Submitter : **Mr. Harold Anderson** **Date: 06/12/2006**

Organization : **Moses Taylor Hospital**

Category : **Hospital**

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

Dear Mr. McClellan:

Oh behalf of Moses Taylor Hospital, we support the proposed rule's provisions.

We support moving to a DRG-weighting methodology based on hospital costs rather than charges (HSRVcc and CS-DRG methodology). We feel this is fair and equitable to hospitals.

We support the proposed implementation of moving to a HSRVcc weighting methodology for FFY 2006-2007.

We support moving to a CS-DRG methodology in FFY 2007-2008. The proposed implementation schedule is fair to hospitals and the Medicare Program, delays and/or other phased-in approaches create a hardship for hospitals and the Medicare Program having to run multiple DRG-based reimbursement processes.

Moses Taylor Hospital appreciates the opportunity to submit these comments.

HSRV Weights

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Moses Taylor Hospital appreciates the opportunity to submit these comments.

CMS-1488-P-1701-Attach-1.DOC

#1701

Moses Taylor Hospital

700 Quincy Avenue, Scranton, PA 18510-1798
(570) 340-2100

June 9, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Mr. McClellan:

Oh behalf of Moses Taylor Hospital, we support the proposed rule's provisions.

- We support moving to a DRG-weighting methodology based on hospital costs rather than charges (HSRVcc and CS-DRG methodology). We feel this is fair and equitable to hospitals.
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Moses Taylor Hospital appreciates the opportunity to submit these comments.

Sincerely,

Harold E. Anderson,
President & CEO

Submitter : **Paul Sahney** **Date: 06/12/2006**

Organization : **Trinity Health**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1488-P-1702-Attach-1.DOC

#1702

June 12, 2006

Honorable Mark B. McClellan, MD, PhD
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, DC 20201

REF: CMS-1488-P

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

Dear Dr. McClellan:

On behalf of our 28 acute care hospitals operating in Maryland, Ohio, Michigan, Iowa, Indiana, Idaho and California, Trinity Health appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding 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 notice.

The rule proposes the most significant changes in the calculation of diagnosis-related group (DRG) relative weights since 1983 by creating a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc). It also proposes refining the DRGs to account for patient severity, with implementation likely in FY 2008. In addition, the rule would update the payment rates, outlier threshold, quality reporting requirements, and payments for rural hospitals and medical education, among other policies.

We believe in the goal of refining the system to create an equal opportunity for return across DRGs, which will provide an equal incentive to treat all types of patients and conditions. We are concerned about the potential unintended consequences and implications of such unproven and essentially untested payment changes on our hospitals and health system. For these reasons, more time is needed to understand the significant proposed policy changes, which redistribute from $1.4 to $1.7 billion within the inpatient system.

In summary, Trinity Health recommends the following:

- **We support moving to a DRG-weighting methodology based upon hospital costs rather than charges. However, we believe that at least one year is needed to determine the most appropriate way to create cost-based weights.**

- **We also caution CMS to carefully evaluate the proposal to refine DRGs based on severity of illness.** We believe that more work understanding the

variation within DRGs and the best classification system to address the variation is still needed before CS-DRGs or any other system should be selected or advanced.

- **We recommend adoption of any changes to weights and classifications (if deemed appropriate) be implemented simultaneously after both pieces are properly analyzed.** This approach should help to insure that redistribution of hospital payments is not unduly disruptive to selected individual hospitals.

- **Finally, we recommend that CMS provide at least a three-year transition period of the proposed policies during which hospitals are protected from major payment disruptions.**

Below we have included expanded thoughts and rationale to explain our recommendations and concerns on the proposed DRG weight and classification system changes. In addition, we provide comments on some of the other sections of the proposed rule.

DRG RECLASSIFICATIONS

New DRG Weights – HSRVcc

We support the move to cost-based weights but respectfully submit that the proposed rule contained methodological inconsistencies and data errors that were determined to have an impact on DRG weights. We recommend that CMS construct a process to test the sensitivity of weights using various methodological assumptions and publicly share the results. These analyses will help determine the most effective and administratively feasible approach for a move to cost-based weights in FY2008. We are willing to work with CMS in a process to develop consensus around the right way to make this change.

New Patient Classification – Severity of Illness

We believe that more careful analysis is needed on the proposal to change the patient classification system. While this proposed change was based upon a Medicare Payment Assessment Commission (MedPAC) recommendation, CMS does 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).

The current DRG system was created to distinguish the resource use required among patient populations. It has been modified over time to reflect changes in clinical practice and technology. APR-DRGs (recommended by MedPAC) is based on severity of illness, not necessarily the resource required to treat the patient. The impact of a move to CS-DRGs (an APR-DRG hybrid) is unclear. In addition, revising the DRGs to recognize severity of illness will have implications to the outlier threshold, the indirect medical education (IME) and the disproportionate share hospital (DSH) adjustments. We would recommend that the consequences of moving to a severity-based system from a resource-based system be fully explored and validated.

Timing and Transition

We are concerned about the potential unintended consequences and implications of such unproven and essentially untested payment changes on our hospitals and health systems. 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 recommendation for postponement also reflects our concerns regarding the need for an appropriate lead time to modify hospitals' coding systems. Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.

Need to Address Inappropriate Incentives of Limited-Service Hospitals

We believe in a goal to refine the system to create an equal opportunity for financial return across DRGs, which will provide an equal incentive to treat all types of patients and conditions. **However, as a system of community hospitals, we would like to emphasize here that payment changes alone will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals.** Physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving low-income patients, practice similar forms of selection for outpatient services and drive up utilization for services.

We strongly urge CMS to rigorously examine the investment structures of physician-owned, limited-service hospitals and consider AHAs comments on the interim report on the strategic plan. **It is imperative that CMS continue the suspension of issuing new provider numbers to physician-owned, limited-service hospitals until the strategic plan developed has been fully implemented and Congress has had an opportunity to consider CMS' final report.**

Outlier Threshold

The rule proposes establishing a fixed-loss cost outlier threshold equal to the inpatient PPS rate for the DRG, including indirect medical education (IME), disproportionate share hospital (DSH), and new technology payments, plus $25,530. While this is not a particularly sizable increase from the FY 2006 payment threshold of $23,600, we remain very concerned that the threshold is too high. **Using the proposed charge inflation methodology will only result in an inappropriately high outlier threshold and a real payment cut to hospitals**. We respectfully request CMS' to consider a methodology that incorporates both cost inflation and charge inflation as submitted by American Hospital Association. We believe the use of more than one indicator will make the threshold calculation more accurate and reliable.

SCH/MDH Changes in Qualification Status

The proposed rule would require an approved sole community hospital (SCH) or Medicare dependent hospital (MDH) to notify the appropriate CMS Regional Office of any change affecting its classification as such. To date, it has been the Fiscal

Intermediary's (FI) responsibility to evaluate hospitals' continuing qualification for SCH or MDH status. CMS expects the hospital to now self-disclose any material changes in circumstances or potentially face a retroactive cancellation of their designation once an FI discovers its ineligibility.

This appears to be an inappropriate shift of the burden from the FIs to hospitals. For instance, hospitals are neither involved in, nor have any control over, the building of new roads or new hospitals and thus should not be accountable to report such changes. It also would be very difficult for hospitals to know when and for how long there were prolonged severe weather conditions that closed area roads, or to note changes to posted speed limits and traffic patterns. In addition, some of the qualifying criteria, such as inpatient admissions at other regional hospitals, would be hard to monitor as the hospitals do not have this sort of data on their competitors. Requiring hospitals to constantly monitor whether they continue to meet these requirements would impose a tremendous and unreasonable administrative burden on hospitals. We recommend that this function remain a responsibility of the FIs, who are in a better position to monitor qualifying criteria. If CMS requires hospitals to report changes in circumstances, then the specific types of situations should be noted and should only include aspects of their operation that are within their control (e.g., number of beds).

CMS' proposal to retroactively withdraw SCH or MDH status if a hospital does not appropriately self-report a change in circumstances could be financially devastating for these specially classified community dependant facilities. CMS should, at minimum, give consideration to whether the hospital had knowledge of the disqualifying circumstance and should develop a prospective process for withdrawing the hospitals' SCH or MDH status.

We believe that a 30-day timetable for losing SCH/MDH status is unrealistic given the financial implications of such a change and the inability for a hospital to plan for this outcome. In addition, the proposal should include an appeal process providing hospitals with a formal appeal avenue that must be concluded prior to hospitals losing their status. We recommend that CMS provide a one year notice prior to revoking the hospitals' status. An alternative recommendation is that hospitals apply and requalify for SCH status every five years with designated timeframes that allow for at least one year of notice prior to loss of status. This would provide these community dependant hospitals with additional stability and allow for proper planning should they ever lose their status.

OTHER DECISIONS AND PROPOSED CHANGES

Quality Data

As a partner in the Hospital Quality Alliance (HQA), Trinity Health and its hospitals fully support the HQA's effort to make more information on hospital quality available to the public, and we join with CMS in wanting to make it happen quickly and accurately. However, as written, the proposed rule would require hospitals to reopen files from which data have already been abstracted, renegotiate agreements with the vendors that assist them in collecting and processing the required information, and resubmit

information to the clinical data warehouse. Such retroactive alterations in the data files are difficult and costly, and open the door for the introduction of many new kinds of errors in the data. To require this reopening of the files makes no sense. **CMS should make the data collection prospective. This could be accomplished by requiring that hospitals that want a full market basket update pledge to submit the relevant data for all 21 measures for patients beginning on or after July 1.**

The DRA gave the Secretary of the Department of Health and Human Services (HHS) the authority to further expand the measures that must be reported to qualify for full market basket update in future years. **We strongly urge CMS to select measures only from those used by the HQA for public reporting**. To choose different measures would thwart efforts to streamline quality reporting, add to the "babble" of quality measurement that currently exists in health care and dilute efforts to create a single source to share solid reliable information with the public. In addition, whenever the Secretary intends to expand the set of measures linked to payment, CMS should consider publishing the proposal at least one full year prior to the start of the fiscal year. This will enable hospitals and their vendors to put the needed data collection processes in place to be able to provide the requested data.

Hospital Quality Data – Value Based Purchasing

Trinity Health is supportive of moving toward transparency, however, we believe that it is important to remember that different audiences need and are able to process different forms of data. Also, we believe that partial data, or data without adequate explanation impedes progress on this front. We do not recommend reporting hospital payments without standardization for area wage index, DSH, GME and IME payments. Without standardization, a teaching hospital located in an urban area that treats a significant amount of uninsured patients will be viewed as a high cost provider when compared to a community hospital without teaching programs.

As CMS has already determined, hospital charges for the same procedure vary widely throughout the country and within states. Publishing this Medicare payment information would not aid consumers. Therefore, we do not support this proposal.

Providing meaningful information to consumers about the price of their hospital care is the most significant challenge hospitals, and CMS, face in increasing transparency of hospital pricing information. Objectives for improving pricing transparency should include:

- Presenting information in a way that is easy for consumers to understand and use;
- Making information easy for consumers to access;
- Using common definitions and language to describe pricing information for consumers;
- Explaining to consumers how and why the price of their care can vary; and
- Encouraging consumers to include price information as just one of several considerations in making health care decisions.

We recommend that CMS convene a workgroup comprised of representatives from hospitals, the AHA , state associations, and Medicare beneficiaries to identify the core issue to be resolved by the transparency initiative. Once that is identified, the hospital industry can provide valuable input to resolve the problem.

