by CMS) in their 1st and 2nd quarter report providing them with an 80% passing rate (which they could not appeal) and actually fail the third quarter which would result in failure of all 3 quarters based on the plan to combine the first three quarters as proposed).
4. The payment update for 2007 will be reduced by 2.0 percentage points for indicator performance that has a track record of poor reliability, especially working diagnosis of pneumonia. Some hospitals resort to answering working diagnosis for pneumonia as a yes for all pneumonia charts regardless of actual documentation, since the penalty is disproportionately more severe if the no answer is found to be incorrect. A couple of mismatches on the no to working diagnosis can drive the hospital to the brink of losing their APU.
5. Under the proposed timeline, January, February and March 2006 data will need to be abstracted and successfully submitted to CMS no later than July 31, 2006. With the CMS comment period deadline of June 12, 2006 and an anticipated response time of 60 days by CMS, the outcome may not be known until August 12, 2006. Hospitals will have to proactively submit data on the 21 indicators & in anticipation of the legislation going into effect. The proposed timelines as outlined are problematic.

Thank you for the opportunity to provide feedback on this important legislation. We believe it will have a negative impact on our organization and wanted CMS to consider the weaknesses and understand the implications. We look forward to your comments and feedback.

Submitter : Ms. Theresa Kortemeyer **Date:** 06/06/2006

Organization : Saint Luke's South Hospital

Category : Nurse

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

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Action of 2005 which will reduce the Annual Payment Update (APU) to hospitals that fail to report the required measures of quality. If the proposed legislation goes through, it will have a significant financial impact on our hospital and we believe it is important that we provide feedback related to this important piece of legislation. Please find our comments below:

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Thank you for the opportunity to provide feedback on this important legislation. We believe it will have a negative impact on our organization and wanted CMS to consider the weaknesses and understand the implications. We look forward to your comments and feedback.

Submitter : Ms. Mary Collins **Date:** 06/06/2006

Organization : OhioHealth

Category : Hospital

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

The impact to adding SOI and ROM will more than double the efforts on the coders part to accurately code a case. Although our hospitals have had an ongoing documentation improvement process with our physicians, even that effort will need more resources to ensure the highest level of clear documentation and proper coding. There just isn't enough time in the proposed timeline to prepare our current staff and hire the additional staff that will be needed for this change. We agree with the need for reform of the DRG system but it needs to be investigated thoroughly to see if 3M is the real solution and that the AHIMA and other coding associations can put together a standard training mechanism that upholds coding integrity and accuracy.

Impact Analysis

Impact Analysis

From what we can gather in researching those facilities that currently use the APR-DRGs, we feel that we will need to double our staffing requirements and retrain all the coders. We have been at a shortage of qualified, trained coders for many years even in an area where there are several schools offering credentially for coding. At best, we could be ready in about 2 years.

Submitter : Dr. Zian Tseng **Date:** 06/06/2006

Organization : University of California, San Francisco

Category : Physician

Issue Areas/Comments

GENERAL

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Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 500-bed hospital located in San Francisco, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

Zian H. Tseng, M.D.

Submitter : Ms. Laurie McBrierty **Date:** 06/06/2006

Organization : AHIMA

Category : Individual

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

CMS needs reconsider its proposed rule change by evaluating the available alternatives for refining the DRG system.

1. Proprietary System The APR-DRGs are a proprietary system that limits full disclosure and the transparency of its casemix grouping and severity adjustment rules. The proprietary logic of this system may be disclosed to government, but it is not likely the same level of transparency will be provided to hospitals and payers. Reliance on a proprietary system is diametrically opposed to the open DRG architecture CMS has fully supported for the past 23 years, and which has served well as a model open to public discussion and scrutiny. It is crucial that the classification system used by CMS meets the standards for public review, discussion, adaptation and transparency.

2. Methodology Due to its inherent complexity, the proposed methodology will cause an immediate and sustained decrease in coder productivity. The consequence is a longer revenue cycle. For the past 23 years, coders have worked in a consistent framework. If CMS adopts the proposed system, all inpatient coders will require retraining.

3. Selection Process CMS did not conduct an objective study to severity-adjust the DRG system. In spite of the fact that alternatives for the APR-DRG system are readily available, there is nothing to indicate that CMS considered any of them for its IPPS. Further, CMS did not conduct a single independent study to determine the impact the implementation of this methodology will have on coding and billing productivity or hospital cash flow.

4. Timeframe Should the proposed rule be enacted, the aggressive implementation timeframe CMS has established would not allow provider organizations to effectively prepare for the changes, including database and information systems modifications, and the required retraining of coders and billing personnel. In addition, shortly after the proposed transition to APR-DRGs will be the prospect of migration to ICD-10, a huge change in billing practices that appears likely to be mandated within the next four years.

Adopting a proprietary system that will, without doubt, increase costs for software acquisition, training and services, and a system that is not fully transparent and accessible to all its constituents is imprudent and irresponsible. The content and methodology that enables hospital coding and casemix classification must be accessible, at no cost, to all in our nation s health care industry. Transparency is imperative if we are to advance health care affordability.

CMS needs reconsider its proposed rule change by evaluating the available alternatives for refining the DRG system.

Submitter : Dr. Eugene Orientale **Date:** 06/06/2006

Organization : UCONN/St Francis Family Medicine Residency

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment, RE: CMS-1488-P

CMS-1488-P-187-Attach-1.TXT

June 5, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid ServicAttention: CMS-1488—P "Resident Time in Patient-Related Activities"

Dear Administrator McClellan:

On behalf of the Asylum Hill Family Medicine Residency (UCONN / St. Francis Hospital & Medical Center) located in Hartford CT, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care
I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

I cannot imagine a didactic lecture, workshop, or journal club in our teaching program that is not directly related to the patients we care for. It is an explicit objective of our program to use patient-case based learning, always keeping our patients as the focus of our teaching sessions. Plain and simple, what CMS is asserting just does not make good sense.

In addition, as director of this program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The

documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs. Sincerely,Eugene Orientale, Jr. MD
Program Director
Associate Professor, Family Medicine
Asylum Hill Family Medicine
UCONN/St Francis Hospital and Medical Center

Submitter : **Dr. bruce samuels** **Date: 06/06/2006**

Organization : **cardiovascular medical group**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

these proposed cuts to hospital reimbursements for cardiology services is a complete joke. these procedures, in particular drug eluting stents, pacemakers, defibrillators, etc... are expensive - yes - but clearly cost effective in the long run. more importantly, they are a critical benefit to our patients. cutting reimbursements for these services will only lead to decreased utilization that will save short term dollars at the expensive of patients' lives. shame on you all.

Submitter : **Mr. Keith Hagen** **Date: 06/06/2006**

Organization : **QuadraMed Corporation**

Category : **Health Care Industry**

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

In the weeks following publication of the April 25, 2006 CMS proposed rule change regarding the existing DRG system, we at QuadraMed Corporation have become increasingly concerned that if enacted in its current form, this change will have a serious, negative impact on our nation s healthcare system as a whole.

After careful examination, we ask that CMS reconsider this proposal based upon four critical concerns we have identified that make such a rule change inherently flawed, with the potential to inflict far-reaching unintended financial consequences that will further exacerbate efforts to control spiraling cost.

First, adopting a proprietary APR-DRG system will limit full disclosure and transparency of the system s case mix grouping and severity adjustment rules. This is a reversal of the position CMS has steadfastly supported for 23 years an open DRG architecture which has served as an outstanding model for open public discussion and scrutiny. It is critical the classification system used by CMS, and therefore the healthcare industry, meets acceptable standards for public review and discussion, transparency and adaptation.

Further, the complexity of the proposed methodology will cause an immediate and sustained decrease in coder productivity. A change of this magnitude will not only require retraining of all inpatient coders, it will result in a longer revenue cycle for providers, thereby having a serious potential to raise healthcare costs. In spite of the potential for these negative consequences, it appears CMS did not conduct an independent study of the impact implementation of this methodology will have on coding productivity or hospital cash flow. Such a study is both prudent and imperative.

Third, there are readily available alternatives to the proposed APR-DRG system. This clearly indicates the need to conduct an objective study is CMS is to severity-adjust the existing DRG system.

Finally, should the proposed rule change be enacted, the aggressive timeframe CMS has proposed for implementation would not allow provider organizations to effectively prepare for the necessary database and information systems modifications, as well as the aforementioned retraining of coders and related billing personnel. But of even greater concern for the long term is the fact that shortly after the proposed transition to a proprietary APR-DRG system would occur there is the real prospect of migration to ICD-10. This needed migration will trigger a monumental change in billing practices that appears likely to be mandated within the next four years.

QuadraMed has and will continue to support efforts by CMS to improve the DRG system. But adopting a proprietary system that will, without doubt, increase costs for software acquisition, training and services, and a system that is not fully transparent and accessible to all its constituents is imprudent and irresponsible. The content and methodology that enables hospital coding and case mix classification must be accessible, at no cost, to all in our nation s health care industry. Transparency is imperative if we are to advance health care affordability.

Therefore, we at QuadraMed ask that CMS reconsider the proposed rule change and evaluate the available alternatives for refining the DRG system. It is in the best interests of all stakeholders the government, the healthcare industry, and the taxpayers who ultimately shoulder the cost of healthcare that systemic changes to the existing DRG system be made only after all reasonable alternatives have been objectively and thoroughly studied and weighed against potential negative impact and unintended consequences.

Sincerely,

Keith Hagen

CMS-1488-P-189-Attach-1.PDF

CMS-1488-P-189-Attach-2.PDF

189

QUADRAMED®

A Letter to CMS Addressing QuadraMed's Concerns Pertaining to the Proposed DRG Severity Rule Change

Keith B. Hagen
President and CEO
QuadraMed Corporation

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Submitter : **Dr. David McKalip** **Date: 06/06/2006**

Organization : **Dr. David McKalip**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

NEW TECHNOLOGIES Section of Rule 1488-P
I believe the X- stop should be approved as a category I CPT code with a reimbursement formula that would be fair to physicians. I agreee with the submitted reimbursement proposal from the Company, St. Francis Medical Technology. By offering this to my patients, I can help there symptoms and avoid multiple trips for epidural steroids which will save money for procedures and other doctor visits. In addition, I will likely decrease the total number of laminectomies my patients need by about 75%.
Thank you

Submitter : Brenda Wood **Date:** 06/06/2006

Organization : QuadraMed

Category : Other Health Care Professional

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

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1. Proprietary System The APR-DRGs are a proprietary system that limits full disclosure and the transparency of its casemix grouping and severity adjustment rules. The proprietary logic of this system may be disclosed to government, but it is not likely the same level of transparency will be provided to hospitals and payers. Reliance on a proprietary system is diametrically opposed to the open DRG architecture CMS has fully supported for the past 23 years, and which has served well as a model open to public discussion and scrutiny. It is crucial that the classification system used by CMS meets the standards for public review, discussion, adaptation and transparency.

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Submitter : **Mrs. Valerie Rinkle** **Date: 06/06/2006**

Organization : **Asante**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-192-Attach-1.DOC

#192

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore MD, 21244-1850

Via Email: http://www.cms.hhs.gov/eRulemaking
CMS-1488-P

Dear Administrator,

Asante owns and operates two acute care hospitals in Southern Oregon. We are dramatically impacted by the proposed changes to the Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year 2007 (FFY07). Please give due consideration to our comments and concerns as expressed below.

HSRVcc Weights

Asante is significantly concerned about the methodology CMS proposes to base DRG weights on calculated hospital costs as opposed to charges.

CMS has a premise that hospitals use different mark-ups for ancillary cost centers versus nursing cost centers. CMS appears to come to this conclusion due to routine cost centers on Worksheet C having higher cost-to-charge ratios (CCR) than ancillary cost centers. However, this result is due to differential charging rules for nursing versus ancillary cost centers and the mismatching of expense and revenue on cost reports. With the advent of outpatient prospective payment, hospitals have had to change charge practices to itemize every service according to CPT coding rules. Most of the CPT coding rules apply to ancillary departments, not to routine nursing departments, with one significant exception – observation patients. For observation outpatients, hospitals must bill the hourly observation charge based on the room and board rate, but also bill hours of infusion, injections and any other bedside service rendered to the patient such as lumbar puncture, bladder scan, etc according to CPT rules.

The following citations from the Provider Reimbursement Manual indicate that once a hospital charges a service to an outpatient, then the same charge for the same service should also be billed to inpatients. Hospitals have not billed these services separately on inpatient accounts because traditional thinking is that these nursing services are part of the room and board rate. However, most of these services are not part of the room and board rate and are not routinely rendered to inpatients and therefore, should be billed separately.

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Please answer these important questions: Is it appropriate to charge these services separately on an inpatient account using a routine revenue code such as 230? If these charges caused an inpatient account to be a cost outlier, would the QIO accept such charges for the outlier payment calculation? If not, are the following citations for using charges for cost apportionment obsolete? If so, then how can CCRs be used for either OPPS APC weight calculations or the proposed HSRVcc DRG weight calculations?

> PRRM Section 2204. Medicare Charges
>
> Medicare charges refer to the regular rates for various covered services which are charged to beneficiaries for inpatient or outpatient services. The Medicare charge for a specific service must be the same as the charge made to non-Medicare patients (including Medicaid, CHAMPUS, private, etc.), must be recorded in the respective income accounts of the facility, and must be related to the cost of the service. (See §2202.4.)
>
> PRRM Chapter 23 2302.6
>
> <u><< Charges>></u> .--The regular rates established by the provider for services rendered beneficiaries and to other paying patients. <u><< Charges>></u> should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient.

Note that the expense for these bedside procedures and services is in the routine cost center, but that hospitals have not itemized charges for these services to inpatients. This has the result of artificially suppressing charges for inpatients in routine cost centers and suppressing the CCRs making it appear that ancillary cost centers have differential mark-ups.

Another reason that the CMS HSRVcc calculations are incorrect is where hospitals have charged for diagnostic services performed by nursing. For example, trained nurses now perform many diagnostic lab tests on nursing units. The hospital's clinical lab performs required proficiency testing and ensures the tests meet all CLIA standards as full-fledged clinical lab tests. In these situations, the tests are billed out with revenue code 300 as laboratory, but the expense resides in a routine cost center.

As a result of these examples and many others, CMS is not able to reliably match revenue and expense. Most hospitals do not reclassify the expense based on revenue codes and CMS does not mandate Fiscal Intermediaries to make this reclassification. The above examples illustrate impacts to routine cost centers, but other examples also illustrate similar impacts to ancillary cost centers, particularly cardiology and surgery cost centers. For example, take

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the significant expense of implants like pacemakers and defibrillators and drug eluting stents. Most often the cardiology cost center purchases these implants and therefore, the costs reside in the cardiology cost center. But these implants must be billed with a medical/surgical supply revenue code 275 or 278. Therefore, CMS associates the charges with the cost-to-charge ratios (CCR) for the supply cost center. Many hospitals do not reclassify the expense of the implants and the revenue billed under 27x to the medical surgical cost center, so CMS will miscalculate the cost of these implants.

CMS must either verify their CCR to revenue code mapping with Fiscal Intermediary audits, or dramatically strengthen cost reporting rules to ensure that revenues and expenses are matched before relying on such a methodology. CMS knows the problems with converting charges to costs using CCRs as a result of their experience with the Outpatient Prospective Payment System. Hospitals and vendors have testified from the inception of OPPS (6 years) that the resulting weights for procedures including high cost devices are well below actual costs – not just for the procedure, but for the out-of-pocket expense for the device itself – payments for procedures like defibrillators, pacemakers and other device-dependent APCs are not calculated correctly with the CMS methodology of matching revenue code charges to hospital-specific cost-to-charge ratios (CCRs). These are the same procedures for which the HSRVcc method (just a variation of the CCR method) significantly reduces payment (over 20%). CMS' experience with OPPS should alert it to the significant flaws in this method!

Another example of mismatched revenue and expense is the unanswered questions of how hospital subscripted cost report lines are treated in this CMS methodology. Table A in the proposed rule says nothing of subscripted cost report lines. So any cost center that has a subscripted line appears to be excluded – these are often are significant cost centers such as cardiac catheterization laboratory, ultrasound, MRI, etc. If these subscripted cost centers are excluded, the HSRVcc method is significantly flawed. How did CMS treat the subscripted cost report lines of each hospital?

Table A illustrates how CMS groups the costs, but there are significant errors in these groupings. For example, outpatient service charges C1.C5.61 should be grouped with Routine Days as these are Observation Services performed in nursing departments. Lithotripsy is not Radiology – it belongs more appropriately with Operating Room. Blood charges belong with Laboratory as Blood Bank is a part of Laboratory. Why would ambulance costs be included since these are paid separately and are not part of the IPPS benefit?

Still another concern of the HSRVcc method is the age of the cost data. For DRGs most dramatically impacted, there have been significant cost shifts toward devices in the last 2-3 years. These costs, such as drug eluting stents, carotid stents and defibrillators, are not reflected in the cost data of cost reports 3-5 year old.

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Discharges from every hospital are weighted the same, for example a small hospital's volume has the same impact as a large hospital's volume. This skews the data. In fact, CMS has taken the public position that hospitals that perform a high volume of a certain surgery or service are likely to have better quality. Most of CMS' National Coverage Determinations for approved facilities require high volumes of the service before they can be approved. Based on this, shouldn't volume of cases be a legitimate consideration in costing the DRGs for those services?

CMS should not implement DRG weights based on costs until several steps are taken: (1) CMS answers the issues concerning subscripted cost centers; (2) CMS verifies the matching of expense and revenue through fiscal intermediary audits and stronger cost reporting rules; (3) CMS answers hospitals' questions about charging for the same service to inpatients and outpatients; (4) CMS tests the reliability of its method; and (5) CMS gives hospitals a chance to plan and respond appropriately to the proposed changes.

Finally, any significant change such as proposed with cost-based weights versus charge-based weights should be phased in – at a minimum 25% a year. There is long-standing precedent for CMS to phase-in significant changes to the IPPS system. Changes in wage indices have been phased-in – CMS should not wreak havoc on the financial livelihood of hospitals by changing payments for significant product lines such as orthopedic surgery and cardiovascular services by making these changes. Finally, do not sacrifice all other acute care hospitals to address the specialty hospital problem – deal with that problem head on rather than forcing all other hospitals to suffer ill-conceived changes in DRG weights.

DRGs: Severity of Illness

CMS proposes to change adjustments for severity of illness from complications and comorbidities (CCs) to Consolidated APR-DRGs. They point to this system as an improvement on the CC method for measuring severity of illness.

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APR-DRGs is a proprietary system developed by 3M and is based on a larger number of diagnoses and procedure codes than CMS used in its analysis. It is likely that the CMS analysis that resulted in the Consolidated APR-DRGs is skewed because the complete data set is truncated and CMS did not use comparable data to what 3M uses for the complete APR-DRGs. CMS should delay Consolidated APR-DRGs until it can analyze complete diagnosis and procedure code data with the implementation of UB04 and the expanded diagnoses and procedure code fields.

In addition, there is no easy way for hospitals to plan for the impact of this change. No vendor supports the Consolidated APR-DRGs and there is not a crosswalk from current DRGs to Consolidated APR-DRGs. Next year we must train coders to track the Present on Admission (POA) indicator for each diagnosis. We must analyze our documentation and train physicians and others to ensure POA information is documented to facilitate coders collecting this information. This is a significant change for coders. Hospitals do not have the means to analyze what additional coding and documentation changes would be needed with the Consolidated APR-DRGs.

Certified coders are in short supply. In our community we have had to train employees to be coders and many are not certified. The proposed changes will slow the coding of each case. Slower coding means that claims are not billed as quickly. This negatively impacts a hospital's cash flow. Currently, CMS imposes the requirement that changes to DRGs cannot be requested more than 90 days from discharge. This means that hospitals must slow down coding to ensure it is correct before the claim is submitted. If CMS implements such a dramatic change to coding, it should allow hospitals to update and correct coding and retroactively request a change to the DRG assignment up to one-year following discharge. This will give hospitals the ability to analyze cases retroactively, while protecting cash flow. The 90-day limit is not sufficient for hospitals to respond.

In addition, CMS should delay implementation of such a change to the DRG system until it conducts nationwide coding and documentation education, particularly to physicians. Furthermore, CMS should find a method to incentivize physicians for correct documentation. Hospital payment under the current DRG system and the proposed Consolidated APR-DRGs is tied to physician documentation. The incentives in this system are backwards – a physician is paid for each day of their services or for their surgery whether or not they properly document signs, symptoms, diagnoses and co-morbidities in the hospital medical record; whereas, the hospital that incurs significant drug, diagnostic testing, nursing and other expenses has its payment limited or denied in some cases, due to the lack of documentation by the physician. Asking hospitals to educate the physicians is burdensome and ineffective.

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CMS must find a way to link physician and hospital incentives with regard to documentation of the severity of illness and quality of care. CMS should contact physicians who bill with place of service inpatient hospital. They could require each physician to go through web-based documentation training applicable to severity of illness and quality of care indicators by a certain date. After that date, CMS could suspend physician payments with place of service inpatient hospital if the physician had not completed the web-based training.

Has CMS modeled the impact of the post-acute care payment limits to these new Consolidated APR-DRGs? Would the DRGs impacted by the post-acute care policy change? Would CMS eliminate the post-acute care policy with this severity of illness refinement to the DRGs?

CC List

CMS should put the CC list on their website along with a DRG calculator. Similar to how a physician can put in a CPT code and their geographic area and get the Medicare RBRVS payment on the CMS web site, a hospital should be able to put in the diagnoses and procedure codes and their geographic area and get a DRG payment amount for their hospital. In addition, the DRG calculator should list the ICD9 codes that are CCs for the DRG pair.

This information should be more readily available to hospitals and this should also be the case for any future refinements such as Consolidated APR-DRGs.

Hospital Quality Data

One of the most significant drawbacks to the quality data is the retrospective nature of the abstracting and data reporting. Hospitals are not able to impact the data for the expanded set of quality measures for FY07 reporting since the indicators are just now defined and will be collected for CY06 discharges.

Hospitals need concurrent data to truly impact the quality of care for patients. In other words, if the hospital knows that smoking cessation counseling was not performed on a heart failure case within 24 hours of admission, notice can be made to the needed parties so that the counseling can be given before discharge. This is a better use of Utilization Review nurse and discharge planner efforts than the recently proposed discharge notice. These staff should be trained in the quality measures. The discharge plan should cover the quality requirements so that abstracting can occur concurrently and if crucial before discharge, discharge does not occur if the clinical requirements that can still be performed on the patient are performed.

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This requires real-time data systems, so CMS should sponsor demonstration projects with hospitals that build upon order entry and real-time electronic medical records to capture this information. In this fashion, CMS could lead the way for improved information technology dissemination in hospitals, particularly technology leading to evidence-based medicine and quality of care.

Transparency of Health Care Information

We are concerned with CMS' ideas to publish Medicare payment data – which they have proceeded with before hospitals have an opportunity to comment. The inference is that with more public awareness of Medicare payment rates, non-insured patients should be able to pay no more than what Medicare pays for a service. This is frightening given that Medicare payments often do not cover the actual cost of care. Indeed, this is one key reason for cost shifting through hospital charges to indemnity insurances.

When hospitals raise concerns regarding commercial insurance companies that use the Medicare DRG system for their payments, CMS responds that it is not responsible for commercial insurance payment policy. However, by publishing Medicare payment rates, CMS is directly influencing commercial payers and uninsured patients. Since the DRG and APC payment information is public, any informed individual can determine what Medicare pays for a service. CMS is obviously trying to inform uninsured patients to negotiate payments no higher than what Medicare would pay.