Although we have learned much about the type of information consumers want about the quality of their health care, we know significantly less about what they want in regard to pricing information. Depending upon whether and how they are insured, consumers need different types of price information as illustrated below:

- Traditional Insurance. Because traditional insurance typically covers nearly all of the cost of hospital care, individuals with this type of coverage are likely to want information about what their personal out-of-pocket cost would be if they receive care at one hospital versus another.
- Health Maintenance Organization (HMO) Insurance. Individuals who have HMO coverage will have more specific price information needs since they typically face no additional cost for care beyond their premium and applicable deductibles and co-payments. Persons covered by an HMO must agree to use physicians and hospitals that are participating in that HMO plan. As a result, these individuals likely have little, if any, need for specific price information.
- High-Deductible or Health Savings Account (HSA) Insurance. Individuals with HSAs have more interest regarding price information compared to a typically-insured person since these plans are designed to make consumers more price-sensitive and encourage consumers to be prudent "shoppers" for the care they need. Since a typical plan of this type has a deductible of $2,500, consumers with HSA coverage are likely to be more interested in price information for physician and ambulatory care than for inpatient hospital care.
- Uninsured Individuals of Limited Means. Uninsured individuals have limited means to pay for the health care services they receive and need to know how much of their hospital or physician bill they may be responsible for paying. In the case of hospital care, the information these patients need must be provided directly by the hospital, after the hospital can ascertain whether the individual is eligible for state insurance programs of which they were unaware, charity care provided by the hospital, or other financial assistance.

Hospital Emergency Services Under EMTALA

We support CMS' proposal to modify the definition of "labor" at 489.24(b) to allow a certified nurse-midwife or other qualified medical personnel operating under their scope of practice, as defined in hospital medical staff bylaws and in state law, to certify that a woman is in false labor. This change recognizes that licensure and scope of practice should remain under the purview of state law and regulation. Further, this change provides hospitals with the staffing flexibility needed to maintain access to and the efficiency of vital obstetrical services, particularly in hospitals located in areas of the country that may find it difficult to attract and retain physicians, such as rural areas.

Under the proposed rule, a hospital with "specialized capability" is required to accept appropriate transfers under EMTALA regardless of whether it has a dedicated ED.

Guidance is still needed on the definition of specialized capability. The EMTALA technical advisory group (TAG) has the ability to make recommendations for clarifying guidance, and we look forward to working with its members on this topic.

We agree that a physician-owned, limited-service hospital should be treated as a hospital "with specialized capability or facilities" under EMTALA without regard to whether it has an ED. However, in the DRA-mandated HHS interim report to Congress on its development of a strategic plan regarding physician investment in specialty hospitals, the Secretary suggested that this interpretation of EMTALA "may result in an increase in the number of specialty hospitals accepting transfers of emergency patients on nights and weekends." We believe it is unlikely this will result in improved access for patients to the specialty care they need.

Many physician-owned, limited-service hospitals have a range of capabilities more similar to a hospital department or ambulatory surgical center. Many of these facilities minimize resource consumption by being almost a Monday through Friday operation. For these reasons, it generally would not be in the best interests of community hospital patients to be transferred to these facilities.

At the same time, many physician-owned, limited-service hospitals have withdrawn specialist services from the community at-large. As their physicians maintain an increasing amount of their practice at these limited-service hospitals or other sites outside the community hospital (e.g., ambulatory surgical centers), they are much less willing to accept on-call responsibility for the broader community's emergency needs. These same physician-owned, limited-service hospitals presume to rely on the community hospital for back-up in the event of complications requiring around-the-clock access to emergency care and inpatient admission to the community hospital. **Every physician-owned, limited-service hospital that relies on the community's emergency services capacity should be obligated to support it.**

Specifically, we recommend the following:

- A physician-owned, limited-service hospital should be required to have a pre-existing agreement with the community hospital(s) it intends to rely on for emergency back-up services.
- The Secretary should establish the terms that must be addressed by an agreement, including:
    - Procedures for an appropriate transfer for patients not covered under EMTALA (e.g., inpatient or outpatient whose condition develops into an emergency beyond the capability of the limited-service hospital and consequently needs to be transferred to a full-service hospital);
    - Continuity of care (e.g., telephone consultation with the receiving hospital and physician, sending the patient's medical records along when transferred, etc.); and
    - Support for maintaining full-time emergency capacity at the community hospital, including on-call coverage (e.g., physician-owned, limited-service hospital physicians serve in on-call panels at the community

hospital, or the physician-owned, limited-service hospital provides financial support to the community hospital to maintain on-call coverage).

Hospital Acquired Infections

In the inpatient PPS, infections acquired in the hospital and other complications, can sometimes trigger higher payments, either as payment outliers or by assignment to a higher-paying DRG. Approximately 121 sets of DRGs are split based on the presence or absence of a complication or comorbidity (CC), and DRGs with a complication or comorbidity generate higher Medicare payments.

By Oct. 1, 2007, the DRA requires the CMS to identify at least two preventable conditions that categorize a patient to a CC DRG. The CMS wants hospitals to identify conditions that either occur frequently or their presence results in significantly higher costs to treat the patient. The CMS is proposing, effective October 1, 2008, hospitals would not receive additional payment for cases in which one of the selected conditions was not present on admission. Instead, the case would be paid as though the hospital-acquired complication was not present.

The DRA also requires hospitals to submit the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007.

Some patients have conditions that are not apparent upon admission that later develop into an infection. It may be impossible to accurately distinguish these from hospital acquired infections without performing a battery of lab and/or radiology procedures on a patient upon admission to determine an accurate baseline. This would inconvenience patients and increase cost for the hospitals only to provide evidence of an infection upon admission that would not limit a hospital from receiving a higher payment if complications arise.

Trinity Health, along with the Michigan Health and Hospital Association (MHA) participated in a joint project with Johns Hopkins, funded by a $1 million grant from the U.S. Agency for Healthcare Research and Quality (AHRQ) to reduce ICU infections through the MHA Keystone Center. Over two years, 77 hospitals and 127 hospital ICUs voluntarily participated in this project to reduce infections in the ICU. After 18 months, the predictive model suggests that teams saved 1,574 lives, over 84,000 ICU days and over $175 million dollars. Infections from central IV catheters plummeted. The median CR-BSI rate in participating ICUs has now been at zero for almost a year. Ventilator associated pneumonia rates in the ICUs have been cut by 40%. Forty six ICUs have gone for over six months with no ventilator associated pneumonias. Fifty-seven ICUs have gone for over six months with no blood stream infections from IV catheters.

We believe proactive projects such as these will result in better patient safety and quality. However, hospitals need the training and funding in order to implement these changes.

We believe the CMS proposal that complications are solely the result of hospital actions is fundamentally flawed. To reduce hospital payments for a condition present upon

admission, but not documented, is too punitive. In addition, there is good evidence to suggest that even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. Rather, **we recommend that CMS expand demonstration projects such as the MHA Keystone Center to truly improve patient safety and quality for Medicare and all patients.**

CONCLUSION

In closing, we want to thank you for the opportunity to comment on the proposed FY 2007 IPPS rule. Not only does the rule propose major changes to the DRG weight determination process but also proposes substantive severity of illness refinements. 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,

Timothy Eckels, VP Public Policy
eckelst@trinity-health.org

Paul Sahney, VP Revenue Management
sahneyp@trinity-health.org

Submitter : **Dr. David Finklea** **Date: 06/12/2006**

Organization : **John Peter Smith Hospital-FMRP**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1703-Attach-1.DOC

#1703

Dear CMS Policy Maker:

I am a family medicine resident in a very busy HPSA. I really need my faculty to teach. Why would you interpret a rule designed to do just that as being unrelated to patient care time? Whether we are having a discussion after a patient encounter, a small group discussion regarding a difficult clinical situation, reviewing our evaluation for our care and didactic tests in a certain disease domain, or participating in lectures – we are learning about, caring for current and protecting our future patients.

My concern is that the faculty are already stretched to produce more patient visits with poor compensation and must cover four of us at a time for supervision in clinic. The hour they spend before and after clinic to discuss a specific topic that is not related to a specific individual patient will disappear with the implementation of the rule you suggest. They will not have time to sit down with us to discuss our overall performance – we will get an email.

The faculty, without support for their own development, will be likely to lose their academic edge as they work to see patients, see more patients and supervise patient care without any incentive to reflect, discuss and research our and their work.

Please help us be better physicians to our patients by supporting a competent and refreshed faculty. Rescind the interpretation of the IME and DME support rule.

Sincerely,

Submitter :

Date: 06/12/2006

Organization :

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Attention: CMS-1488 P
Dear Administrator McClellan:
Sentara Healthcare 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). Sentara Healthcare, located in Southeastern Virginia, is a system of seven hospitals, multiple SNFs, physician practices, Home Health and Hospice. Our hospitals range from 100 to 400+ beds. This letter focuses primarily on two areas of the proposed rule: a) proposed changes to the diagnosis-related group (DRG) weighting and classification systems, and b) a clarification that would prohibit hospitals from counting much of the resident time spent in didactic activities when calculating indirect medical education (IME) and direct graduate medical education (DGME) payments.
PROPOSED CHANGES TO THE DRG WEIGHTING AND CLASSIFICATION METHODOLOGIES
We do not oppose moving from a charge to a cost-based DRG weighting methodology, but believe that a one-year postponement is necessary to ensure that the best possible methodology ultimately is implemented. However, we do believe using 2003 Cost Report data (the majority probably unaudited) to calculate cost for FFY 2007 overlooks the cost associated with new technology and artificially deflates the cost-to-charge ratios. We also support refinement of the DRGs but believe that the proposed consolidated severity-adjusted DRGs (CS-DRGs) require further examination and likely modifications before implementation. We believe that these changes should be implemented simultaneously to ensure equity and minimize payment volatility for hospitals. We do not support an effective date of October 1, 2006; there is simply not enough time for our facilities to implement the new IBM grouper and educate our coders on the severity-adjusted DRG system. Our cash flow would be severely affected.
At the DRG level, the proposed rule notes that a number of DRGs would experience payment reductions, particularly DRGs involving cardiac care. For example, cardiac procedures involving stents, both drug eluting and non drug eluting, would see payment reductions. We are concerned about such drastic reductions for these and other cardiac procedures. While the payment reductions could potentially reduce the incentives . . . for the further development of specialty hospitals (71 Fed. Reg. at 24006), we are concerned that the reductions significantly affect our hospitals that do significant amounts of cardiac care. Unlike many specialty hospitals, we have emergency rooms (two hospitals are designated trauma centers), treat significant numbers of Medicaid (two hospitals are DSH) and uninsured patients, and also accept complex cardiac cases. We have calculated a decrease in reimbursement of over $6 million for our large teaching hospital due to the rebasing.
DIDACTIC ACTIVITIES
We strongly urge 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) payment.The stated rationale for the exclusion of time devoted to these activities is that they are not related to patient care. 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. We urge CMS to withdraw 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 thei

Submitter : **Dr. Myra Gillean** **Date: 06/12/2006**

Organization : **John Peter Smith Hospital-FMRP**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1705-Attach-1.DOC

#1705

Dear CMS policy maker

I am a family medicine resident in a very busy HPSA. I really need my faculty to teach. Why would you interpret a rule designed to do just that as being un related to patient care time? Whether we are having a discussion after a patient encounter, a small group discussion regarding a difficult clinical situation, reviewing our evaluation for our care and didactic tests in a certain disease domain, or participating in lectures – we are learning about, caring for current and protecting our future patients.

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Please help us be better physicians to our patients by supporting a competent and refreshed faculty . Rescind the interpretation of the IME and DME support rule

Sincerely,

Submitter : Robert Olsen **Date:** 06/12/2006

Organization : MHA An Assoc of MT Health Care Providers

Category : Health Care Provider/Association

Issue Areas/Comments

EMTALA

EMTALA

MHA supports the clarification that hospitals without an emergency room must comply with EMTALA transfer provisions for specialty services. There is a trend developing in which physicians are increasingly unwilling to provide on-call services to the hospital. This is of particular concern when a physician is on staff at a specialty hospital that does not provide emergency care.

GENERAL

GENERAL

MHA comments pertaining to the DRG weights and severity adjustment are attached. See attachment.

Hospital Quality Data

Hospital Quality Data

All of Montana's PPS-paid hospitals participate in reporting quality data. The expanded data set does not pose a problem, except in regards to the effective date of service to be reportred. By the time the final regulation is adopted the opportunity to report quality data on a timely basis is past us. MHA recommends that CMS adopt an effective date for reporting the expanded set of quality measures closer to the effective date of the regulation, but no sooner than dates of service on or after July 1, 2006.