Publishing hospital prices is also fraught with problems. Hospital charges or prices are used as a reporting mechanism for cost reporting and apportionment of costs – this is driven by Medicare rules. Publishing prices will serve to confuse the public and not provide information. In fact, a vast majority of hospital services are due to emergencies where the patient has no ability to cost or quality compare prior to the service. CMS is interested in rewarding high quality care at a value – care performed efficiency with no unnecessary services. This requires a solution that addresses cost and quality data across settings where the consumer is making a choice for elective medical care. The information should include hospitals, Ambulatory Surgery Centers, and physicians performing the service. The information should address quality standards and recommended volume and experience as well as outcomes and cost to the consumer.

CMS can influence this through other means. For example, CMS can use the conditions of participation to encourage hospitals to publicize and practice outreach activities surrounding their financial assistance policies. CMS should publish example or model policies and require hospitals to have formal written charity or financial assistance policies that are advertised to patients. CMS should clarify whether hospitals can qualify a patient as

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indigent for an extended period of time like 6 months after their initial qualification date with no additional application needed. CMS can encourage hospitals to advertise their Financial Assistance policies to patients. CMS can encourage hospitals to employ Financial Assistance Counselors to work with patients.

CMS should blend quality and cost data so as to provide information on value to consumers. For example, for those hospitals that qualify as covered facilities under Medicare's NDCs having facility criteria – determine the average, low and high charges for these services. Publish this information along with the qualifying providers. Provide information as to volume thresholds for certain procedures and ways to evaluate outcomes.

We encourage CMS to work with state hospital associations such as Wisconsin and New Hampshire with their PricePoint Websites (http://www.wipricepoint.org/ and www.nhpricepoint.org). One key reason for encouraging transparency is the need to support the under or uninsured populations. With this premise, perhaps CMS can encourage States to work out solutions for transparency with the State hospital associations and encourage these through incentives tied to Medicaid matching fund requirements. These solutions would be better than one federal requirement for all hospitals.

Thank you for this opportunity to comment.

Valerie A. Rinkle, MPA
Revenue Cycle Director
Asante Health System

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Submitter : **Dr. Brian Goodell** **Date: 06/06/2006**

Organization : **St. Luke's Hospital**

Category : **Hospital**

Issue Areas/Comments

New Technology

New Technology

June 6, 2006

To Whom It May Concern:

On behalf of St. Luke's Hospital, I am posting comments to CMS to support the application for docket number CMS-1488-P New Technology.

St. Luke's provides healthcare services to the San Francisco community and its physicians. For several months now, we have been performing X STOP surgical procedures and they have been well received. We believe the device is safe and effective according to the FDA indications for use. We urge that CMS approve the Add-On application as the financial piece is important in the decision making process in adoption of new technologies.

We appreciate your consideration. Thank you in advance for your support.

Sincerely,

Brian Goodell, M.D.
Interim Chief Administrative Officer
St. Luke s Hospital
San Francisco, CA

CMS-1488-P-193-Attach-1.PDF

St. Luke's Hospital
A Sutter Health Affiliate

3555 Cesar Chavez St.
San Francisco, CA 94110
(415) 647-8600

June 6, 2006

To Whom It May Concern:

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We appreciate your consideration. Thank you in advance for your support.

Sincerely,

Brian Goodell, M.D.
Interim Chief Administrative Officer
St. Luke's Hospital
San Francisco, CA

Submitter : **Jody Jahn** **Date: 06/06/2006**

Organization : **Jody Jahn**

Category : **Individual**

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

CMS needs reconsider its proposed rule change by evaluating the available alternatives for refining the DRG system.

APR-DRGs are a proprietary system that limits full disclosure and the transparency of its case-mix grouping and severity adjustment rules. The proprietary logic of this system may be disclosed to government, but it is not likely the same level of transparency will be provided to hospitals and payers. Reliance on a proprietary system is diametrically opposed to the open DRG architecture CMS has fully supported for the past 23 years, and which has served well as a model open to public discussion and scrutiny. It is crucial that the classification system used by CMS meets the standards for public review, discussion, adaptation and transparency.

Due to its inherent complexity, the proposed methodology will cause an immediate and sustained decrease in coder productivity. The consequence is a longer revenue cycle. For the past 23 years, coders have worked in a consistent framework. If CMS adopts the proposed system, all inpatient coders will require retraining.

CMS did not conduct an objective study to severity-adjust the DRG system. In spite of the fact that alternatives for the APR-DRG system are readily available, there is nothing to indicate that CMS considered any of them for its IPPS. Further, CMS did not conduct a single independent study to determine the impact the implementation of this methodology will have on coding and billing productivity or hospital cash flow.

Should the proposed rule be enacted, the aggressive implementation timeframe CMS has established would not allow provider organizations to effectively prepare for the changes, including database and information systems modifications, and the required retraining of coders and billing personnel. In addition, shortly after the proposed transition to APR-DRGs will be the prospect of migration to ICD-10, a huge change in billing practices that appears likely to be mandated within the next four years.

Adopting a proprietary system that will, without doubt, increase costs for software acquisition, training and services, and a system that is not fully transparent and accessible to all its constituents is imprudent and irresponsible. The content and methodology that enables hospital coding and case-mix classification must be accessible, at no cost, to all in our nation s health care industry. Transparency is imperative if we are to advance health care affordability.

Submitter : Mrs. Renee Mazeroll **Date:** 06/06/2006

Organization : St. Joseph Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

My hospital is a 412 bed acute care hospital located in Orange, California. As a major health care provider in our area, we implant medical devices and perform other cardiac procedures on a significant number of Medicare beneficiaries in the inpatient setting. Because inpatient services are a key component of what we provide, I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to change the way Medicare pays for inpatient services.

First, it adopts a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver cardiology services. Second, it adopts a new and untested approach to what are known as cost-based DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of all procedures in the DRG system. And finally, even within the new CMS methodology, there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by about 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.

With regard to the severity adjustment proposed for next year (FY08), severity does not include the technology costs paid by hospitals for more complex cases. As a result, my technology costs could be underpaid.

The payment methodology changes that CMS has proposed would have a severe financial impact on my hospital without accurate data to justify the change. This is particularly true for device intensive cardiology DRGs where the proposed payment level is often significantly less than my hospital s actual cost to deliver the service.

The reduction in payment for cardiology services would also have a severe impact on the infrastructure I have built up over the years to treat the number one killer in America today - heart disease. In addition to requiring the potential dismantling of this infrastructure I would now face the uncertainty of knowing that next year, or any other year, CMS could decide to under-fund whatever service area I build up next to meet patient needs. Obviously, as I'm forced to scale back or not develop service capacity due to payment swings and financial uncertainties, patient access could be negatively affected.

I respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity adjusted DRGs should not be implemented until the technology costs incurred by my hospital can be appropriately reflected in the DRG payments.

Thank you for your consideration.

Sincerely,

Renee Mazeroll, RN, MSN
Executive Director, Cardiac and Vascular Services
St. Joseph Hospital

cc. Dianne Feinstein
cc. Barbara Boxer

Date: 06/07/2006

Submitter : Dr. Jeffrey epstein

Organization : Dr. Jeffrey epstein

Category : Physician

Issue Areas/Comments

New Technology

New Technology

X-Stop; Great device. Has improved patient's symptoms without the need for a more formal lumbar spine decompressive surgical procedure. Has great benefit in that it is minimally invasive, requires a short oerative time which translates into less complications since you a re treating a neurologic problem that is very commonly found in "senior citizens", the very same patients that are at a greater risk of complications when it comes to more classic surgical procedures. Until the X-Stop (by St. Francis Medical Technologies) was FDA approved, any patient with Lumbar stenosis who was symptomatic with leg and/or back pain that worsened with ambulation and improved with sitting, was subjuct to a major spinal surgical procedure (if they were healthy enough). For all those patients greater than age 50 who felt better while walking hunched over a shopping cart rather than standing more erect and walking on their own, this surgically implanted device has improved their quality of life tremendously, without the need for major surgical intervention. The procedure can even be done using local anesthesia, and patients can go home the next day, or even be done as an outpatient if the patients has no other major medical problems. For my back, give me an X-stop any day over a laminectomy. It is a no brainer (and as a neurosurgeon, this is something that I am familiar with!!) JE

Submitter : **Dr. Nick Shamie** **Date: 06/07/2006**

Organization : **UCLA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
RE: X Stop interspinous process decompression
P.O. Box 8011
Baltimore, MD 21244-1850

To whom it may concern:

I have implanted 6 X Stop interspinous decompression devices in the last four months and have been very pleased with the results. In my view, the X Stop has revolutionized the way we treat lumbar stenosis patients. The majority of my spinal stenosis patients are not candidates for surgery, and I consider the X Stop a very attractive option for them. Biomechanically, the X Stop appears to increase foraminal height and produce minimal reversal of lordosis, as measured by post-operative x-rays. My patients report their pain is halved after the procedure. For example, I had an elderly patient with critical aortic stenosis, who suffered in pain for over a year. She was unable to ambulate outside her home due to the condition. She was not a candidate for laminectomy, but she was able to undergo the X Stop procedure. After the procedure, the patient was able to walk. She said, This is a miracle treatment.

I have presented my clinical findings to my peers in the hospital system, and they are significantly impressed with the outcomes associated with X Stop. I believe it offers significant improvement over previous treatments for lumbar spinal stenosis. It can truly help patients who formerly had no treatment options. I strongly believe that Medicare should reimburse for X Stop in the hospital payment system.

Sincerely,

A. Nick Shamie, M.D.

CMS-1488-P-197-Attach-1.PDF

#197

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UCLA

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UCLA Comprehensive Spine Center
1250 16th Street, Suite 709
Santa Monica, California 90404

June 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
RE: X Stop interspinous process decompression
P.O. Box 8011
Baltimore, MD 21244-1850

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Sincerely,

Anya Nick Shamie

A. Nick Shamie, M.D.

Submitter : **Dr. Rainer Boehm** **Date: 06/07/2006**

Organization : **Novartis Pharmaceuticals**

Category : **Drug Industry**

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

see attachment

CMS-1488-P-198-Attach-1.PDF

#198

Rainer Boehm, MD
Senior Vice President &
North American Region Head

Novartis Pharmaceuticals Corporation
180 Park Avenue
105/3W254
Florham Park, NJ 07932

Tel 862-778-6092
Fax 973-781- 3134

NOVARTIS
ONCOLOGY

June 7, 2006

BY HAND DELIVERY

Mark B. McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 433-G Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: **Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal year 2007 Rates, Notice of Proposed Rulemaking – CMS-1488-P**

Dear Dr. McClellan:

On behalf of Novartis Pharmaceuticals Corporation (Novartis), I appreciate this opportunity to comment on the Centers for Medicare & Medicaid ("CMS's") proposed rule on revisions to the Hospital Inpatient Prospective Payment System (IPPS) for fiscal year 2007 (FY2007), published in the *Federal Register* on April 25, 2006. Novartis is part of the Novartis Group of Companies, a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. Of particular relevance to this rulemaking, Novartis manufactures and markets high-dose interleukin-2 (HDIL-2) under the brand name Proleukin®[1]. Proleukin® is approved for the treatment of metastatic renal cell cancer and metastatic melanoma. HD-IL2 therapy is generally delivered in the inpatient setting and offers the only possibility of a complete and durable response in patients affected by these otherwise fatal cancer disease states. Novartis' goal is to ensure that patients have meaningful access to effective therapies in the context of adequate and appropriate reimbursement to providers. We believe that this goal would be adversely affected for patients requiring HD-IL2 therapy if the CSA-DRG system is implemented as proposed. We support CMS's effort to better reflect disease severity in assigning DRGs; however, the proposed CSA-DRG system does not provide adequate reimbursement for medical conditions where the patient's admission status is relatively good but the course of treatment is very complex and resource intensive as is the case with metastatic renal cell cancer and metastatic melanoma treated with HD-IL2. Hospitals providing HD-IL2 in the treatment of the above cancers would face a reduction of approximately 58% if the proposed CSA-DRG system were implemented. We urge CMS not to implement the CSA-DRG system as proposed in either 2007 or 2008 given that it does not take into account the situation where a resource intensive treatment such as HD-IL2 is administered to treat an otherwise fatal condition but where the patient's ambulatory status is relatively good. Instead, we ask CMS to make certain any new classification system take into account the situation described

[1] Novartis acquired Proleukin® as part of its acquisition of Chiron Corporation in April 2006.

immediately above involving the administration of HD-IL2 therapy and allow for procedure code 00.15 to map to a DRG with an appropriate reimbursement. The agency did this in 2003 and doing so again would be an effective way to ensure that hospitals receive adequate reimbursement for HD-IL2 therapy and patients maintain access to this treatment. Our reasons behind this concern are detailed below along with a background of HD-IL2 therapy and previous CMS DRG coding changes with this therapy.

Background of High-Dose IL-2 Therapy and previous coding changes:

High-dose IL-2 therapy was approved by the FDA in 1992 and remains the only therapeutic possibility for a complete and durable response in patients with metastatic renal cell carcinoma and metastatic melanoma. Metastatic renal cell carcinoma and metastatic melanoma occur relatively infrequently, and only a small proportion of patients insured by Medicare are eligible to receive this intensive treatment. In 2004 there were only 559 Medicare claims for HD-IL2 therapy.

It is important to note that as an immunotherapy, high-dose IL-2 therapy differs from conventional chemotherapy in the resources required to administer it. Unlike conventional chemotherapy which is given to patients either on an outpatient basis or through a series of short (i.e. one to three days) inpatient stays, HD-IL2 is a much more intensive intervention that requires administration in an intensive care unit or equivalent setting over five to six days. In addition, HD-IL2 must be given according to a precisely defined protocol, with round-the-clock nursing support available in order to guard patients against certain expected and well-understood adverse events (e.g., metabolic acidosis, acute renal failure, cardiac arrhythmias, respiratory distress syndrome, thrombocytopenia, hyperthyroidism, and psychosis).

Previous Medicare coding changes regarding HD-IL2 therapy:

In 2002 and 2003, the Chiron Corporation, leading medical centers, and the Kidney Foundation worked closely with CMS to address issues related to the coding and reimbursement of HD-IL2. Before October 2003, there was no specific DRG or ICD-9 procedural code assigned to HD-IL2 patient admissions; as a result hospitals received an IPPS reimbursement rate far below the true hospital costs. These stakeholders requested a DRG re-classification based on the resource intensive nature of HD-IL2 in the clinical setting which would make this life saving treatment more available to patients.

In the FY2004 final rule (CMS-1470-F), CMS issued the procedure code 00.15 for high-dose interleukin-2 and re-classified DRG 492 to include high dose interleukin-2 admissions. CMS determined that DRG 492 appropriately reflected the resource intensity of this therapy. Adopting the proposed CSA-DRG payment system would, once again, make administration of high-dose IL-2 financially unfeasible for many medical centers and would deny access to this important therapy.

Summary of Issue

Under the current DRG system, high-dose interleukin-2 (procedure code 00.15) is reimbursed under DRG 492. In the proposed CSA-DRG system, DRG 492 does not exist. Novartis performed an analysis of the 2004 MedPAR files to: 1) determine to which CSA-DRGs claims with procedure code 00.15 would map: and, 2) estimate the impact that the proposed system would have on high-dose IL-2 reimbursement.

In the 2004 MedPAR files, there were 559 Medicare claims with procedure code 00.15. In the proposed CSA-DRG system, 48% of these 559 claims would map to CSA-DRG 736 (Chemotherapy SOI 2) and 28% would map to CSA-DRG 737 (Chemotherapy SOI 3). The proposed weights for these two CSA-DRGs are 0.9771 and 2.5486, respectively. Thus the payment (using the current national standardized amounts) for 00.15 in CSA-DRG 736 would be $8,804 which would be a **58% reduction in payment** when compared to the proposed FY 2007 relative weight for DRG 492 of 3.6663.

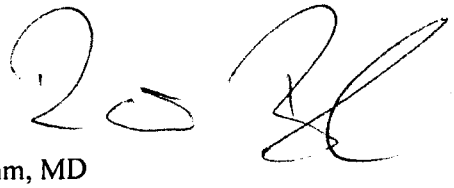
On average, the actual hospital cost of administering high-dose IL-2 is between $20,000 to $25,000 per admission. The base payment rate for DRG 492 in FY2007 is $17,876. An analysis of the actual CMS payment to hospitals billing for 00.15 was approximately $23,000 in 2004 after the base rate was adjusted for hospital-specific factors. A 58% reduction in payments to hospitals administering this therapy would be financially devastating and could lead to the closure of high-dose IL-2 programs, thus denying patients access to this important, life-saving treatment. Under the proposed CSA-DRG system, the "severity of illness" (SOI) is based on the patient's status at admission. In order for a patient to receive high dose IL-2, the patient must have a performance status of 0 to 1 (i.e. ambulatory and in relatively good health). Therefore, it is highly unlikely that a patient admitted for Proleukin would receive an SOI of greater than 2-3. High-dose IL-2 is an intensive medical treatment for cancer and often causes severe side-effects that can be life-threatening. Patients are generally well managed through these side effects, but hospital resources expended are often complex and go far beyond the typical resources used with usual chemotherapy.

Under the current DRG system, high-dose IL-2 therapy (procedure code 00.15) rather than the primary diagnosis code (V58.1) triggers assignment to the DRG. Under the proposed system, the diagnosis at admission triggers DRG assignment , which would not take into account the significant resources required to administer this intensive therapy.

In summary, we urge CMS not to implement the CSA-DRG system as proposed in either 2007 or 2008 given that it does not take into account the situation where a resource intensive treatment such as HD-IL2 is administered to treat an otherwise fatal condition but where the patient's ambulatory status is relatively good. CMS should once again recognize the unique clinical demands and resources involved with administering HD-IL2 and implement an appropriate mechanism to ensure that hospitals are not burdened financially moving forward and that patient access is preserved. Allowing certain procedure codes to map to a DRG with an appropriate reimbursement (as is the current situation with DRG 492 and procedure code 00.15) would be an effective way to ensure hospital receive adequate reimbursement for HD-IL2 therapy.

If you have any questions or require clarification on our concerns, do not hesitate to contact me.

Sincerely,



Rainer Boehm, MD
Sr. Vice President and North American Head
Novartis Oncology

cc: Marc Hartstein
Tom Gustafson
Liz Richter

Submitter : Dr. David Hayes **Date:** 06/07/2006

Organization : Mayo

Category : Physician

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: File Code CMS-1488-P

Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

The purpose of this letter is to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 Federal Register.

HSRV Weights

I agree with the intention of increasing payment accuracy of claims, but disagree strongly with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. The following should be considered for postponing the implementation of the DRG weight changes proposed for FY 2007 until at least FY 2008:

The proposal to move to a hospital specific relative value (HSRV) weighting method will have significant impacts to tertiary hospitals, and more significant impacts to the cardiology departments of these hospitals. CMS should ensure that the new methodology is correct and improves payment accuracy. Several professional associations and analysts have reported errors in the methodology, including the following: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs were included in the calculation of the transplant DRGs. Postponing implementation will allow CMS and stakeholders time to analyze the proposal and revise potential inadequacies in the proposed methodology.

The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented.

In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal.

This proposal has been described as the most significant to the inpatient payment system since DRGs were implemented. These proposed complex changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comments. I further recommend that CMS implement all proposed payment corrections simultaneously.

The impact on CV departments and hospitals are significant. Consider a phase-in of the proposals to limit the negative impact, and provide time to adjust to the new reimbursement environment.

Thank you for the opportunity to comment on this proposed rule and for consideration of my comments. I may be contacted at 507-284-4554.

Submitter : Ms. **Date:** 06/07/2006

Organization : Ms.

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Based on the nurse-patient interaction necessary for patient treatment and improvement, a nursing adjustment to the DRG for payment should be seriously considered.

Submitter : Dr. Deborah Jasovsky **Date:** 06/07/2006

Organization : Raritan Bay Medical Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

support the Medical University of South Carolina proposal to adjust DRG payment by nursing intensity or support the initiative to include direct nursing costs in the payment formula rather than routine/intensive care fixed rates.

Submitter : **Dr. Arshad Jahangir** **Date: 06/07/2006**

Organization : **Mayo Clinic**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: File Code CMS-1488-P Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

The purpose of this letter is to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 Federal Register. HSRV Weights . I agree with the intention of increasing payment accuracy of claims, but disagree strongly with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. The following should be considered for postponing the implementation of the DRG weight changes proposed for FY 2007 until at least FY 2008: The proposal to move to a hospital specific relative value (HSRV) weighting method will have significant impacts to tertiary hospitals, and more significant impacts to the cardiology departments of these hospitals. CMS should ensure that the new methodology is correct and improves payment accuracy. Several professional associations and analysts have reported errors in the methodology, including the following: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs were included in the calculation of the transplant DRGs. Postponing implementation will allow CMS and stakeholders time to analyze the proposal and revise potential inadequacies in the proposed methodology. The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented. In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal. This proposal has been described as the most significant to the inpatient payment system since DRGs were implemented. These proposed complex changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comments. I further recommend that CMS implement all proposed payment corrections simultaneously. The impact on CV departments and hospitals are significant. Consider a phase-in of the proposals to limit the negative impact, and provide time to adjust to the new reimbursement environment. Thank you for the opportunity to comment on this proposed rule and for consideration of my comments. I may be contacted at 507-284-0519.

Arshad Jahangir, MD

Submitter : Dr. Earl Kemp **Date:** 06/07/2006

Organization : Center for Family Medicine

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-203-Attach-1.DOC

CMS-1488-P-203-Attach-2.DOC

#203

DRAFT RESPONSE TO FEDERAL REGISTER NOTICE
DUE JUNE 12TH

VIA [REGULAR MAIL vs OVERNIGHT MAIL vs ELECTRONIC SUBMISSION]

June 7, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

Attention: **CMS-1488—P "Resident Time in Patient-Related Activities"**

Dear Administrator McClellan:

On behalf of the Sioux Falls Family Medicine Residency, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are

an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

Even practicing physicians hold conferences to discuss both individual patient problems and the generic approach to patient care, and these discussions are an ordinary part of patient care. Separation of these components in the graduate medical education setting are arbitrary, artificial and entirely counter productive.

In addition, as director of this program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Earl D. Kemp, M.D., Director
Center for Family Medicine
Sioux Falls Family Medicine Residency
1115 E. 20th St.
Sioux Falls, SD 57105
Ph: (605) 339-1783
Fax: (605) 335-1006

DRAFT RESPONSE TO FEDERAL REGISTER NOTICE
DUE JUNE 12TH

VIA [REGULAR MAIL vs OVERNIGHT MAIL vs ELECTRONIC SUBMISSION]

June 7, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

Attention: **CMS-1488—P "Resident Time in Patient-Related Activities"**

Dear Administrator McClellan:

On behalf of the Sioux Falls Family Medicine Residency, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are

an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care
I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

Even practicing physicians hold conferences to discuss both individual patient problems and the generic approach to patient care, and these discussions are an ordinary part of patient care. Separation of these components in the graduate medical education setting are arbitrary, artificial and entirely counter productive.

In addition, as director of this program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Earl D. Kemp, M.D., Director
Center for Family Medicine
Sioux Falls Family Medicine Residency
1115 E. 20th St.
Sioux Falls, SD 57105
Ph: (605) 339-1783
Fax: (605) 335-1006

Submitter : Dr. Robert Simari **Date:** 06/07/2006

Organization : Mayo Clinic

Category : Physician

Issue Areas/Comments

HSRV Weights

HSRV Weights

Please accept these comments as intended. I fundamentally agree with the intention of increasing payment accuracy of claims. However, I profoundly disagree with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. Please consider the following reasons for postponing the implementation of the DRG weight changes proposed for FY 2007 until at least FY 2008:

The proposal to move to a hospital specific relative value (HSRV) weighting method will have critical impact to tertiary hospitals, and more significant impacts to the cardiology departments of these hospitals. Because of the significant impact to hospitals, CMS should ensure that the new methodology is correct and improves payment accuracy. Several professional associations and analysts have reported errors in the methodology, including the following: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs were included in the calculation of the transplant DRGs. Postponing the implementation will allow CMS and stakeholders adequate time to analyze the proposal and revise any potential inadequacies in the proposed methodology.