CMS-1488-P-1706-Attach-1.DOC

#1706

MHA AN ASSOCIATION OF MONTANA HEALTH CARE PROVIDERS

June 5, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-4105-P
P.O. Box 8010
Baltimore, MD 21244-1850

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

MHA, An Association of Montana Health Care Providers, on behalf of its 55 hospital members, appreciates the opportunity to comment on the above referenced regulations. The proposal before the public is far-ranging and may represent the most significant change in payment policy since the advent of Medicare's prospective payment system. Montana hospitals note that the CMS proposal lowers Medicare payments from their current level. Since the policy changes, specifically the change toward occupational mix-adjusted wage indices and cost-based DRG weights were intended to improve payments for rural hospitals, we are skeptical about the proposed policy changes.

For this reason, MHA supports and endorses AHA's proposal for the following:

- One-year Delay: The AHA supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology. The AHA and the hospital field are committed to working with CMS over the next year to address these concerns.

- Valid Cost-based Weights: We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed.

- A New Classification System Only if the Need Can Be Demonstrated: The AHA does not support a new classification system at this time, as the need for a new system is still unclear. Much more work

understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.

- Simultaneous Adoption of Any Changes to Weights and Classifications: If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.

- Three-year Transition: Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.

- Collaborative Approach to Moving Forward: The AHA commits to working with CMS to develop and evaluate alternatives for new weights and classifications.

MHA also endorses the comments submitted by AHA on a variety of issues addressed in the proposed regulation. We are especially interested in the policy clarification for EMTALA standards at hospitals that don't have an emergency department and the adjustment for low volume hospitals.

MHA also believes that the policy requiring that hospitals report an expanded number of quality measures should be made effective with discharges occurring after July 1, 2006. Hospitals may not be able to provide reports on a timely basis retroactive to January 1, 2006.

Sincerely,

Robert W. Olsen
Vice President

Submitter : **Mrs. Laurel Sweeney** **Date: 06/12/2006**

Organization : **Philips Medical Systems**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-1707-Attach-1.DOC

#1707

PHILIPS

Philips Medical Systems

June 14, 2006

Via Electronic and U.S. Mail

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Ave, S.W.
Washington, DC 20201

File Code CMS-1488-P: Comments Related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

Philips Medical Systems ("Philips Medical") is delighted to have this opportunity to comment on the proposed changes to the Medicare hospital inpatient prospective payment system (HIPPS) and fiscal year 2007 rates (CMS-1488-P) ("the Proposed Rule"). Philips Medical is one of the largest manufacturers of medical systems in the world. Philips' product line includes technologies in general imaging and cardiac ultrasound, X-ray, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), nuclear medicine (including Positron Emission Tomography (PET)), radiation therapy planning, catheterization labs, patient monitoring and resuscitation, as well as information technology solutions.

Philips Medical is very concerned about the proposed changes in the HIPPS set forth in the Proposed Rule. For many hospitals, the payment reductions that would result from implementation of the Proposed Rule are profound. The magnitude of the cuts that would be imposed on urban teaching hospitals due to the use of this approach, even those located in primarily rural states, could have major adverse consequences for patient care. We are also concerned about the magnitude of the reductions for cardiac services and procedures, which will significantly affect not only specialized cardiac hospitals but also general hospitals with state of the art cardiac units, including cardiac catheterization facilities. In light of the extraordinary potential impact of the Proposed Rule on hospitals and the patients they serve, it is disturbing to us that the details of the proposal were not formulated in conjunction with the affected hospital community and other affected parties.

Moreover, while we fully support efforts to base payments on the cost of providing services, it is unclear to us whether the proposal achieves that goal. Hospital analysts have found that the proposal has methodological flaws (including collapsing of cost centers) and is based on weak or inaccurate data. This is not surprising since hospital cost reports, which serve as the fundamental source of data used under the proposed system, were not designed with the prospective system in mind; have not been used to establish individual hospital rates for inpatient services for some time; and have not been the focus of the type of intensive internal hospital review necessary to ensure accuracy.

PHILIPS
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810
Tel: 978 687 1501, Fax: 978 794 7646
www.medical.philips.com

PHILIPS

We are equally troubled by the proposed two-step implementation, whereby CMS would implement the movement from charge-based weights to cost-based weights in one year and would implement an entirely new set of DRGs to account for patient severity in a subsequent year. Each of these two major reforms will have substantial impact on individual hospitals' bottom lines: The changes, as proposed, likely would result in wide swings in payment rates for many diagnosis-related groups, resulting in less predictable and stable payment streams for hospitals. Such instability has a profound impact on hospitals' ability to plan effectively, especially for necessary major medical equipment purchases and other capital expenditures.

For the same reasons, we urge CMS to give hospitals sufficient time to adapt to any changes resulting from adoption of a cost-based methodology and any new severity adjustment system that are to be implemented. A significant lead-time before changes are implemented could help hospitals budget accurately.

We also believe that any new system should be phased in, in light of the magnitude of the revenue shifts likely to result for individual hospitals' bottom lines. This recommendation is consistent with that made by MedPAC, which is urging CMS to provide a transition to the new rate setting system.

In short, we urge CMS not to implement either of the major reforms described in the Proposed Rule in FY 2007 and to work with the affected community to address the significant issues that have been identified during the comment period. When and if major reforms are adopted, we would hope that hospitals and CMS contractors will be given sufficient lead time to prepare for implementation and that a multi-year transition period will be instituted, during which any errors in DRG calculations can be identified and remedied.

We also have a number of comments with respect to other aspects of the Proposed Rule:

*With respect to hospital quality measures, we believe that any process standards regarding the use of particular technologies should provide explicit mechanisms to recognize new technology promptly and appropriately, to ensure that the measures to not provide incentives for providers to keep older technologies in place after they are outdated.

*We urge CMS to include manufacturers of medical technology in the process of developing quality and cost standards.

*We urge CMS not to adopt reporting requirements on hospital efficiency and costs of care that provide inappropriate incentives to reduce quality or that inhibit hospitals from adopting improved patient care technologies.

*We support expedited adoption of health information technology (HIT) (including electronic health records) throughout the health care system, and urge CMS to include incentives for adoption and use of HIT in any value-based purchasing system.

*We urge CMS to consider performance measures that actually provide incentives to reduce inpatient hospital care, such as remote patient monitoring, telemedicine, and virtual physician visits.

We appreciate the opportunity to comment on the Proposed Rule. If you have any questions, please do not hesitate to contact me at (978) 659-2972.

Sincerely yours,

Laurel Sweeney
Senior Director
Reimbursement & Legislative Affairs

Submitter : Dr. Lisa Goldstein **Date:** 06/12/2006

Organization : John Peter Smith Hospital-FMRP

Category : Health Care Professional or Association

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1708-Attach-1.DOC

#1708

Currently I am completing my residency in family medicine. When I became aware that CMS would stop funding payment to faculty for teaching, preparing curriculum and evaluating my performance through GME -- IME and DME support – I became alarmed.

We are in a state with a huge health care professional shortage in communities under 25,000. These communities cannot afford to support several nurse practitioners and visiting specialists when the services are delivered by a pluri-potential well trained family medicine specialist who is part of their community. The training programs, like mine, which prepare us for these types of venues are in very short supply. We need to be exceptionally well trained.

Someone at CMS will need to explain to me, how the teaching, curriculum development and evaluation process for the six required ACGME physician skill competencies is not related to patient care. Isn't this exactly what the IOM has criticized our training professions for? In fact, our program currently evaluates us in all these competencies as a continuing quality improvement process DURING patient care. Without time to discuss and reflect our experiences and outcomes we will not be serving the needs of our current and future patients.

Should indeed this come to pass, we will have faculty who will be caught in the productivity race with no time for us. We may get pop-up feed back from an Electronic Health Record in sites that have them that we have made an error or we are not following a guideline. No discussion there. What is being proposed is dangerous for our current patients and our future patients. Our patients deserve for us to have a better education than you are proposing.

Why does the American taxpayer support medical students at over $200,000 per student per year and offers the faculty of residencies less than $15,000 for teaching per resident per year? I am getting a lot more from my residency training to protect and serve my patients of the future than all of medical school combined. Please do not cut us any more – rescind the clarification of this dangerous and capricious rule.

Medical Resident

Submitter : Mr. Richard Eaton **Date:** 06/12/2006

Organization : NEMA

Category : Other Association

Issue Areas/Comments

DRG Weights

DRG Weights

see attachment

#1709

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. Chad Hammett** **Date: 06/12/2006**

Organization : **John Peter Smith Hospital-FMRP**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GME Payments

GME Payments

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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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1710-Attach-1.DOC

#1710

Dear CMS Policy Maker:

I am a family medicine resident in a very busy HPSA. I really need my faculty to teach. Why would you interpret a rule designed to do just that as being unrelated to patient care time? Whether we are having a discussion after a patient encounter, a small group discussion regarding a difficult clinical situation, reviewing our evaluation for our care and didactic tests in a certain disease domain, or participating in lectures – we are learning about, caring for current and protecting our future patients.

My concern is that the faculty are already stretched to produce more patient visits with poor compensation and must cover four of us at a time for supervision in clinic. The hour they spend before and after clinic to discuss a specific topic that is not related to a specific individual patient will disappear with the implementation of the rule you suggest. They will not have time to sit down with us to discuss our overall performance – we will get an email.

The faculty, without support for their own development, will be likely to lose their academic edge as they work to see patients, see more patients and supervise patient care without any incentive to reflect, discuss and research our and their work.

Please help us be better physicians to our patients by supporting a competent and refreshed faculty. Rescind the interpretation of the IME and DME support rule.

Sincerely,

Submitter : Dr. Roxanne Ho **Date:** 06/12/2006

Organization : John Peter Smith Hospital-FMRP

Category : Health Care Professional or Association

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1711-Attach-1.DOC

#1711

Dear CMS policy maker

I am a family medicine resident in a very busy HPSA. I really need my faculty to teach. Why would you interpret a rule designed to do just that as being un related to patient care time? Whether we are having a discussion after a patient encounter, a small group discussion regarding a difficult clinical situation, reviewing our evaluation for our care and didactic tests in a certain disease domain, or participating in lectures – we are learning about, caring for current and protecting our future patients.

My concern is that the faculty are already stretched to produce more patient visits with poor compensation and must cover four of us at a time for supervision in clinic. That hour they spend before and after clinic to discuss a specific topic that is not related to a specific individual patient will disappear with the implementation of the rule you suggest. They will not have time to sit down with us to discuss our overall performance – we will get an email.

The faculty, without support for their own development, will be likely to lose their academic edge as they work to see patients, see more patients and supervise patient care without any incentive to reflect, discuss and research our and their work.

Please help us be better physicians to our patients by supporting a competent and refreshed faculty . Rescind the interpretation of the IME and DME support rule

Sincerely,

Submitter : Mr. Donald Thieme **Date:** 06/12/2006

Organization : Mass.Council of Community Hospitals

Category : Hospital

Issue Areas/Comments

DRG Weights

DRG Weights

The Massachusetts Coouncil of Community Hospitals(MCCH) is an association of 24 not for profit independent community hospitals. MCCH is supportive of the proposed transition of payment for inpatient services from a charge based system to a cost based system, specifically the HSRVcc methodology. The current inequalities in payment amongst the several different types of providers will be partially correted by the HSRVcc methodology. We urge you to continue the process of refining this proposed new system to more accurately mirror the costs of care. Community hospitals have been historically disadvantaged by the present payment system. The present system has created incentives that reward behaviors that cause distortions in the market palce leading to over utilization of certain services and care at inappropriate sites of care.This new system begins to address such issues. By adopting the HSRVcc metholodology you create the conditions for a more rational allocation of resources. The current growth of niche providers and specialty hospitals that has led to redundant capital investments with little improvement in quality or reduced cost of care is a result of the current imperfections in the payment system. Hopefully, the introduction of HSRVcc and diligence in perfecting the cost of care estimates, bettter public policy will result as the provider community adjsuts to the new payment scheme.