The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will actually decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented.

In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that on average, multiple stents are used during procedures. We use on average 1.4- 1.5 stentrs/patient. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal.

The change in proposed calculations of DRG payments are described as the most significant to the inpatient payment system since DRGs were implemented. The significance and complexity of the proposed changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comment period. I further recommend that CMS implement all proposed payment corrections simultaneously.

Finally, the impacts on cardiovascular departments and hospitals are significant. I suggest a phase-in of the proposals to limit the negative impact to hospitals, and provide time to adjust their practice to the new reimbursement environment.

Please contact me for questions.

Sincerely,
Dr Robert Simari 507 284-372
Professor of Medicine
Mayo Clinic College of Medicine

Submitter : **Frank Brozovich** **Date: 06/07/2006**

Organization : **Frank Brozovich**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: File Code CMS-1488-P Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule The purpose of this letter is to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 Federal Register. HSRV Weights While I agree with the intention of increasing payment accuracy of claims, I strongly disagree with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. The following should be considered for postponing the implementation of the DRG weight changes proposed for FY 2007 until at least FY 2008: The proposal to move to a hospital specific relative value (HSRV) weighting method will have significant impact to tertiary care hospitals, and more significant impacts to the cardiology departments of these hospitals. CMS should ensure that the new methodology is correct and improves payment accuracy. Many professional associations and analysts have reported errors in the methodology, including: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs were included in the calculation of the transplant DRGs. Postponing implementation will allow CMS and stakeholders time to analyze the proposal and revise potential inadequacies in the proposed methodology. The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented. In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal. This proposal has been described as the most significant to the inpatient payment system since DRGs were implemented. These proposed complex changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comments. I further recommend that CMS implement all proposed payment corrections simultaneously. The impact on CV departments and hospitals are significant. Consider a phase-in of the proposals to limit the negative impact, and provide time to adjust to the new reimbursement environment. Thank you for the opportunity to comment on this proposed rule and for consideration of my comments. I may be contacted at 507-266-0324.

Submitter : **Dr. Farris Timimi** **Date: 06/07/2006**

Organization : **Mayo Clinic**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

I am writing in regards to File Code CMS-1488-P Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule. My hope is to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 Federal Register, HSRV Weights. While I agree with the intent of increasing payment accuracy of claims, I strongly disagree with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. The following should be considered for postponing the implementation of the DRG weight changes proposed for FY 2007 until at least FY 2008: The proposal to move to a hospital specific relative value (HSRV) weighting method will have a dramatic impact on tertiary hospitals, and more important impact to the Cardiology departments of these hospitals. CMS should ensure that the new methodology is correct and improves payment accuracy. Multiple professional associations and analysts have reported errors in the methodology, including the following: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs being included in the calculation of the transplant DRGs. Postponing implementation will allow CMS and stakeholders time to analyze the proposal and revise potential inadequacies in the proposed methodology. The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. I would note that table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented. In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Importantly, it is well recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to more adequately determine the costs of the DRGs that are most impacted by this proposal. This proposal has been described as the most significant to the inpatient payment system since DRGs were implemented. These proposed complex changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comments. I further recommend that CMS implement all proposed payment corrections simultaneously. The impact on CV departments and hospitals are significant. Consider a phase-in of the proposals to limit the negative impact, and provide time to adjust to the new reimbursement environment. Thank you for the chance to comment on this proposed rule and for consideration of my comments. I may be contacted at 507-284-4554.

Submitter : **Date: 06/07/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: File Code CMS-1488-P Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

The purpose of this letter is to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 Federal Register.

HSRV Weights

Increasing payment accuracy of claims is a good idea, but I disagree with the timing of the implementation of the DRG weight calculation changes that are proposed for the fiscal year of 2007. The proposal to move to a hospital specific relative value (HSRV) weighting method should be delayed by at least another year to allow CMS and stakeholders time to study the proposal in more detail and make necessary changes to the proposal. There are unresolved issues with the proposal including the exclusion of a significant number of hospitals from the analysis. Also, implementing the DRG weight calculation to the HSRV without implementation of corrections to all identified payment inaccuracies will cause payments swings as already pointed out by MedPAC and the American Hospital Association and Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for fiscal year 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction.

Thank you for the opportunity to comment.

Submitter : **Dr. naser ammash** **Date: 06/07/2006**

Organization : **Mayo Clinic**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

June 12, 2006

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

Re: File Code CMS-1488-P

Comments to Proposed Rule 71 FR 23995.

I appreciate the opportunity to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) that were published in the April 25, 2006 Federal Register.

HSRV Weights

I would like you to consider postponing its implementation till 2008 though I agree in principle with the intention of increasing payment accuracy of claims. However, I disagree with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007.

The proposal to move to a hospital specific relative value (HSRV) weighting method will have material impacts to cardiology departments and their affiliated tertiary hospitals. As a result, we should ensure that the new methodology is correct and improves payment accuracy of claims. Many respected analysts have reported errors in the methodology, including the following: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs were included in the calculation of the transplant DRGs. Postponing the implementation will allow CMS and stakeholders adequate time to analyze the proposal and potentially revise any inadequacies in the proposed methodology.

The implementation of the DRG weight calculation to the proposed HSRVs is not right without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will actually decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented, may be by 2008.

In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent whereas frequently in our practice more than one stent is used during certain procedures, but those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal.

Given the significance and complexity of the proposed changes to DRG payments, all stake holders should be given adequate times to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I again respectfully recommend postponing the implementation of the HSRV weighting method, and providing an extended period of time for comment period. In addtion,I suggest a phase-in of the proposals to limit the negative impact to hospitals, and provide time to adjust their practice to the new reimbursement environment.

Thank you for the opportunity to comment on this proposed rule and for consideration of my comments. If you have any questions, please feel free to contact me at the address below .

Sincerely yours,

Naser Ammash MD
Mayo Clinic
200 first street SW
Rochester MN 55905
Phone number: 507-2841644

Submitter : **Dr. Jae Oh** **Date: 06/07/2006**

Organization : **Mayo CLinic**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

June 08, 2006

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

Re: File Code CMS-1488-P

Re: Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

I like to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) that were published in the April 25, 2006 Federal Register.

HSRV Weights

I agree with the intention of increasing payment accuracy of claims. However, I have a concern about the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. I like to give following reasons for postponing the implementation of the DRG weight changes proposed for FY 2007 until at least FY 2008:

The proposal to move to a hospital specific relative value (HSRV) weighting method will have material impacts to tertiary hospitals, and more significant impacts to the cardiology departments of these hospitals. The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will actually decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented.

In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal.

The impacts on cardiovascular departments and hospitals are significant. I suggest a phase-in of the proposals to limit the negative impact to hospitals, and provide time to adjust their practice to the new reimbursement environment.

Thank you for the opportunity to comment on this proposed rule and for consideration of my comments.

Sincerely yours,

Jae K. Oh. MD
Professor of Medicine
Mayo Clinic College of Medicine

bcc: Chris Tholen, Mayo Foundation
Bruce Kelly, Mayo Foundation

Submitter : **Dr. Margaret Redfield** **Date: 06/07/2006**

Organization : **Mayo Clinic**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: File Code CMS-1488-P

I appreciate the opportunity to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) that were published in the April 25, 2006 Federal Register.

HSRV Weights

I disagree with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. Implementation of the DRG weight changes proposed for FY 2007 until at least FY 2008 for the following reasons:

The proposal to move to a hospital specific relative value (HSRV) weighting method will have material impacts to tertiary hospitals, and more significant impacts to the cardiology departments of these hospitals. Because of the significant impact to hospitals, CMS should ensure that the new methodology is correct and improves payment accuracy. Several independent analysts have reported significant errors in the methodology, including the following: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs were included in the calculation of the transplant DRGs. Postponing the implementation will allow CMS and stakeholders adequate time to analyze the proposal and revise any potential inadequacies in the proposed methodology. Lets get it right the first time.

The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will actually decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, postponing the implementation of HSRVs until all proposed changes can be implemented is the only option that makes sense.

In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal.

The change in proposed calculations of DRG payments are described as the most significant to the inpatient payment system since DRGs were implemented. The significance and complexity of the proposed changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comment period. Finally, CMS implement all proposed payment corrections simultaneously.

As the impacts on cardiovascular departments and hospitals are significant, a phase-in of the proposals to limit the negative impact to hospitals, and provide time to adjust their practice to the new reimbursement environment seems judicious.

Respectfully submitted,

Margaret M Redfield, MD
Mayo Clinic
Rochester, MN
507-284-2511

Submitter : Dr. George Carayannopoulos **Date:** 06/07/2006

Organization : Heart Rhythm Consultants of New York

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, who practices at several hospitals located in Long Island, New York, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,
George Carayannopoulos, MD

Submitter : Dr. Janice Nevin **Date:** 06/07/2006

Organization : Christiana Care Health System

Category : Physician

Issue Areas/Comments

GME Payments

GME Payments

As a the Chair of a Family Medicine Department, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician s office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care .

This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care
I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician s educational development into an autonomous practitioner.

In addition, as Chair of the Department that supports a family medicine residency program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS s newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Janice E. Nevin, MD, MPH
Chair, Department of Family and Community Medicine
Christiana Care Health System
Wilmington, Delaware

Submitter : Dr. Anthony Costa **Date:** 06/07/2006

Organization : Northeastern Ohio Universities College of Medicine

Category : Physician

Issue Areas/Comments

GME Payments

GME Payments

As a family medicine department chair, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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In addition, as director of this program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS s newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and, recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Anthony J. Costa, MD
Professor & Chair, Department of Family Medicine
Northeastern Ohio Universities College of Medicine
4209 State Route 44
P.O. Box 95
Rootstown, OH 44272-0095
330-325-6767 (Phone)
330-325-5903 (FAX)

Submitter : **Dr. Thomas Rosenthal** **Date: 06/07/2006**

Organization : **University at Buffalo**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a family medicine residency program director, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

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To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Thomas C. Rosenthal MD

Submitter : Mr. Will Rodgers **Date:** 06/07/2006

Organization : Alton Memorial Hospital

Category : Nurse

Issue Areas/Comments

Rural Community Hospital Demonstration Program

Rural Community Hospital Demonstration Program

The proposed changes in reimbursement for device implants and coronary intervention has the potential to impact smaller rural hospitals such as ours in that we provide this much needed service to our patients in a timely and effective manner, thus preventing them from having to travel another 45-60 minutes across state lines to receive this service. In a life threatening emergency such as an acute myocardial infarction, this time delay can be make the difference between life or death. A reduction as substantial as the CMS proposal indicates, may alter our ability to provide this important service line to our surrounding communities. With the cost of supplies continuing to escalate added to decreasing reimbursements, our ability to provide life saving procedures such as coronary stent placement and implantable defibrillators is seriously jeopardized. Thank you for the opportunity to express our viewpoint, respectfully submitted, W. Rodgers Manager Cardiovascular Services, Alton Memorial Hospital, Alton, Illinois. 62002

Submitter : **Dr. Charles Bruce** **Date: 06/07/2006**

Organization : **Mayo Clinic**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: File Code CMS-1488-P Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule The purpose of this letter is to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 Federal Register. HSRV Weights I agree with the intention of increasing payment accuracy of claims, but disagree strongly with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. Please consider the following for postponing implementation of the DRG weight changes proposed for FY 2007: The proposal to move to a hospital specific relative value (HSRV) weighting method will impact tertiary hospitals severely, felt most by the cardiology departments of these hospitals. CMS should ensure that the new methodology is correct and improves payment accuracy especially since several professional associations and analysts have reported errors in the methodology, including the following: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs were included in the calculation of the transplant DRGs. Postponing implementation will allow CMS and stakeholders time to analyze the proposal and revise potential inadequacies in the proposed methodology. The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented. In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal. This proposal has been described as the most significant to the inpatient payment system since DRGs were implemented. These proposed complex changes require sufficient time for all stakeholders to analyze the rule before implementation, to ensure potential inadequacies of the proposed methodology are identified and corrected. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comments. I further recommend that CMS implement all proposed payment corrections simultaneously. The impact on CV departments and hospitals are significant. Please consider a phase-in of the proposals to limit the negative impact, and provide time to adjust to the new reimbursement environment. Thank you for the opportunity to comment on this proposed rule and for consideration of my comments.