Submitter : **Dr. Hali Hammer** **Date: 06/12/2006**

Organization : **UCSF/SFGH Department of Family and Community Medic**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

June 12, 2006

To Whom it May Concern:

As a faculty member and Associate Residency Director of the UCSF Department of Family and Community 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.

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, 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,

Hali Hammer, MD

Submitter : **Dr. Kory Martin** **Date: 06/12/2006**

Organization : **John Peter Smith Hospital-FMRP**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1714-Attach-1.DOC

#1714

Dear CMS policy maker

I am a family medicine resident in a very busy HPSA. I really need my faculty to teach. Why would you interpret a rule designed to do just that as being un related to patient care time? Whether we are having a discussion after a patient encounter, a small group discussion regarding a difficult clinical situation, reviewing our evaluation for our care and didactic tests in a certain disease domain, or participating in lectures – we are learning about, caring for current and protecting our future patients.

My concern is that the faculty are already stretched to produce more patient visits with poor compensation and must cover four of us at a time for supervision in clinic. That hour they spend before and after clinic to discuss a specific topic that is not related to a specific individual patient will disappear with the implementation of the rule you suggest. They will not have time to sit down with us to discuss our overall performance – we will get an email.

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Please help us be better physicians to our patients by supporting a competent and refreshed faculty . Rescind the interpretation of the IME and DME support rule

Sincerely,

Submitter : **Dr. Andrew Metz** **Date: 06/12/2006**

Organization : **John Peter Smith Hospital-FMRP**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GME Payments

GME Payments

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.

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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.

CMS-1488-P-1715-Attach-1.DOC

#1715

Currently I am completing my residency in family medicine. When I became aware that CMS would stop funding payment to faculty for teaching, preparing curriculum and evaluating my performance through GME -- IME and DME support – I became alarmed.

We are in a state with a huge health care professional shortage in communities under 25,000. These communities cannot afford to support several nurse practitioners and visiting specialists when the services are delivered by a pluri-potential well trained family medicine specialist who is part of their community. The training programs, like mine, which prepare us for these types of venues are in very short supply. We need to be exceptionally well trained.

Someone at CMS will need to explain to me, how the teaching, curriculum development and evaluation process for the six required ACGME physician skill competencies is not related to patient care. Isn't this exactly what the IOM has criticized our training professions for? In fact, our program currently evaluates us in all these competencies as a continuing quality improvement process DURING patient care. Without time to discuss and reflect our experiences and outcomes we will not be serving the needs of our current and future patients.

Should indeed this come to pass, we will have faculty who will be caught in the productivity race with no time for us. We may get pop-up feed back from an Electronic Health Record in sites that have them that we have made an error or we are not following a guideline. No discussion there. What is being proposed is dangerous for our current patients and our future patients. Our patients deserve for us to have a better education than you are proposing.

Why does the American taxpayer support medical students at over $200,000 per student per year and offers the faculty of residencies less than $15,000 for teaching per resident per year? I am getting a lot more from my residency training to protect and serve my patients of the future than all of medical school combined. Please do not cut us any more – rescind the clarification of this dangerous and capricious rule.

Medical Resident

Submitter : Dr. Kevin Bozic **Date:** 06/12/2006

Organization : American Association of Hip and Knee Surgeons

Category : Physician

Issue Areas/Comments

DRGs: Hip and Knee Replacements

DRGs: Hip and Knee Replacements

The American Association of Hip & Knee Surgeons (AAHKS) and its participating institutions and surgeons would like to formally comment on the proposed rule changes to the Medicare Inpatient Prospective Patient System (IPPS), specifically as it relates to hip and knee replacement procedures (DRG s 544 and 545). We previously presented data to CMS on the important differences in clinical characteristics and resource utilization between primary and revision total joint replacement (TJR) procedures. The creation of a separate DRG (DRG 545) for revision total joint replacement procedures in October, 2005 resulted in an increase in reimbursement for hospitals that perform a disproportionate share of revision TJR procedures, recognizing the higher resource utilization associated with these procedures. This important policy change has led to increased access to care for patients with failed total joint replacements, and has ensured that high volume TJR centers can continue to provide a high standard of care for these patients.

We have concerns about the changes that CMS has proposed to the IPPS for FY 2007 and FY 2008, and how this will impact high volume TJR hospitals and TJR patients. Our specific concerns relate to the following issues:

1. INADEQUATE RISK ADJUSTMENT FOR TREATMENT COMPLEXITY The proposal to use consolidated severity adjusted DRG s does not adequately recognize differences in treatment complexity (e.g. revision vs. primary) among TJR procedures. Although we agree that severity of illness is an important consideration in differentiating relevant disparities in clinical characteristics and resource utilization in TJR patients, the data that we have previously shared with CMS strongly supports the fact that BOTH treatment complexity AND severity of illness influence relative resource use and clinically relevant differences in TJR procedures.

o The COMPLEXITY of a procedure (e.g., primary vs. revision) influences the volume and types of diagnostic, therapeutic, and routine services needed and provided to patients - a measure of relative resource use. It also has a significant influence on patient outcomes, as revision TJR procedures are associated with higher risk of complications and less favorable clinical outcomes.

o Although treatment complexity and severity of illness are frequently correlated, in many cases, they each provide an independent contribution to resource needs, as our prior research has demonstrated.

2. We believe that in order to be clinically relevant, fiscally equitable, and to avoid perverse incentives for selection bias among orthopaedic providers and institutions any changes to the IPPS related to DRG s 544 and 545 should include recognition of BOTH complexity AND severity of illness.

RECOMMENDATION

We strongly recommend that CMS maintain separate base DRG s for primary (DRG 544) and revision (DRG 545) lower extremity TJR procedures until more data is available from the refined ICD-9-CM procedure codes and DRG s related to primary and revision TJR. We would note that these changes were only recently implemented in October of 2005, and it would be premature to make any changes until a sufficient amount administrative claims data is available to assess the true financial impact to hospitals. Any proposed rule changes to adequately address issues of treatment complexity AND severity of illness.

We are enthusiastic about working with CMS to evaluate policy-relevant differences in clinical characteristics and resource utilization among hip and knee replacement patients and suggest further refinements to the orthopaedic DRG s based on differences in treatment complexity and severity of illness. We think this approach would more closely accomplish the goal of matching hospital reimbursement to resource utilization for primary and revision TJR procedures, and minimize perverse incetives for selection bias among orthopaedic providers and institutions.

CMS-1488-P-1716-Attach-1.DOC

#1716

June 12, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-FC
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Proposed changes to orthopaedic DRGs 544 and 545 - "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule" April 25, 2006 [CMS–1488–P]

The American Association of Hip & Knee Surgeons (AAHKS) and its participating institutions and surgeons would like to formally comment on the proposed rule changes to the Medicare Inpatient Prospective Patient System (IPPS), specifically as it relates to hip and knee replacement procedures (DRG's 544 and 545). As you know, we previously presented data to CMS on the important differences in clinical characteristics and resource utilization between primary and revision total joint replacement procedures. The creation of a separate DRG (DRG 545) for revision total joint replacement (TJR) procedures in October, 2005 resulted in an increase in reimbursement for hospitals that perform a disproportionate share of revision TJR procedures, recognizing the higher resource utilization associated with these procedures. This important policy change has led to increased access to care for patients with failed total joint replacements, and has ensured that high volume TJR centers can continue to provide a high standard of care for these challenging patients.

We have concerns about the changes that CMS has proposed to the IPPS for FY 2007 and FY 2008, and how this will impact high volume TJR hospitals and TJR patients. Although we agree (and our data supports) that medical severity of illness significantly impacts resource utilization, we would point out that our research indicates that certain co-morbidities have a disproportionately greater impact on clinical complexity and resource utilization associated with TJR procedures. Our specific concerns relate to the following issues:

1. **Reversal of previous DRG changes related to TJR procedures** – The proposal to use consolidated severity adjusted DRG's in 2008 or earlier does not adequately recognize differences in ***treatment complexity*** (e.g. revision vs. primary) among TJR procedures. Although we agree that severity of illness is an important consideration in differentiating relevant disparities in clinical characteristics and resource utilization in TJR patients, the data that we have previously shared with CMS strongly supports the fact that ***both treatment complexity and severity of illness*** influence relative resource use and clinically relevant differences in TJR procedures.
    - **The complexity of a procedure (e.g., primary vs. revision)** influences the volume and types of diagnostic, therapeutic, and bed services needed and provided to patients - a measure of relative resource use. It also has a significant influence on patient outcomes, as revision TJR procedures are associated with higher risk of complications and less favorable clinical outcomes.

- **Severity of Illness**, as defined by the extent of physiologic decompensation or organ system loss of function, is primarily driven by interactions of multiple co-morbid diseases.
- **Relative resources and clinically meaningful differences** are dependent on ***both treatment complexity and severity of illness***. Although they are frequently correlated, in many cases, they each provide an independent contribution to resource needs, as our prior research has demonstrated.

2. We believe that in order to be clinically relevant and fiscally equitable, any changes to the IPPS related to DRG's 544 and 545 should include recognition of ***BOTH complexity and severity of illness***.
   - Since the intent of the Medicare DRGs are to set payment rates proportional to relative resource use, both complexity and severity of illness issues that increase or decrease the use of resources should be incorporated for payment equity and to avoid perverse incentives for selection bias among orthopaedic providers and institutions.
3. Although many of the new ICD-9-CM diagnosis codes related to failed TJR's that were implemented in October of 2005 (996.41-996.48) are labeled as "complications", this nomenclature is deceptive. The majority of these "complications" (with the exception of 996.42, dislocation of a prosthetic joint) are due to long-term wear of the prosthesis, and therefore are not under the control of the hospital or surgeon performing the operation. The proposed rule change does not adequately recognize the additional treatment complexity and resource utilization associated with treating patients with these so-called "complications". Although we are in agreement with CMS that any proposed reimbursement system should provide incentives for improved quality of care, mis-representing these ICD-9-CM diagnosis codes as "complications" could create perverse incentives for selection bias among orthopaedic providers and institutions.

Recommendation

We strongly recommend that CMS maintain *separate base DRG's for primary (DRG 544) and revision (DRG 545) lower extremity TJR procedures* until more data is available from the refined ICD-9-CM procedure codes and DRG's related to primary and revision TJR. We would note that these changes were only recently implemented in October of 2005, and it would be premature to make any changes until a sufficient amount administrative claims data is available to assess the true financial impact to hospitals. Any proposed rule changes to adequately address issues of *treatment complexity (including "complications" that are present at the time of admission)* and *severity of illness.*

We (AAHKS, AAOS, UCSF, Massachusetts General Hospital, and Mayo Clinic) are enthusiastic about working with CMS to evaluate policy-relevant differences in clinical characteristics and resource utilization among hip and knee replacement patients and suggest further refinements to the orthopaedic DRG's based on differences in *treatment complexity* and *severity of illness*. We think this approach would more closely accomplish the goal of matching hospital reimbursement to resource utilization for primary and revision TJR procedures, and minimize incentives for certain institutions and physicians to selectively treat patients with less complex orthopaedic conditions whose procedures are less resource intensive. We would note that Medicare is the primary payer for over 60% of the roughly 800,000 hip and knee replacement procedures that are performed annually in the United States, and major arthroplasty procedures of the lower extremity represent the largest dollar volume DRG in the Medicare system.

We look forward to continuing to work with you in this collaborative effort to improve the quality of the administrative claims data related to TJR and to more appropriately match hospital reimbursement to actual resource utilization, with the ultimate goal of improving patient access to care and clinical outcomes for our TJR patients.

Sincerely,

Kevin J. Bozic, MD, MBA
University of California, San Francisco
American Association of Hip & Knee Surgeons
Co-Director, Health Policy Committee

Daniel J. Berry, MD
Mayo Clinic
Chairman, Department of Orthopaedics
President-Elect, American Association of Hip & Knee Surgery

Harry E. Rubash, MD
Massachusetts General Hospital
Chairman, Department of Orthopaedics

Submitter : **Ms. Barbara Lane** **Date: 06/12/2006**

Organization : **QuadraMed Corporation**

Category : **Other Health Care Professional**

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

June 12, 2006

To: CMS

Re: Severity Adjusted DRGs

As an HIM coding professional for the past 22 years, I wish to comment on the CMS 2007 Proposed Rule. I am writing to express concern over the proposed rule announced on April 25, 2006.

I have worked as a coder and as a Coding Manager in the recent past. I can say from firsthand experience that the task of accurately coding a record and dropping the bill in a timely manner is a very delicate proposition. I have always felt strongly that complete and accurate coding should be the highest priority. Dropping the bill in a timely manner is in the hospital s best interest. In the real world, there are very legitimate reasons why there can be delays in dropping bills. In order to obtain all the information needed to code accurately, there is an increasing need to query the physician in order to clarify information. Unfortunately, the issues with precise physician documentation still prevail. A severity-adjusted DRG system will only increase the need to query.

While I believe that a severity-adjusted system is long overdue, I feel that the rapid implementation schedule suggested in Transmittal 1488-P will be very difficult, if not impossible, for healthcare facilities to implement. Systems will have to be integrated, large amounts of money spent, coders retrained, all of which will be a drag on hospital cash flow (which is already a problem). There will be a learning curve for coders and billers and coding backlog will occur.

I am also concerned with the proprietary aspects of the proposed system. I believe that CMS needs to maintain and provide open access to whatever grouper logic is finally selected. Public suggestions and scrutiny should be helpful in creating a system we can all live with.

Also, with ICD-10 just around the corner, the introduction and implementation of the proposed severity-adjusted system may just be proverbial straw that broke the camel s back. Both a severity-adjusted system and ICD-10 need to be implemented, but not so hastily in the case of the former. How will this all fit together? I feel that the implementation of ICD-10 should not be delayed since we are running out of codes in the present ICD-9 system.

I hope that my comments and those of many others in the healthcare field will sound an alarm. I believe that CMS needs to investigate further and study the larger picture before implementing a potentially problematic series of events that will further increase the costs of healthcare and will pose a hardship on many hospitals as they try to comply.

Thank you for allowing me to comment on this proposed rule.

Barbara B. Lane. R.H.I.T.
QuadraMed Corporation
blane@quadramed.com

Submitter : Ms. Laura Loeb **Date:** 06/12/2006

Organization : Society of Critical Care Medicine

Category : Health Care Provider/Association

Issue Areas/Comments

DRGs: Severe Sepsis

DRGs: Severe Sepsis

Believe CMS should create two new DRGs for Severe Sepsis.

CMS-1488-P-1718-Attach-1.PDF

#1718

Society of
Critical Care Medicine
The Intensive Care Professionals

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June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 443-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Attention: CMS-1488-P

RE: DRGs: Severe Sepsis

Dear Administrator McClellan:

The Society of Critical Care Medicine (the "Society") appreciates this opportunity to comment on the proposed rule for changes to the hospital inpatient prospective payment systems and fiscal year 2007 rates. Specifically, the Society wishes to comment on MDC 18 (Infectious and Parasitic Diseases) and the need for separate DRGs, medical and surgical, for severe sepsis.

The Society is the leading professional organization dedicated to ensuring excellence and consistency in the practice of critical care medicine. With more than 13,000 members worldwide, the Society is the only professional organization devoted exclusively to the advancement of multiprofessional intensive care through excellence in patient care, professional education, public education, research and advocacy. Members of the Society include intensivists, critical care nurses, critical care pharmacists, clinical pharmacologists, respiratory care practitioners and other professionals with an interest in critical care, including physician assistants, social workers and dietitians.

As CMS noted in the proposed rule, the Society has met with CMS officials and provided data on the need for two new DRGs for severe sepsis patients with organ support -- a medical DRG and a surgical DRG. As described in more detail below, the MedPAR data clearly show that patients with severe sepsis with organ support are a clinically coherent population with very similar resource use. These patients are not simply the most costly cases in a DRG. Rather, they are cases with a common acute illness, managed in a similar clinical fashion, with similar resource use and clinical outcomes.

Based on the 2005 MedPAR data, the mortality rate of Medicare patients with severe sepsis with organ support was 43%. One in five of all the Medicare hospital mortalities are patients with severe sepsis.

We do believe that the severity-adjusted DRGs proposed by CMS are a step in the right direction, and we commend CMS for proposing to link Medicare payments more closely to the

severity of illness. These are the patients that Society members treat and we look forward to working with CMS to further refine this methodology so that it appropriately recognizes the costs that hospitals expend to treat these patients.

However, the new system as currently proposed, and as CMS acknowledges, does not accurately reflect the complexity of care that is often independent of severity of illness. That is, the APR DRGs proposed by CMS in this new system do not include the improvements that CMS itself has made in the categories of DRGs in recent years.

Thus, this new system as proposed would not fully address the needs of the severe sepsis cases, particularly with respect to surgical patients, as further described below. We believe that the severity-adjusted methodology, when further refined to take into account complexity of care, will lead eventually to a more appropriate reimbursement for severe sepsis. Nevertheless, there should be no further delay in creating new DRGs for severe sepsis as we wait for this needed refinement to the newly proposed system.

In sum, we strongly believe that severe sepsis patients must be segregated into their own DRGs for fiscal year 2007. This matter should be a CMS priority. Based on a review of the 2005 MedPAR database, the costs of caring for these patients is greater than the DRG payment for these patients in the overwhelming majority of cases. Indeed, for the minority of cases where the Medicare payment actually covers the cost of care, two-thirds of those patients die in the hospital.

Our comments will respond to each concern raised by CMS in the proposed rule concerning the creation of new DRGs for severe sepsis.

CMS Comment: "The commenter [SCCM] requested that all cases in which severe sepsis is present on admission, as well as those cases in which it develops after admission (which are currently classified elsewhere), be included in this new DRG."

CMS claimed that the Society requested that all severe sepsis cases be placed in a single DRG for both principal and secondary diagnosis of severe sepsis.

Response: The Society presented different possible scenarios, each of which included both a medical and a surgical DRG, recognizing the vastly different resource use that is associated with surgical cases. One alternative the Society presented was for a pair of Pre-MDC DRGs to capture all cases of severe sepsis requiring organ support. These cases are among the most expensive in the whole inpatient prospective payment system, and the new DRGs would be similar in structure to the current tracheotomy with prolonged mechanical ventilation DRGs that do not make any specific requirement concerning the exact principal diagnosis for the case. The primary difference would be that instead of looking only at mechanical ventilation, other organ support technologies such as use of renal replacement therapy and vasopressors to manage septic shock would be included as well as a diagnosis of severe sepsis or septic shock.

The Society believes that grouping this clinically coherent, resource intensive group of patients into these **two** DRGs would best capture this group of patients who are uniform in their disease management but coming from body system infection or surgical sites in the administrative system in a way that parallels their clinical situation.

A second scenario the Society presented was simply to divide each of DRGs 415 and 416 into DRGs with and without severe sepsis cases. There is a large enough number of cases of severe sepsis in these DRGs with very different resource use and outcome from the non-severe sepsis cases that splitting these two DRGs into severe sepsis and non-severe sepsis DRGs would indeed be warranted as detailed further below.

CMS Comment: "We did not believe the current clinical definition of severe sepsis was specific enough to identify a meaningful cohort of patients in terms of clinical coherence and resource utilization to warrant a separate DRG. Sepsis is found across hundreds of medical and surgical DRGs, and the term 'organ dysfunction' implicates numerous currently existing diagnosis codes."

Response: The current definition of severe sepsis was adopted following a 1992 consensus panel of the American College of Chest Physicians and the Society of Critical Care Medicine, and reaffirmed ten years later in a 2002 consensus conference. The panel defined severe sepsis as a systemic inflammatory response to infection that leads to acute organ dysfunction.

The definition has been adopted by the 11 different professional organizations that sponsored the panel and has been successfully used to identify tens of thousands of patients enrolled in clinical trials seeking ways to reduce mortality and morbidity associated with severe sepsis. Further, this definition has been used in more than 30 large-scale clinical trials.

The Society of Critical Care Medicine is surprised by CMS's unsupported contention that severe sepsis does not define a clinically coherent patient population. Thousands of our member professionals daily identify and care for these patients, the majority of whom are Medicare beneficiaries. Quality improvement initiatives for the care of severe sepsis patients have been developed by the Voluntary Hospital Association and the Surviving Sepsis Campaign. These quality measures identify patients using the same criteria. Health care practitioners work each day to improve the care of severe sepsis patients using these criteria to identify these patients.

The same disease state can be found across many DRGs for two basic reasons. First, the disease state can be very common, and second, it could be that there is no particular place for those cases to go. It is surprising that CMS uses the fact that severe sepsis cases are spread across hundreds of DRGs, as a reason to not provide separate severe sepsis DRGs, when these cases are dispersed widely because the lack of particular DRGs for these cases leaves no alternative.

A comparative example is instructive. Acute myocardial infraction (AMI, ICD-9-CM 410.XX)

was used in 546,696 discharges in the FY 2005 MedPAR database. These cases were spread across 416 different DRGs, because it is a common diagnosis. However, in contrast to severe sepsis case where there are no specific DRGs, 77% of AMI cases were grouped into DRGs specifically associated with coronary artery disease.

With respect to clinical coherence, severe sepsis cases are clinically coherent with a common underlying problem (systemic inflammatory response to infection) leading to a common set of complications (acute organ dysfunctions independent of the site of infection) and managed in a common way (advanced life support in intensive care units to manage the acute organ dysfunctions that would otherwise be fatal).

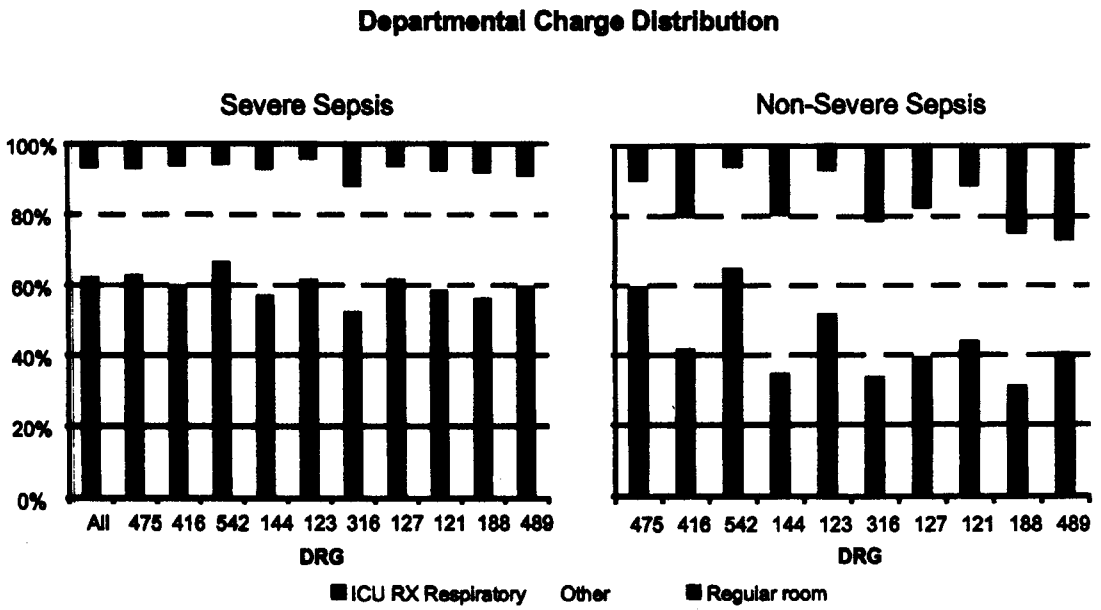
This clinical coherence leads to resource use coherence, making the severe sepsis cases in different DRGs more like each other than the other cases in their current DRGs. We examined the degree to which severe sepsis cases are more like each other than their source DRGs by identifying the 10 medical and 10 surgical DRGs with the most severe sepsis (995.92) and septic shock (785.42) cases that required organ support in the FY 2004 MedPAR database.