Submitter : **Dr. Mark Belfer** **Date: 06/07/2006**

Organization : **Akron General Medical Center**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a family medicine residency program director, I
appreciate the opportunity to comment on the Centers for Medicare &
Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25,2006). I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities."
The effect of the proposed rule is to exclude medical resident time
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integral nature of these activities to the patient care experiences of residents during their residency programs.
Sincerely,

Mark H. Belfer, DO, FAAFP
Director, Family Medicine Residency Program

Submitter : Dr. Jeff Harrison **Date:** 06/07/2006

Organization : Univeristy of Nebraska Medical Center

Category : Academic

Issue Areas/Comments

GME Payments

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Sincerely,

Jeff Harrison ,MD

Submitter : **Dr. Patrick Tranmer** **Date: 06/07/2006**

Organization : **University of Illinois at Chicago**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a chair of a department of family medicine, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

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Sincerely,

Patrick A. Tranmer MD MPH

Submitter : **Dr. Elliot Davidson** **Date: 06/07/2006**

Organization : **Akron General Center for Family Medicine**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a family medicine residency Medical Director, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled 'Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.' 71 Fed. Reg. 23996 (April 25, 2006). I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in 'patient care activities.' The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. BackgroundThe proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not 'related to patient care'. This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include 'scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty.' [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs. Residency Program Activities and Patient CareI firmly believe that with the possible exception of extended time for 'bench research,' there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner. In addition, as director of this program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined 'patient care time' from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden. To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.
Thank you for your consideration.
Elliot B. Davidson, MD, FAAFP
Medical Director, Center for Family Medicine
Akron General Medical Center

Submitter : Dr. Fletcher Miller, Jr. **Date:** 06/07/2006

Organization : Mayo Clinic

Category : Physician

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: File Code CMS-1488-P Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule The purpose of this letter is to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 Federal Register. HSRV Weights I agree with trying to increase payment accuracy of claims, but I strongly disagree with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. The following should be considered as reasons for postponing the implementation of the proposed DRG weight until at least FY 2008: 1) CMS should ensure that the new methodology is correct and improves payment accuracy. Several professional associations and analysts have reported errors in the methodology, including non-inclusion of several hundred hospitals in the analysis and using unweighted cost to charge ratios rather than weighted cost to charge ratios. In addition, pre-transplant costs were included in the calculation of the transplant DRGs. Postponing implementation will allow CMS and stakeholders time to analyze the proposal and revise potential inadequacies in the proposed methodology. The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. 2) MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented. 3) In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. It is well-recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal.

This proposal has been described as the most significant to the inpatient payment system since DRGs were implemented. These proposed complex changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comments. I further recommend that CMS implement all proposed payment corrections simultaneously. The impact on CV departments and hospitals are significant. Consider a phase-in of the proposals to limit the negative impact, and provide time to adjust to the new reimbursement environment. Thank you for the opportunity to comment on this proposed rule and for consideration of my comments. I may be contacted at 507-284-3682.

Submitter : **Ms. Sima Bennett** **Date: 06/07/2006**

Organization : **UMDNJ- School of Osteopathic Medicine**

Category : **Academic**

Issue Areas/Comments

GME Payments

GME Payments

As a family medicine educational program director, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006). I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care". This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs. Residency Program Activities and Patient CareI firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner. In addition, as director of this program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden. To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency program

Submitter : Dr. Leslie Cooper **Date:** 06/07/2006

Organization : Mayo Clinic

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To whom it may concern: RE File Code CMS-1488-P Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule The purpose of this letter is to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 Federal Register. HSRV Weights I agree with the intention of increasing payment accuracy of claims, but disagree strongly with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. The following should be considered for postponing the implementation of the DRG weight changes proposed for FY 2007 until at least FY 2008: The proposal to move to a hospital specific relative value (HSRV) weighting method will have significant impacts to tertiary hospitals, and more significant impacts to the cardiology departments of these hospitals. Postponing implementation will allow CMS and stakeholders time to analyze the proposal and revise potential inadequacies in the proposed methodology. The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented. In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that on average, multiple stents are used during procedures. Those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal. This proposal has been described as the most significant to the inpatient payment system since DRGs were implemented. These proposed complex changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comments. I further recommend that CMS implement all proposed payment corrections simultaneously. The impact on CV departments and hospitals are significant. Consider a phase-in of the proposals to limit the negative impact, and provide time to adjust to the new reimbursement environment. Thank you for the opportunity to comment on this proposed rule and for consideration of my comments. I may be contacted at 507-284-3660. Leslie Cooper

Submitter : **Date: 06/07/2006**

Organization :

Category : **Private Industry**

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

test

Submitter : Dr. Stephen Hammill **Date:** 06/07/2006

Organization : Mayo Clinic

Category : Physician

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: File Code CMS-1488-P Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule The purpose of this letter is to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 Federal Register. HSRV Weights I agree with the intention of increasing payment accuracy of claims, but disagree strongly with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. The following should be considered for postponing the implementation of the DRG weight changes proposed for FY 2007 until at least FY 2008: The proposal to move to a hospital specific relative value (HSRV) weighting method will have a significant impact on the Mayo Clinic-St Marys Hospital. CMS should ensure that the new methodology is correct and improves payment accuracy. Several professional associations and analysts have reported errors in the methodology, including the following: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs were included in the calculation of the transplant DRGs. Postponing implementation will allow CMS and stakeholders time to analyze the proposal and revise potential inadequacies in the proposed methodology. The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented. In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal. This proposal has been described as the most significant to the inpatient payment system since DRGs were implemented. These proposed complex changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comments. I further recommend that CMS implement all proposed payment corrections simultaneously. The impact on our CV department and hospitals at Mayo are significant. Consider a phase-in of the proposals to limit the negative impact, and provide time to adjust to the new reimbursement environment. Thank you for the opportunity to comment on this proposed rule and for consideration of my comments. I may be contacted at 507-284-4888.

Submitter : Dr. Sharon Dawso **Date:** 06/07/2006

Organization : Forum Health WRCS Family Practice Residency

Category : Physician

Issue Areas/Comments

GME Payments

GME Payments

As a Family Medicine Residency Associate Director, I
appreciate the opportunity to comment on the Centers for Medicare &
Medicaid Services' (CMS or the Agency) proposed rule entitled 'Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.' 71 Fed. Reg. 23996 (April 25, 2006). I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in 'patient care activities.'
Time spent in didactic activities directly improves patient care, by increasing the knowledge of the physicians providing care, and is an essential component in medical education.

Submitter : **Date: 06/07/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

As a chair of a department of family medicine, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician s office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care .

This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care
I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician s educational development into an autonomous practitioner.

In addition, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS s newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Michael L. Coates, M.D., M.S.
Professor and Chair
Family & Community Medicine
Wake Forest University Health Sciences
Winston-Salem, NC 27157

Submitter : Dr. Hon-Chi Lee **Date:** 06/07/2006

Organization : Mayo Clinic

Category : Physician

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: File Code CMS-1488-P

Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

Thank you for the opportunity to comment on the proposed changes to the Inpatient Prospective Payment System (IPPS) that were published in the April 25, 2006 Federal Register.

HSRV Weights

It is important to increase payment accuracy of claims, but I do not agree with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. The following reasons should be considered for postponing the implementation of the DRG weight changes proposed for FY 2007 until at least FY 2008 or later:

The proposal to move to a hospital specific relative value (HSRV) weighting method will have material impacts to tertiary hospitals, especially their cardiology departments. CMS should therefore ensure that the new methodology is correct and improves payment accuracy. Some professional associations and analysts have reported errors in the methodology, including: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs were included in the calculation of the transplant DRGs. Implementation should be postponed to allow CMS and stakeholders adequate time to analyze the proposal and revise any potential inadequacies in the proposed methodology.

The DRG weight calculation to the proposed HSRVs should not be implemented until implementation of corrections to all identified payment inaccuracies has occurred. MedPAC, the Otherwise, implementation of only HSRVs will actually decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented.

This proposal has been described as the most significant to the inpatient payment system since DRGs were implemented and this deserves adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comment period. I further recommend that CMS implement all proposed payment corrections simultaneously.

Finally, the impacts on cardiovascular departments and hospitals are tremendous. I suggest a phase-in of the proposals to limit the negative impact to hospitals, and provide time to adjust their practice to the new reimbursement environment.

Thank you for the opportunity to comment on this proposed rule. I may be contacted at 507-255-8353.

Submitter : **Dr. Joshua Freeman** **Date: 06/07/2006**

Organization : **Dept. of Family Medicine, University of Kansas SOM**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As Chair of the Department of Family Medicine at the University of Kansas School of Medicine I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in 'patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician s office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care .

This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care
I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician s educational development into an autonomous practitioner.

In addition, as Chair of this department, responsible though our program director for the residency program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS s newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Joshua Freeman, MD
Chair, Dept of Family Medicine, KUMC
jfreeman3@kumc.edu

Submitter : Mr. Greg Jerger **Date:** 06/07/2006

Organization : Memorial Health Care Systems

Category : Critical Access Hospital

Issue Areas/Comments

CAHs

CAHs

Last year's FY06 final inpatient rule stated that CAHs that were reclassified to an urban core based statistical area did not need to get a rural reclassification to maintain their CAH status. In other words, these facilities could keep their rural status for CAH payment purposes. CAHs in these areas, however, are currently being denied the opportunity to apply for CRNA pass through payments, even if they meet the criteria of having less than 800 surgeries. Our facility actually applied for and received a rural reclassification prior to the FY06 final rule telling us that this was not needed. Even the rural reclassification apparently doesn't qualify for rural status. The reason being given by the intermediaries is that the rural CAH status granted by the inpatient final rule and/or rural reclassification (under 1886(d)(8)(E)) does not mean rural for CRNA pass through payment. I believe it to be only logical that the rural status grandfathered to the CAH facilities in the FY06 final rule, and rural reclassification under 1886(d)(8)(E), both qualify as rural status for CRNA pass through payment as well. I believe this only effects a very few hospitals. The dollar amounts involved here are extremely small to the Medicare program, but it is very important to the ones that were hit by this interpretation. I believe that CMS should clarify in this regulation that the rural status grandfathered to CAHs, and the rural reclassifications, do qualify as rural status for CRNA pass through payments.

Submitter : **Dr. Verghese Mathew** **Date: 06/07/2006**

Organization : **Mayo Clinic**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Thank you for the opportunity to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) that were published in the April 25, 2006 Federal Register.

HSRV Weights

I agree with the intention of increasing payment accuracy of claims. However, I disagree with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. Please consider the following reasons for postponing the implementation of the DRG weight changes proposed for FY 2007 until at least FY 2008:

Moving to a hospital specific relative value (HSRV) weighting method will have significant impact to tertiary hospitals, and more substantial impact to the cardiology departments of these hospitals. Because of the significant impact to hospitals, CMS should ensure that the new methodology is correct and improves payment accuracy. Several professional associations and analysts have reported errors in the methodology. Postponing the implementation will allow CMS and stakeholders adequate time to (re)analyze the proposal and revise any potential inadequacies in the proposed methodology.

The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. The American Hospital Association and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will actually decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction.

In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that frequently, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal.

The proposed change in calculations of DRG payments are described as the most significant to the inpatient payment system since DRGs were implemented. The significance and complexity of the proposed changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comment period. I further recommend that CMS implement all proposed payment corrections simultaneously.

Finally, the impacts on cardiovascular departments and hospitals are significant. I suggest a phase-in of the proposals to limit the negative impact to hospitals, and provide time to adjust their practice to the new reimbursement environment.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,

Verghese Mathew, MD

Submitter : Dr. Eric Skye **Date:** 06/07/2006

Organization : University of Michigan

Category : Physician

Issue Areas/Comments

Impact Analysis

Impact Analysis

As a family medicine residency program director, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare
Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25,2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities."

The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. BackgroundThe proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care". This position reverses the Agency's position expressed as recently as 1999,at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

I firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner. In addition, as director of this program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Submitter : **Mr. Rick Fernandez** **Date: 06/07/2006**

Organization : **Asante Health System**

Category : **Hospital**

Issue Areas/Comments

HSRV Weights

HSRV Weights

Please see attached Microsoft Word file.

CMS-1488-P-233-Attach-1.DOC

June 6, 2006

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore MD, 21244-1850

Via Email: http://www.cms.hhs.gov/eRulemaking
CMS-1488-P

Dear Administrator,

Asante owns and operates two acute care hospitals in Southern Oregon. We are dramatically impacted by the proposed changes to the Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year 2007 (FFY07). Please give due consideration to our comments and concerns as expressed below.

HSRVcc Weights

1. The system proposed by CMS is seriously flawed in that it does not account accurately for DRG's that require expensive implantable devices. These devices include implantable defibrillators, pacemakers, heart valves, stents, hips and knees. The proposed DRG recalibration fails to recognize the high cost of these devices and consequently under-reimburses for DRG's 515, 544, 557, 558 and others.

For example, under the proposed payment rates, our hospital would be reimbursed $25,048 for DRG 515 (Cardiac Defibrillator Implant W/O Cardiac Cath). But the average cost of a defibrillator alone is about $26,000. This means that DRG 515 not only under-reimburses for the device itself, it also reimburses nothing at all for routine days, intensive care days, operating room services, supplies, drugs, laboratory, cardiology or any other medical service provided to the patient. Under the proposed recalibration, all of these unreimbursed costs would be shifted over to other DRG's and therefore to other hospitals that do not provide these services.

This problem is clearly the result of a flawed recalibration method that applies an average cost-to-charge ratio of 33.4% to the charge for the implantable device (i.e. Step 4 of 6 in the HSRVcc method), then applies the resulting scaling factor of 11.5% to the charge relative weights (i.e. Step 5 of 6 in the HSRVcc method). In reality, implantable devices and other

supplies accounts for a much higher percentage of the charges and costs for these cases than 11.5 percent. For example, in the case of our hospital, for DRG 515, the implantable device accounts for an average 56% of total charges and an even higher percentage of cost due to its having a lower markup than other services. The problem is that using global scaling factors hides the true variation in cost among DRG's.

In the proposed rule, CMS states that it is trying to find "an administratively feasible approach to improving the accuracy of the DRG weights" (FR 71, Page 24006). The HSRVcc method may be administratively feasible, but it is certainly not more accurate than the current system, and it penalizes hospitals that provide more intense services. The recalibration system must do a better job of accounting for variation in cost among DRG's.

2. The inappropriate shift in payments away from hospitals with cardiac and joint-replacement programs will result in an overall increase in expenditures for hospital care nationwide. The reason is that these hospitals, in response to multi-million-dollar decreases in reimbursement for cardiac and joint-replacement services, will be forced to shift these losses to other payors in their markets. Large hospitals will be forced to seek higher rates from insurance payors, while smaller hospitals will have no incentive whatever to reduce their contracted rates upon receiving higher payments from Medicare. The result will be an overall increase in national expenditures for hospital care.

3. The 10 cost center charge groups are incomplete and inaccurate for two reasons. First, they do not account for any subscripted line numbers in the Medicare cost report. A subscripted line is one that is inserted into the cost report among the other existing cost centers to define a new cost center. These line numbers are identified by the presence of a decimal point and two digits to the right of the decimal point. For example, at our facility, Line 59.04 identifies MRI services and Line 59.03 indicates Cardiac Cath Lab services. The problem with the CMS proposal is that it disregards all subscripted lines which, at our facility, accounts for a full 8% of the hospital's cost.

The second problem is that the cost-report line numbers listed in Table A (FR 71, pages 24009 to 24010) do not necessarily apply to all hospital cost reports uniformly. For example, Table A defines Line 42 as "MRI Serivces", but at our facility, Line 42 is for Radiation Therapy services. MRI services are found on Line 59.04 on our cost report and, as stated above, are entirely excluded from the calculation of the national cost center CCR's (i.e. Step 3 of 6 in the HSRVcc method). This example applies only to our hospital. Other hospitals will have their own unique exceptions, none of which are addressed in the proposed rule.

For these reasons, I recommend that the transition to cost-based DRG weights be postponed for one year. This would allow sufficient time for CMS to devise a recalibration system that more accurately distributes cost among DRG's.

In its discussion about the MedPAC recommendations (FR 71, page 24006), CMS states that the proposed recalibration would "potentially reduce the incentives that Medicare payments may provide for the further development of specialty hospitals". The proposed rule would likely accomplish this goal, but ironically, it does so because of payment *inaccuracies*, not because of more accurate payments. Therefore, if CMS desires to adjust payments that would target specialty hospitals particularly, I recommend that it devised a separate rate schedule for specialty hospitals – one that takes into account their very limited mix of cases and their resulting increased efficiency and lower cost.

Thank you very much for considering my comments.

Sincerely,

Rick Fernandez
Reimbursement Manager
Asante Health System
100 East Main Street, Suite A
Medford, Oregon 97501

ASANTE® HEALTH SYSTEM

Submitter : Dr. Peter Spittell **Date:** 06/07/2006

Organization : Mayo

Category : Physician

Issue Areas/Comments

HSRV Weights

HSRV Weights

Re: File Code CMS-1488-P Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule The purpose of this letter is to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 Federal Register. HSRV Weights I agree with the intention of increasing payment accuracy of claims, but disagree strongly with the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. The following should be considered for postponing the implementation of the DRG weight changes proposed for FY 2007 until at least FY 2008: The proposal to move to a hospital specific relative value (HSRV) weighting method will have significant impacts to tertiary hospitals, and more significant impacts to the cardiology departments of these hospitals. CMS should ensure that the new methodology is correct and improves payment accuracy. Several professional associations and analysts have reported errors in the methodology, including the following: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs were included in the calculation of the transplant DRGs. Postponing implementation will allow CMS and stakeholders time to analyze the proposal and revise potential inadequacies in the proposed methodology. The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, I respectfully request postponing the implementation of HSRVs until all proposed changes can be implemented. In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal. This proposal has been described as the most significant to the inpatient payment system since DRGs were implemented. These proposed complex changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comments. I further recommend that CMS implement all proposed payment corrections simultaneously. The impact on CV departments and hospitals are significant. Consider a phase-in of the proposals to limit the negative impact, and provide time to adjust to the new reimbursement environment. Thank you for the opportunity to comment on this proposed rule and for consideration of my comments. I may be contacted at 507-284-1644.

Submitter : **Dr. Allan S Jaffe** **Date: 06/07/2006**

Organization : **Mayo Clinic**

Category : **Physician**

Issue Areas/Comments

HSRV Weights

HSRV Weights

June 12, 2006

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

Re: File Code CMS-1488-P

Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

I appreciate the opportunity to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) that were published in the April 25, 2006 Federal Register.

HSRV Weights

I think we all agree with the goal of increasing the accuracy of claims for payment. However, there are substantial issues that are require clarification. Since these change will have material impacts to tertiary hospitals, and more significant impacts to the cardiology departments of these hospitals, it is essential to get it right. To ensure that, I hope you will consider postponing these changes until at least FY 2008.

Several professional associations and analysts have reported errors in the methodology, including the following: non-inclusion of several hundred hospitals in the analysis, using unweighted cost to charge ratios rather than weighted cost to charge ratios, and pre-transplant costs were included in the calculation of the transplant DRGs. These issues require adjudication prior to implementation of any new rules.

The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies. MedPAC, the American Hospital Association, and others have all suggested implementing all proposed changes simultaneously to avoid payment swings. Implementation of only HSRVs will actually decrease the overall payment accuracy of the DRG system at a facility level for most hospitals. Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. This is another reason to postpone these changes until 2008.

In the FY 2006 final rule, CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs reflect charges for only one stent. Practically, it is recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process.
The change in proposed calculations of DRG payments are described as the most significant to the inpatient payment system since DRGs were implemented. The significance and complexity of the proposed changes require adequate time for all stakeholders to analyze the rule, and ensure potential inadequacies of the proposed methodology are corrected before implementation. I recommend postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comment period. I further recommend that CMS implement all proposed payment corrections simultaneously.

Finally, the impacts on cardiovascular departments and hospitals are significant. I suggest a phase-in of the proposals to limit the negative impact to hospitals, and provide time to adjust their practice to the new reimbursement environment.

Thank you for the opportunity to comment on this proposed rule and for consideration of my comments. If you have any questions, please contact me at

Very truly yours,

Allan S. Jaffe, M.D.
Mayo Clinic
Rochester, Minnesota 55905

Submitter :

Date: 06/07/2006

Organization :

Category : Physician

Issue Areas/Comments

HSRV Weights

HSRV Weights

I agree with the intention of increasing payment accuracy of claims, but have deep reservations regarding the timing of the implementation of the DRG weight calculation changes that are proposed for FY 2007. The proposal to move to a hospital specific relative value (HSRV) weighting method will have important impact tertiary hospitals, and in particular to the cardiology departments of these hospitals. CMS should ensure that the new methodology is correct and improves payment accuracy. Several professional associations and analysts have reported errors in the methodology, including the following: non-inclusion of several hundred hospitals in the analysis, use of unweighted cost to charge ratios rather than weighted cost to charge ratios, and inclusion of pre-transplant costs in the calculation of transplant DRGs. Postponing implementation will allow CMS and stakeholders time to analyze the proposal and revise potential inadequacies in the proposed methodology. The implementation of the DRG weight calculation to the proposed HSRVs is inappropriate without implementation of corrections to all identified payment inaccuracies.

Table K of the Proposed Rule (72 FR 24024) reports that implementation of only the HSRVs for FY 2007 will result in larger payment inaccuracies across hospitals than not implementing the correction. Since the implementation of the consolidated severity adjusted DRGs is not possible by the beginning of FY 2007, it would seem to make more sense to postpone the implementation of HSRVs until all proposed changes can be implemented. Additionally, the proposed complex changes require adequate time for all stakeholders to analyze the rule. I would urge postponing the implementation of the HSRV weighting method, proposing the changes in a separate Federal Register issuance, and providing an extended period of time for comments. I further recommend that CMS implement all proposed payment corrections simultaneously. The impact on CV departments and hospitals are significant. Consider a phase-in of the proposals to limit the negative impact, and provide time to adjust to the new reimbursement environment. Thank you for the opportunity to comment on this proposed rule and for consideration of my comments. I may be contacted at 507-255-2446.

Submitter : Dr. James Arbogast **Date:** 06/07/2006

Organization : West Virginia University Department of Family Medi

Category : Academic

Issue Areas/Comments

GME Payments

GME Payments

As a chair of a department of family medicine, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician s office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care .

This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care
I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician s educational development into an autonomous practitioner.

In addition, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS s newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

James G. Arbogast, MD
Professor and Chair

Submitter : Dr. Helen McIlvain **Date:** 06/07/2006

Organization : University of Nebraska Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

GME Payments

GME Payments

As a faculty in a department of family medicine, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
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This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

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To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Helen E. McIlvain, PhD
Professor and Director of Research
Dept. of Family Medicine
University of Nebraska Medical Center
Omaha, NE.