Taking all cases in these 20 DRGs, relative resource use was examined in three consolidated cost centers: routine care; ICU, coronary care, pharmacy, and respiratory therapy; and all remaining cost centers. The proportion of total charges in each of the consolidated cost centers was examined for those with and without severe sepsis across the DRGs.

Among the medical DRGs, routine care accounted for 7.4% of charges in the severe sepsis cases with a standard deviation of 2.1% between the DRGs; in contrast, the standard deviation for the difference between the severe sepsis and non-severe sepsis cases across DRGs had a standard deviation three times greater (6.3%). That is, severe sepsis cases were three times more like each other than like the other cases in their current DRGs.

The ICU, pharmacy, respiratory therapy consolidated cost centers behaved in a similar fashion, accounting for 59.7% of charges in the severe sepsis cases with a standard deviation of 4.1% and a standard deviation between severe sepsis and non-severe sepsis cases twice as great (8.1%). Therefore, as shown in Figure 1, medical severe sepsis cases are much more like each other than they are like the other cases in the DRGs from which they are drawn.

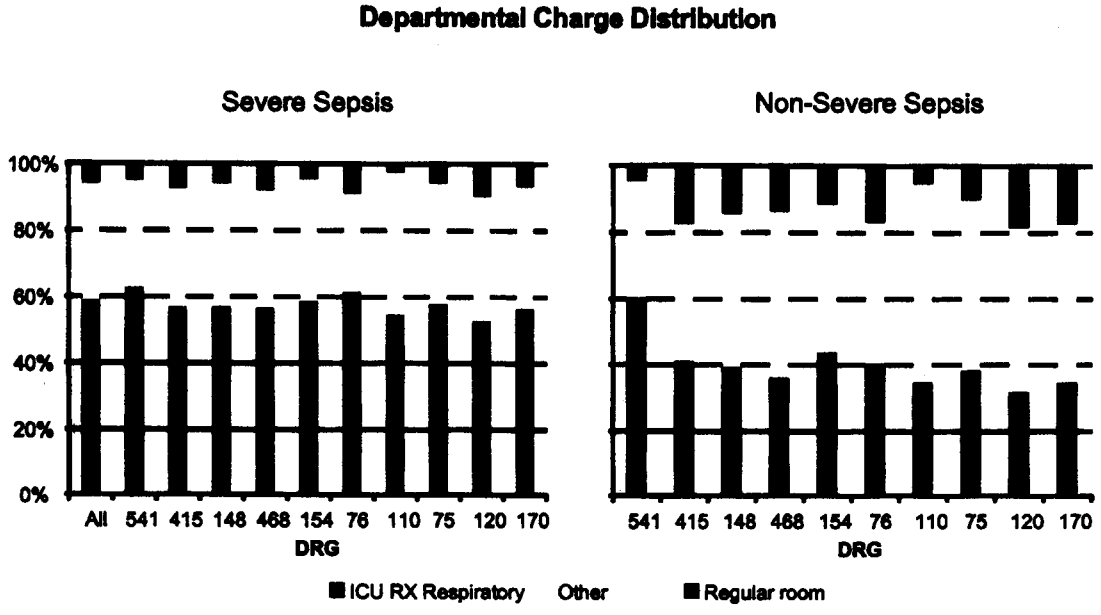
Figure 1 Resource use profile for major medical DRGs with and without severe sepsis



Among surgical DRGs, routine care accounted for 6.2% of charges in the severe sepsis cases with a standard deviation of 2.2% between the DRGs; in contrast, the standard deviation for the difference between the severe sepsis and non-severe sepsis cases across DRGs had a standard deviation 50% greater (3.4%). That is, severe sepsis cases were 50% more like each other than like the other cases in their current DRGs for routine care charges.

The ICU, pharmacy, respiratory therapy, and consolidated cost centers behaved in a similar fashion, accounting for 57.4% of charges in the severe sepsis cases with a standard deviation of 3.0% and a standard deviation between severe sepsis and non-severe sepsis cases twice as great (6.9%). Therefore, surgical severe sepsis cases are much more like each other than they are like the other cases in the DRGs from which they are drawn. (Figure 2)

Figure 2 Resource use profile for major surgical DRGs with and without severe sepsis



Therefore, severe sepsis cases across DRGs, as expected, are much more like each other, *i.e,* clinically coherent, and not like the non-severe sepsis cases in their current DRGs. Severe sepsis cases have both a clinical and resource use coherence that justifies their consolidation into a few DRGs instead of being spread across the whole inpatient prospective payment system.

In trying to understand the clinical and resource coherence of severe sepsis cases, CMS officials wondered whether severe sepsis cases simply represent the tails of the cost distributions from many different DRGs, *i.e.*, the most expensive cases. Any set of discharges (DRG) must have cases that are most expensive. CMS wondered if we were simply attaching the name "severe sepsis" to what were simply the most resource intensive cases in different DRGs.

However, we identified cases based on their disease characteristics, and then we found their cost distribution. Many severe sepsis patients die quickly and have relatively low costs (in two-thirds of all cases where the DRG payment actually covers the costs of treating patients with severe sepsis, the patients die quickly).

However, to respond to the CMS concern that these are just the most expensive cases in existing DRGs, and that removing this tail would just leave another, we investigated the extent to which severe sepsis cases are prevalent in the high cost tails of each DRG. Using the FY 2005 MedPAR discharge database, we found the 90th percentile point of standardized charges for each DRG and selected all cases where the standardized charges for the case exceeded the 90th percentile point for its DRG.

Severe sepsis cases were only 17% of cases in the high cost tail. While this is a much greater concentration than severe sepsis overall, severe sepsis cases are not in any sense simply the most expensive cases in any DRG. Therefore, severe sepsis cases that are identified based on their clinical characteristics are not simply the most expensive cases.

CMS Comment: "While we recognize that Medicare beneficiaries with severe sepsis are quite ill and require extensive hospital resources, in the past we have not found that they can be identified adequately to justify removing them from all of the other DRGs in which they appear."

Response: While there has been some confusion over the use of the 995.9 family of codes over the past three years, this confusion has been mainly associated with the other codes and not the severe sepsis (995.92) code. In particular, 995.91 (formerly systemic inflammatory response syndrome associated with infection without organ dysfunction) caused a degree of confusion since it could be applied to almost any case of hospitalized infection, and it was not clear to coders when and how it should be used.

An examination of the MedPAR database for the three years that severe sepsis codes have been available, 2003-2005, reveals that the adoption of codes for severe sepsis (995.92) and septic shock (785.52) is proceeding aggressively from only 6,676 uses in 2003 to 102,298 in 2004, and 159,170 in 2005. The mortality rate for these patients coded as having severe sepsis or septic shock is 43% based on the MedPAR data. This very high mortality rate, which is similar to that appearing in the clinical research literature, should go far in allaying CMS concerns that the severe sepsis codes would be used in patients with a low severity of illness.

While improved coding guidance is welcome, there are more than enough cases currently being identified to make changes to the DRG classification. Again, looking at the FY 2005 MedPAR database, we found that severe sepsis (995.92) is within the 150 most often coded diagnoses and that septic shock (785.52) is within the top 200 diagnoses after just two years. **Taken together (9995.92 and 785.52), severe sepsis is one of the top 100 diagnoses recorded in the 2005 MedPAR database. Therefore, there is more than enough data available to make changes.**

CMS Comment: "For this FY 2007 proposed rule, we again received a request to consider creating a separate DRG for patients diagnosed with severe sepsis. The information and data available to us from hospital bills with respect to identifying patients with severe sepsis have not changed since last year."

Response: Prior to this past year, communication with CMS was limited to FY 2003 data, where there was little use of the severe sepsis code in its first year, with only 6,676 cases identified. The most recent discussions that the Society of Critical Care Medicine had with CMS made use of FY 2004 data, which showed 102,298 cases of severe sepsis and septic shock. The 2005

MedPAR data shows 159,170 cases of severe sepsis or septic shock. Clearly, there has been a change with respect to identifying patients with severe sepsis. CMS now has at its disposal sufficient data to better understand the current use of the severe sepsis codes, but has simply not used it.

CMS Comment: "We believe that implementation of the modified SIRS diagnosis codes and the updated coding guidelines over the next year could begin the process of improving data for this group of patients. The desired outcome is to be able to better evaluate Medicare beneficiaries with severe sepsis with regard to their clinical coherence, resource utilization, and charges."

Response: The only coding modification that directly effects the severe sepsis coding is to change its name to "Severe Sepsis," and that there is no need to use both severe sepsis (995.92) and septic shock (785.52) in the same discharge. We believe that the 260,000 uses of severe sepsis and septic shock in 2004 and 2005 represent a very large and consistent body of data to use in defining new DRGs for severe sepsis cases.

If CMS finds the creation of the Pre-MDC DRGs too problematic at this point, then a much simpler modification would lead to substantial improve in the DRG system's ability to recognize the burden of severe sepsis. The simplest thing to do would be to split DRGs 415 and 416 into separate parts for those with and without severe sepsis.

Cases with severe sepsis or septic shock account for 24% (N=65,841) of the 276,977 cases in DRG 416 in FY 2005 (Table 1). For this DRG, cases with a severe sepsis diagnosis have triple the mortality (40.3% vs 13.6%), have five times the use of mechanical ventilation (24.4% vs. 13.6%), and have 45% higher standardized charges than cases without a severe sepsis diagnosis.

Splitting DRG 415, cases with a severe sepsis diagnosis have quadruple the mortality (31.3% vs. 7.4%), have five times the use of mechanical ventilation (34.8% vs. 7.1%), and nearly double the standardized charges ($99,314 vs. $56,612) than cases without a severe sepsis code.

A DRG created from the severe sepsis coded portion of DRG 416 would be within the top 35 medical DRGs by volume in the inpatient prospective payment system. A surgical severe sepsis DRG made from severe sepsis cases in DRG 415 would be in the top 80 surgical DRGs by volume and have more cases than 150 other surgical DRGs.

Table 1: Comparison of relative size, resource use and outcome for cases with and without coded severe sepsis in the Septicemia DRGs from the FY 2005 MedPAR database

Current DRG	Severe Sepsis	Cases	LOS All	LOS Alive	Hospital Mortality	Mechanical Ventilation	Mean Standardized Charge
415	No	44,481	13.4	13.0	7.4%	7.1%	$56,612
415	Yes	9,067	17.4	18.8	31.3%	34.8%	$99,314
416	No	211,136	7.4	7.5	13.6%	4.5%	$25,730
416	Yes	65,841	7.7	9.4	40.3%	24.4%	$37,286

CMS Comments: "It is possible that the consolidated severity-adjusted DRG system that we are planning to adopt would better recognize the extensive resources that hospitals use to treat patients with severe sepsis."

Response: The Society of Critical Care Medicine commends CMS for recognizing the importance of severity of illness in accounting for resource use in patients both with and without severe sepsis. An examination of the supplemental FY 2004 MedPAR data file containing the consolidated severity adjusted DRG information showed that 76% of medical severe sepsis cases with organ support would be grouped into severity level 4 DRGs, and an additional 21% would be grouped into severity level 3 DRGs, leaving only 3% of cases in severity level 1 and 2 DRGs. Similar results come from looking at surgical cases where 97% of all severe sepsis cases would be in severity level 3 or 4 DRGs. This change would result in a 63% improvement in payment for medical cases of severe sepsis, but only a 12% increase for surgical severe sepsis cases.

The use of the APR-DRG base set of DRGs instead of the base CMS DRGs is the root cause of the imbalance in payment improvement between medical and surgical DRGs under the proposed new system. Surgical cases from MDC 05 (Circulatory disease) make up 45% of all surgical ICU cases and so surgical severe sepsis cases. Because the APR-DRG base set of DRGs do not account for the complexity of care (angioplasty without stenting, bare metal stents and drug-eluting stents are all in the same base DRG in the APR system), many far less resource intensive cases are grouped with more resource use intensive cases, reducing the average resource use associated with the base DRG.