Submitter : Catherine Sinning **Date:** 06/07/2006

Organization : Spectrum Health Hospitals

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

see attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
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 : Dr. George Kikano **Date:** 06/07/2006

Organization : Dr. George Kikano

Category : Academic

Issue Areas/Comments

GME Payments

GME Payments

As a chair of a department of family medicine, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician s office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care .

This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care
I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician s educational development into an autonomous practitioner.

In addition, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS s newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

George Kikano, MD, FAAFP, CPE
Professor and Chair
Department of Family Medicine
CWRU/UHC

Submitter : **Dr. Jeff Susman** **Date: 06/07/2006**

Organization : **Dr. Jeff Susman**

Category : **Individual**

Issue Areas/Comments

GME Payments

GME Payments

As a chair of the Department of Family Medicine at the University of Cincinnati, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician s office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care .

This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care
I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician s educational development into an autonomous practitioner.

In addition, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS s newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

In sum, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Jeff Susman, MD
Chair, Family Medicine
University of Cincinnati

Submitter : Dr. **Date: 06/07/2006**

Organization : Dr.

Category : Physician

Issue Areas/Comments

GME Payments

GME Payments

As a faculty member in a family medicine residency, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physicians office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care.

This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physicians educational development into an autonomous practitioner.

In addition, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS s newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Nipa Shah, MD
312-413-7349

Submitter : **Dr. Daniel Lasser** **Date: 06/07/2006**

Organization : **University of Massachusetts Medical School**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As Chair of the Family Medicine Department at the University of Massachusetts Medical School, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician s office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care .

This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care
I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician s educational development into an autonomous practitioner.

In addition, as a Department Chair, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS s newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Daniel Lasser, MD, MPH

Submitter : **Dr. Anne Sullivan** **Date: 06/07/2006**

Organization : **University of Iowa dept. of Family Medicine**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As an associate director of a Family Medicine residency program, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician s office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care .

This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

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In addition, as associate director of this program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS s newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Anne Sullivan, MD
Associate Residency Director
University of Iowa Department of Family Medicine

Submitter : Dr. Robert Chasuk **Date:** 06/07/2006

Organization : Family Med Residency Program Baton Rouge General

Category : Academic

Issue Areas/Comments

GME Payments

GME Payments

As a family medicine residency program director, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006). I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. BackgroundThe proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care". This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency
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programs.

Submitter : **Dr. Lois Margaret Nora** **Date: 06/07/2006**

Organization : **Northeastern Ohio Universities College of Medicine**

Category : **Academic**

Issue Areas/Comments

GME Payments

GME Payments

Dear Administrator McClellan:

The Northeastern Ohio Universities College of Medicine welcomes this opportunity to comment on the Center for Medicare & Medicaid Services' (CMS) proposed rule entitled "Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates," 71 Fed. Reg. 23996 (April 25, 2006). We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background:
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting, and for DGME payments when activities occur in a nonhospital setting, such as a physican's office of affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position is in stark contract to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures...and presentation of papers and research results to fellow residents, medical students, and faculty." (September 24, 1999, letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins.) We concur with the Agency's 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

While journal clubs, classroom lectures and seminars are not "direct" patient care, they are invaluable to doctors in training to be able to deliver appropriate patient care. These young physicians need the advice and experience of seasoned clinicians to become outstanding physicians themselves. Teaching at the bedside often moves to the classroom for further explanation. It does not seem logical to "count" bedside teaching and not classroom lectures.

To reiterate, we urge CME to rescind its clarification in the proposed rule relating to counting didactic time for the purposes of DGME and IME payments and to recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Lois Margaret Nora, M.D.
President, College of Medicine

and

Jay C. Williamson, M.D.
Associate Dean for Clinical Sciences

Submitter : Dr. Jerry Kruse **Date:** 06/07/2006

Organization : Southern Illinois University School of Medicine

Category : Physician

Issue Areas/Comments

GME Payments

GME Payments

As chair of the Southern Illinois Univeristy Department of Family & Community Medicine, and an educator who oversees four family medicine residency programs, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006).

I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician s office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care .

This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care
I firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician s educational development into an autonomous practitioner.

In addition, as director of this program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS s newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Jerry Kruse
Professor & Chair
Dept of Family & Community Medicine
Southern Illinois University School of Medicine

Submitter : **Mr. Les Donahue** **Date: 06/07/2006**

Organization : **Saint Thomas Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1488-P-248-Attach-1.PDF

Saint Thomas Hospital
A Member of Saint Thomas Health Services

Date May 22, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Saint Thomas Hospital is a 541-bed, acute care, faith-based, not-for-profit facility located in Nashville, Tennessee. Since its inception in 1898, Saint Thomas has evolved into a tertiary referral center for many especially complex procedures including cardiac services. As a nationally recognized center for superior cardiac care, we implant devices, provide access to new technologies and treatments, including heart transplants, and receive clinically complex referrals from the surrounding region for hundreds of miles. Our hospital provides care for approximately 12,500 traditional Medicare inpatient admissions per year and an additional 1,200 Medicare Advantage cases annually. The services provided at Saint Thomas are not cardiac alone and range throughout a variety of areas in adult medicine and surgery, including orthopedics, neurosciences, emergency medicine, pulmonary medicine, oncology and hematology to name only a few. Unfortunately, as a result of developing our particular expertise in the area of cardiac services, our hospital stands to lose $13.6 million in Medicare reimbursement, if the proposed prospective payment rule is adopted as drafted. A loss of $13.6 million dollars will significantly hurt our hospital's ability to support ongoing significant investments in technology and clinical expertise and will put at risk the excellent programs our organization has developed. Thus, in response to your request for comments on the Proposed IPPS for fiscal 2007, I am writing to express my utmost concern regarding the published recommendations to change the way Medicare pays for inpatient services.

In particular, I have the following concerns about the proposed changes:

1. **First, it adopts a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver complex cardiology and neuroscience services.**

   The intent appears to be to target 'Specialty Hospitals', yet all hospitals with significant cardiology, orthopedic joint replacement and/or neurosurgery services will suffer major reductions in payment for such services regardless of whether they fit this definition. Supposed offsetting increases to selected DRGs intended to neutralize the overall impact to hospitals do not appear proportionate to the decreases, when one considers the impact of removing low Medicare volume DRGs such as pediatrics and

obstetrics; rare and specialized DRGs such as transplants, behavioral health and burn categories and eliminates cases rarely done in an inpatient setting from the calculation.

The proposed rule instead appears to target high volume, high dollar implant cases particularly in the areas of neurosurgery and cardiology for reductions of 25% -36%. This compares to only modest increases for the most prevalent medicine DRGs in these same service categories such as CHF (DRG 127- 2.9% increase in relative weight) or Stroke (DRG 14- 0.2% increase in relative weight). The intent may have been to eliminate reimbursement incentives for specialty hospitals to steer the most profitable cases to themselves, but the result appears to be punitive to all hospitals serving the most prevalent diagnoses within the Medicare population.

2. **Second, it adopts "cost-based" DRG weighting in place of the current charge based system without accounting for tiered mark-ups on high dollar supplies and inconsistent mapping of supplies to cost report lines among providers.**

It is common industry practice to have higher cost line items charged at a lower mark-up than relatively lower cost items. The methodology for instituting the proposed 'cost basis' however, does not account for the fact that the supply mark-up cost to charge ratio that is calculated from the data is the result of an average of all supplies, not just the specific supplies used in the services that are being isolated for payment recalculation. The result materially underestimates the true cost of any DRG with a disproportionate amount of total charges represented by supply items that are marked up at a rate less than the average mark-up (thus having a higher than average cost to charge ratio). This misapplication of the supply ratio inappropriately reduces payments for cardiology procedures featuring high cost device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. (DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.)

If CMS is determined to pursue this methodology it is a reasonable expectation on the providers' part that an indication of the change in method be given in sufficient time prior to execution for providers to take steps to improve the accuracy of the source information being used. Mandating a common mark-up on all supplies to ensure the validity of the ratio derived or setting aside a specific cost report line for such targeted supplies are options available for gathering this data on a go-forward basis.

It is not intuitive that any hospital would mark-up a $25,000 implant at the same rate it would a $250 implant, in this charge conscious industry. If it is CMS's desire that providers <u>should</u> <u>do so</u> in order to ascertain a more accurate ratio calculation, then such expectations should be made clear and the public prepared for the consequences

in the form of exponentially higher charge totals for procedures that entail use of high cost implants and devices.

Alternatively, if there are high dollar implants that CMS wishes to segregate without mandating pricing, then unique revenue codes should be set aside for just such line items with specific cost report mapping required consistently among all providers. The proposed rule's methodology instead takes revenue codes that represent a wide variety of supplies, supply mark-ups and services and then makes assumptions about the mapping of their cost and charges without accounting for the disparity among providers' cost reports. Subscripted cost report lines specific to cardiology services that were omitted as part of CMS's initial analysis are evidence of the pitfalls of using this data source in the absence of clear guidelines provided **in advance** for how and where data is expected to be recorded.

3. **With regard to the severity adjustment proposed for next year (FY08), severity does not include the technology costs paid by hospitals for more complex cases.**

   The proposed APR-DRG system only acknowledges complications of the case and co-morbidities of the patient. Tools for abstracting complexity and the presence of new technologies however are severely hampered by the current ICD-9 codes available. Emerging and expensive technologies that are intended to extend the mobility and health of a patient who does not fall into a high-risk APR-DRG stratification would not be accounted for in the proposed reimbursement methodology, thus limiting access to these technologies to Medicare beneficiaries in the long run.

   The payment methodology changes that CMS has proposed would have a severe financial impact on our hospital – without accurate data to justify the change. This is particularly true for device intensive cardiology DRGs where the proposed payment level is often significantly less than my hospital's actual cost to deliver these services. The reduction in payment for cardiology services would also have a severe impact on the infrastructure we have built up over the years to treat the number one killer in America today - heart disease.

Saint Thomas Hospital is not a specialty hospital. This hospital has no private investors or physician owners. There is no opportunity for our hospital to steer either away or towards a selected population of patients other than by offering high quality services with compassion and expertise. The inpatient reimbursement changes proposed will make our facility the unintended victim of the otherwise laudable goals of improving payment methods and reducing the steerage of unprofitable referrals.

We respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the validity and equity of the proposed payments. If Specialty Hospitals

with physician ownership are to be targeted, then we also request that special attention in the final analysis be given to non-specialty hospitals harmed by targeted reductions to ensure equity in the redistribution of payment among other services. Additionally, severity adjusted DRGs should not be implemented until the technology costs incurred by hospitals can be appropriately reflected in the DRG payments.

Thank you for your consideration.

Sincerely,

Les Donahue
President and CEO
Saint Thomas Hospital

c. AHA: dlloyd@aha.org (Danielle Lloyd)

c. Bill Frist
509 HART SENATE OFFICE BUILDING
WASHINGTON DC 20510
(202) 224-3344
http://frist.senate.gov/index.cfm?FuseAction=AboutSenatorFrist.ContactFo

c. The Honorable Lamar Alexander
Office of Senator Lamar Alexander
SH-302
Washington, DC 20510

c. The Honorable Jim Cooper
1536 Longworth House Office Building
Washington, DC 20515
fax (202) 226-1035

c. The Honorable Bart Gordon
2304 Rayburn House Office Building
Washington, DC 20515
fax (202) 225-6887

Submitter : Dr. Sallie Rixey **Date:** 06/07/2006

Organization : Franklin Square Hospital Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

As a family medicine residency program director, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006). I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. BackgroundThe proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care". This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs. Residency Program Activities and Patient CareI firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner. In addition, as director of this program, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden. To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,
Sallie Rixey MD, MEd

Submitter : Dr. Gary Goforth **Date:** 06/07/2006

Organization : Self Regional Healthcare Family Medicine Residency

Category : Physician

Issue Areas/Comments

GME Payments

GME Payments

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