Adding severity adjustment then recovers most of what was lost by not accounting for complexity of care with no real net benefit. Even though most of the problems with poor base DRGs are limited to MDC 05, since this MDC is responsible for nearly half of all surgical patients in intensive care units, it has significant repercussions resulting in only a 2% improvement in payment for surgical severe sepsis cases in MDC 05 and only 12% overall for surgical severe sepsis cases. **Further refinement of any proposed system for incorporation of severity of illness into the inpatient prospective payment system is required to recognize the**

extensive resources that hospitals use to treat surgical patients with severe sepsis and overall.

Conclusion

We stand ready at the Society to assist CMS in analyzing the 2005 MedPAR data to best move severe sepsis cases into new DRGs. We strongly urge that these new DRGs be created for fiscal year 2007. The sweeping nature of the proposed severity-adjusted DRG system makes implementation of appropriate changes to recognize severe sepsis cases unlike in 2007. The data is available now that show that a significant volume of patients can be appropriately identified as having severe sepsis and that these patients are a clinically coherent group with similar resource utilization. Thus, these patients meet CMS's requirements for the creation of separate DRGs. We believe that creating these separate DRGs will lead to more appropriate payment to hospitals and better care for these patients.

If you have any questions concerning these comments, please contact Eric Chandler at the Society at 847-827-6866.

Respectfully submitted by,

Charles G. Durbin, Jr.,M.D., FCCM

Submitter : **Mr. JOHN FRANKE** **Date: 06/12/2006**

Organization : **Central Baptist Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-1719-Attach-1.DOC

#1719

BAPTIST HEALTHCARE SYSTEM

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502-896-5000

Electronically Submitted

June 12, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Provider Comments
Proposed Changes to Inpatient PPS
DRG Reclassifications and Severity of Illness

On behalf of the Central Baptist Hospital, a member of Baptist Healthcare System, Inc. (BHS), we appreciate the opportunity to comment on the fiscal year (FY) 2007 proposed changes to the hospital inpatient prospective payment system.

BHS supports meaningful improvements to Medicare's inpatient prospective system and shares CMS's desire to develop a payment system that provides an equal financial incentive (margin) to treat all patients, regardless of diagnosis or severity of illness. BHS further acknowledges that this payment system must be statistically robust, clinically meaningful and at the same time, administratively feasible.

BHS submits the following recommendations to the current proposals:

1. The proposed changes to the DRG weights based upon Hospital Specific Relative Value cost center (HSRVcc) and introduction of Consolidated Severity Adjusted DRGs (CS-DRGs) should be implemented simultaneously.

2. The proposed changes to the DRG weights (HSRVcc) and introduction of CS-DRGs should be implemented on or after October 1, 2008.

3. Valid cost-based weights must be developed and utilized.

4. Further refinement of the proposed CS-DRG methodology needs to be done to ensure it promotes (rather than inhibits) the accomplishment of CMS's stated goals.

Discussion and rationale for recommendations:

Recommendation 1: Simultaneous Implementation

a. The proposed HSRVcc changes in FY2007 are projected to reduce reimbursement to BHS from the current FY2006 amount by nearly $8.5 million.

b. The proposed implementation of CS-DRGs in FY2008 is projected to increase reimbursement from the FY2007 amount by nearly $8.2 million (which represents a reduction of approximately $300,000 from the current FY2006 amount). This significant volatility in reimbursement has several implications.

   First, BHS will **permanently** lose $8.2 million in reimbursement in FY2007.

   Second, BHS will **potentially** receive an increase in reimbursement in FY2008. BHS has utilized the 3M APR-DRG grouper for many years, largely as part of internal quality initiatives and the Premier Hospital Quality Incentive Demonstration. As a result, BHS had the internal APR-DRG data to convert to CS-DRGs and calculate the impact of the FY2008 proposal.

   However, the underlying assumptions in the impact analysis are: (1) coding in the future is consistent with current coding practices, and (2) that Medicare will allow current coding in the future reimbursement model. Because these are assumptions and not givens, BHS has significant concerns regarding the ability to accurately forecast the proposals impact beyond FY2007, which is critical.

   Third, the increase in reimbursement in FY2008 under the CS-DRG system indicates that BHS hospitals treat more severe patients on average. This finding is consistent with the mission and values of its member hospitals.

   BHS is comprised of five hospitals within the state of Kentucky. It operates urban hospitals in Louisville, La Grange and Lexington, rural referral centers in Corbin and Paducah. Collectively, BHS has the largest number of inpatient admissions in Kentucky and is one of the largest providers of Medicaid services within the state.

   The primary and secondary markets for BHS hospitals is comprised of 40 of the 120 counties in Kentucky and range across the central, western and southeastern parts of the state. Five of the poorest ten counties are located with the BHS service area.

   Medicaid, charity and uninsured patients represent over 17% of BHS inpatient business. As part of BHS's Christ-centered mission, each BHS hospital has not only expanded its general acute care services, but also its highly specialized tertiary programs in an effort to provide a full range of surgical and medical services to all patients regardless of their ability to pay or severity of illness. Central Baptist Hospital, a disproportionate share facility, serves an even higher percentage of Medicaid, charity and uninsured patients than BHS as a whole, with this population accounting for over 18.5% of our inpatient business. Central Baptist Hospital offers a broad range of tertiary care services to all

patients, regardless of ability to pay, including being a regional leader in the offering of high acuity services and new technologies in neonatology, oncology, neurology, cardiology, and orthopedics.

Given the mission of BHS and demographics of the communities it serves, it is clear that BHS hospitals are not specialty hospitals that target services that provide higher margins. However, given the high severity of illness for the patient population BHS hospitals serve, unless the HSRVcc and CS-DRG proposals are implemented simultaneously, unfair financial hardship will be experienced, threatening our ability to provide the same level of access to cutting edge technologies currently offered.

Fourth, CMS suggests that a budget neutrality factor may be applied to offset improvements in c oding p ractices. T his t oo, r epresents a s ignificant unkno wn in t he current proposal that needs to be accurately evaluated and communicated for which additional time is necessary.

Recommendation 2: Delay until October 1, 2008

a. It is imperative that the GROUPER technology be made available to hospitals and vendors. Without direct access to the GROUPER by hospitals, it will be virtually impossible to understand its logic. Without access by multiple vendors, it will be more difficult to purchase at a competitive price and will be more difficult to integrate into existing hospital systems.

b. In addition, many current hospital software programs will need to be modified to handle the new payment and billing system. An implementation date before October 1, 2008 will not allow adequate time to make all the necessary system changes and upgrades.

c. CMS stated that one option to the software issue is for hospitals to submit claims without being grouped and allow CMS to assign the CS-DRG. This raises several serious concerns.

   First, without the CS-DRG information, revenues and patient receivables cannot be recorded accurately. Statement of Position (SOP)-00-1(6) states, "Health care entities need to estimate amounts that ultimately will be realizable in order for revenues to be fairly stated in accordance with generally accepted accounting principles (GAAP)." Paragraph (9) states "Management is responsible for the fair presentation of its financial statements in conformity with GAAP".

   Currently, the DRG assignment is critical in making an accurate estimate of the net realizable value of accounts receivable. Given the significance of and the increased uncertainty of the impact of the proposed changes for FY2007 and FY2008, it will be even more important for patient bills to be grouped prior to billing.

   Second, the Medicare inpatient business represents over 41% of BHS total inpatient business. As such, changes to the Medicare payment system have a significant impact on BHS's ability to accurately estimate payments in evaluating strategic initiatives, business

plans, budgets, marketing, staffing and other critical decisions. With the significance of the proposed changes, more time is required to understand and perform impact analysis.

d. Four of five BHS hospitals are disproportionate share hospitals (DSH). Last year these hospitals received approximately $14.7 million in DSH reimbursement. It is anticipated that the CS-DRGs will have a material impact on DSH payments and in order for hospitals to adequately plan and make appropriate adjustments in a timely manner, BHS recommends that further analysis be prepared and accurate impact estimates published prior to implementation of the proposed changes.

e. Additional time is required to determine the impact from other third party payers (including Medicaid) that have historically modeled reimbursement rules and methodologies from the Medicare payment system. It is anticipated that these third party payers will adopt the new Medicare payment system at some time in the near future following implementation by Medicare. However, given the complexity of the proposed changes, additional time is necessary for payers and hospitals to better understand these changes and make appropriate systematic changes.

Recommendation 3: Valid Cost Weights

a. Under the HSRV weight calculation method, the ten cost center categories were developed based on broad accounting definitions, where each cost center category represents at least five percent of the charges in the claims data. BHS acknowledges the need to remove bias introduced by individual hospital characteristics (i.e. unique cost centers reported on the cost report), but it appears that this resulted in incorrect cost center groupings in the CMS study that raises concerns regarding the accuracy of the cost-to-charge ratio (CCR) data.

   For example, according to CMS-1488-P, Table-A (pp.66-67 and pp.186-187) the HSRV Cardiology cost center includes cost report lines 53 and 54. However, one BHS hospital includes its Catherization Lab revenues and expenses on cost report line 42.01, which according to the table appears to be incorrectly grouped with the HSRV Radiology cost center that includes cost report lines 41,42 and 43.

   BHS is very concerned that grouping errors such as the one described here could materially impact the CCR used to calculate the DRG weights. Therefore, BHS recommends that CMS work through the Medicare intermediaries to audit the cost report line definitions for all hospitals to ensure groupings are accurate.

b. The weighting calculation used to determine the scaling factors gives equal weight to each hospital regardless of size or volume. This methodology results not only in an inaccurate national cost-to-charge ratio, but is inconsistent with the method used when averaging the ten cost center DRG weights to which the scaling factors are applied. Therefore, BHS recommends that a consistent weighting methodology be utilized to calculate the scaling factors.

c. HSRVcc costs were based on the 2004 cost reports. Significant changes in medical technologies, products and services have been introduced, which have significantly impacted the CCR. Therefore, BHS recommends that a more recent audited cost report be used, after audit procedures have been performed as recommended in (a.) above.

d. Central Baptist Hospital is also concerned that partial data from a number of large hospitals whose cost to charge ratios were classified as outliers were excluded from the analysis. The exclusion of this data, which, because of the size of excluded facilities, collectively accounts for a large percentage of Medicare inpatient admissions nationally, materially impacts the resulting calculations, and, in particular, causes routine care cost to charge ratios to be much higher as used in the CMS calculations than the actual national averages reflect. Furthermore, this problem is compounded by the fact that CMS continues to use partial data from these same facilities

Recommendation 4: Consolidated Severity-Adjusted DRG Methodology

a. CS-DRGs are developed by grouping APR DRGs considering average length of stay and average charges. This grouping methodology is inconsistent with the cost-based intention of the proposed changes. Average cost, using the HSRVcc methodology (applying the recommended changes), for each APR DRG by severity level should be the determinant for grouping APR DRGs into CS DRGs.

b. CMS believes that the adoption of consolidated severity-adjusted DRGs would create a risk of increased aggregate levels of payment, similar to the 2% increase associated with the implementation of the current DRG system in 1983 and has recommended the application of a compensating budget neutrality factor. Because of the significance of even a 2% reduction in reimbursement, BHS recommends that this be further studied before implementation.

Thank you for your consideration of our recommendations. We certainly hope you can see and appreciate the legitimacy of the concerns raised. If you have any questions, please feel free to contact me at (859) 260-6113 or at jfranke@bhsi.com.

John B. Franke
Director of Finance
Central Baptist Hospital

Submitter : Mr. Jeffrey Reed

Date: 06/12/2006

Organization : Exempla Lutheran Medical Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Please see attachement regarding proposed DRG rebasing

Submitter : Mr. Mark Leahey **Date:** 06/12/2006

Organization : Medical Device Manufacturers Association

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-1721-Attach-1.PDF

#1721

MDMA

MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today For Better Health Care Tomorrow™

June 12, 2006

Via Electronic Submission

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

RE: [CMS-1488-P], Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year (FY) 2007 Rates

Dear Dr. McClellan:

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, I am filing the following comments to the proposed changes to the hospital inpatient prospective payment system. MDMA represents hundreds of medical device companies, and our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

Introduction and Summary of Issues and Recommendations

We appreciate the opportunity to comment on the FY 2007 Inpatient Prospective Payment System (IPPS) proposed rule published on April 12, 2006.[1] The Centers for Medicare and Medicaid Services (CMS) has described the proposed rule as the "first significant revision of the

[1] 71 Fed. Reg. 23995 (April 25, 2006).

inpatient PPS since its implementation in 1983."[2] Compared to other years' revisions, this year's proposed rule incorporates significantly more complex and far-reaching changes to the IPPS. Although MDMA supports CMS' goal of improving the accuracy of the IPPS, MDMA also believes it is critical that stakeholders have ample opportunity to fully analyze the proposed changes to verify that they do, in fact, produce more accurate payment rates. CMS also must have sufficient time to consider the comments, analyze potential implications, and present possible solutions to concerns raised by stakeholders. These changes are too significant to be implemented in haste.

Once CMS and stakeholders have validated the accuracy of any revisions to the IPPS, CMS must implement these changes, including the shift to a cost-based payment methodology and severity and complexity adjusted diagnosis-related groups (DRGs), simultaneously in order to assure that Medicare beneficiaries continue to have access to appropriate treatments. Additionally, to minimize the burden on providers and ensure that the IPPS reforms use the most specific coding available, we urge CMS to implement the IPPS reforms at the same time as the ICD-10 coding system, no sooner than FY 2010.

MDMA recommends that CMS delay implementation of the proposed changes until FY 2010 to give CMS and stakeholders the opportunity to fully analyze and refine the proposed changes.

During this delay, MDMA recommends that CMS address the following issues and recommendations:

- In the proposed rule, CMS uses out-of-date cost data to calculate new weights and DRG groupings.
    - *Recommendation*: CMS should implement a cost-based system in FY 2010 after it assures that the rates are based on the best available cost report data.

[2] CMS, Medicare Proposes Payment and Policy Changes for Acute Care Hospital Services to Inpatients, April 12, 2006, http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1833.

- *Recommendation*: CMS should expedite settlements of the most recent cost reports (ahead of prior years) to ensure that the agency has the most current data for the 2010 implementation date and accumulate data from no less than 60 percent of hospitals (with a representative mix of community, urban, rural and teaching) to serve as the basis for revised weights and DRG assignments.
- *Recommendation*: CMS should provide hospitals with clear instructions to ensure that all hospitals complete cost reports in a consistent manner to make certain that the methodology for calculating cost-based weights is accurate.

- The proposed DRG assignment methodology does not recognize the complexity of procedures using advanced devices.
  - *Recommendation*: Within the severity adjusted DRGs, a mechanism should be established to escalate the severity level of device-dependent DRGs and to redefine the DRGs to include both patient severity as well as complexity of care.

- CMS has not clearly defined how specific diagnoses and procedures affect severity-based DRG assignments.
  - *Recommendation*: CMS should make transparent how diagnoses for co-morbidities and complications, including preexisting conditions, are reflected within the severity levels.
  - *Recommendation*: CMS needs to make transparent the algorithm for determining what constitutes a specific severity level. Hospital billing and coding departments need to fully understand the hierarchy of diagnosis coding within each DRG to understand how the system will work and to code and bill for each service appropriately.

- Although the Medicare Payment Advisory Commission (MedPAC) recommended the simultaneous implementation of cost-based weights and severity-adjusted DRGs to avoid creating new distortions in the payment system, CMS considers implementing them separately.

- *Recommendation*: After further discussions with stakeholders to refine the proposals, CMS should implement the cost-based weights and severity and complexity-adjusted DRGs simultaneously.

- Hospitals will face an enormous burden and increased costs if the IPPS changes are not implemented at the same time as the ICD-10 coding system.
  - *Recommendation*: CMS should establish a schedule to expedite implementation of ICD-10 (for hospital inpatient use only) simultaneously with the new DRG system to ensure accurate coding and greater granularity. The current limitations on the availability of ICD-9 codes could impair accounting for new procedure codes that describe newer, high technology complex services. The expanded ICD-10 code set will allow recognition of more procedures and technologies and describe diagnoses in greater detail, which will help to improve the accuracy of IPPS rates.

- CMS cannot implement necessary reforms to the threshold for outlier payments, as recommended by MedPAC, without a statutory change.
  - *Recommendation*: As recommended by MedPAC, CMS should postpone implementation of IPPS reforms until it has been granted authority to make the recommended changes to outlier payments.

- CMS proposes to postpone several key refinements to DRG classifications until it implements the severity-adjusted DRGs.
  - *Recommendation*: CMS should implement refinements to DRG classifications, such as the requested changes to DRG 533 (extracranial procedures with complications and comorbidities) now to protect access to advanced technologies.

- CMS should reconsider the New Technology Add-On criteria in light of the reductions in reimbursement under the new payment system. CMS should provide greater opportunity for devices to qualify for new technology add-on payments to protect patients' access to new technologies.

- *Recommendation*: CMS should reestablish the criteria for how a new technology meets the cost criteria based on the revised DRG weighting methodology.
- *Recommendation*: CMS should make a revised dataset publicly available for no charge.
- *Recommendation*: CMS should extend the definition of "new" by one year to allow reconsideration of applications for new technology add-on payments.

- Although specialty hospitals are different from "full service" acute care hospitals in many important respects, CMS' continues to reimburse them under a single payment system.
  - *Recommendation*: Specialty hospitals should be removed from the current IPPS system, and CMS should establish a PPS specific to their unique patient population (similar to Long Term Care DRGs, Rehabilitation PPS, etc.)

These recommendations are detailed below.

CMS MUST ALLOW MORE TIME FOR THE AGENCY AND STAKEHOLDERS TO ANALYZE THE PROPOSED METHODOLOGIES (HSRV Weights; DRG Weights)

MDMA believes that it is imperative that both CMS and industry have time to fully analyze the proposed methodologies in order to appropriately comment on their strengths and weaknesses. CMS staff acknowledged during the Open Door Forum on May 3 that they "rushed" to release the rule. The sixty day comment period and CMS' delay in releasing the data have not given stakeholders sufficient time to fully evaluate the complex proposed changes. Furthermore, because many stakeholders could not afford the $3,655 fee of purchasing the Expanded Modified Medicare Provider Analysis and Review (MedPAR) file data and hiring specialty vendors to analyze it, all stakeholders have not had an equal opportunity to review CMS' methodology. As a result, neither CMS nor stakeholders have had the opportunity to fully examine and re-examine the information to assure the methodology is transparent, reproducible, and accurate. By providing additional time to review the methodology, CMS and all stakeholders will be able to recommend and evaluate changes to make it stronger and more accurate.

CMS MUST ENSURE THAT ITS DATA REPRESENT THE COSTS OF ADVANCED TECHNOLOGIES (HSRV Weights; DRG Weights)

CMS proposes to set payments for FY 2007 by using cost report data from FY 2003 and fiscal year 2005 MedPAR data.[3] Because these data sets do not include the costs of new technologies introduced in the past few years, the payment rates for FY 2007 are not likely to reflect those costs adequately. To address this problem, we recommend that CMS settle the most recent cost reports sooner than earlier years to reconcile the data in time for a 2010 implementation. Prior to instituting the program in 2010, current cost reports should not only be settled but should be resolved with a mechanism to adjust current cost reports for charge compression of expensive devices. CMS also should update the data set to include no less than sixty percent of a representative hospital mix (rural, urban, teaching, and community hospitals). MDMA realizes that by doing this, CMS will be settling newer reports ahead of prior years' reports. However, it is important to do so in order to appropriately reimburse newer treatments and technologies that may not be captured in the older data. Without this data, the cost-based weights not only will introduce significant disadvantages for newer treatments and technologies, but may even penalize technology-intensive, short stay procedures.

MDMA also recommends that CMS accept external data to assure that device and procedure costs are accurately captured. As we have commented in the past, we believe that if supplemental data exists in addition to or in the absence of CMS's own internal data, it should be considered in rate setting. MDMA further believes that CMS should be receptive to external data especially for new technologies when internal data does not exist or is an insufficient basis for payment. Additionally, MDMA emphasizes that CMS will not be able to collect quality data unless the agency agrees to maintain confidentiality of the source of the data. Manufacturers and hospitals will be unwilling to release to CMS proprietary information that could be useful to competitors. Making a firm commitment to keep external data confidential would prevent that conflict and will serve to improve the data set for the IPPS.

[3] 71 Fed. Reg. at 24008, 24045.

CMS SHOULD ADD PROCEDURE COMPLEXITY TO THE SEVERITY-ADJUSTED DRG METHODOLOGY (DRGs: Severity of Illness)

MDMA appreciates that CMS would like to refine the DRG system to take into consideration a patient's severity of illness.[4] We believe that IPPS reimbursement also should reflect the complexity of medical procedures. Specifically, MDMA recommends that device dependent surgical DRGs should be elevated in severity or, preferably, DRGs should include both a patient severity and a procedural complexity weighting to account for the cost of the device(s), the complexity of the procedure and aftercare of the patient.

Under the proposed severity-adjusted DRGs, many procedures using advanced devices would face dramatic reductions in reimbursement. For example, in 2006, the implantation of a permanent spinal cord stimulation system in a chronic pain patient with a co-morbid condition would many times map to DRG 531, spinal procedures with CC. For 2006, the average payment for DRG 531 is $14,799.57. In 2007, if CMS moves to the APR-DRG system, the same diagnosis and procedure would map to APR-DRG 31, spinal procedures with a severity of illness level 2, with an average payment of $10,324.65. This represents a reduction in payment of $4,474.92, a 30 percent decrease in just one year and would not cover the device related cost of this procedure which could range from $11,000 to $24,000. The cost of the devices remains the same regardless of the severity of illness, so the payment rate for any DRG involving these devices must cover the device's cost at a minimum. An accurate payment system must begin by appropriately recognizing the cost of care and adjusting payment based on severity and complexity from that baseline.

A second example of the dramatic reduction in payments for a device dependent surgical DRG under CMS' proposed severity-adjusted DRGs is DRG 115/551, permanent cardiac pacemaker implant with AMI/heart failure/shock or AICD lead or pulse generator procedure. The cost of a dual chamber or other pulse generator is approximately as follows:

- System (generator and leads) totals approximately $12,500-$16,000;
- Pulse generator/BV Pacemaker are approximately $8,000-$15,000; and

[4] Id. at 24014.

- Leads are $1500-$4000.

In 2005, DRG 115 was reimbursed $16,365. In 2006, reimbursement for DRG 551, which replaced DRG 115, fell to $14,670. Under the proposed cost-based weight methodology for FY 2007, the reimbursement for DRG 551would fall again to $12,864, a 21 percent reduction since 2005. Under the proposed corresponding FY 2007 CSA-DRGs, payment levels for severity of illness (SOI) levels 1 and 2 also decline measurably, as follows:

- 228 PERMANENT CARDIAC PACEMAKER IMPLANT W AMI, HEART FAILURE OR SHOCK SOI 1 $11,305.39
- 229 PERMANENT CARDIAC PACEMAKER IMPLANT W AMI, HEART FAILURE OR SHOCK SOI 2 $13,256.61
- 230 PERMANENT CARDIAC PACEMAKER IMPLANT W AMI, HEART FAILURE OR SHOCK SOI 3 $17,651.88

These payment levels do not accommodate the cost of the devices noted above used in addition to the complexity of care provided over an average length of stay of four to six days. Further, these patients typically have Stage 3 or 4 heart failure and have multiple comorbidities and complications that make them eligible for treatment. Based on our review of the 3M All Patient Refined (APR) DRG groupings, used by CMS to create the CSA-DRGs, it appears that the SOI 1 and SOI 2 groups do not reflect the minimal amount of complications most of these patients have just by virtue of being eligible for the procedure. After inputting common primary and secondary diagnoses and common procedures for cases that map to these DRGs, we found that it is rare that patients will fall into DRG 230, leaving hospitals at a considerable financial loss for supplying this therapy. These examples demonstrate that certain fixed costs, such as the cost of the devices used, remain the same regardless of severity of illness, and those costs are not being captured in the proposed severity-adjusted DRGs. This creates a real risk to patient access of critically needed therapies.

CMS SHOULD DEFINE HOW SPECIFIC DIAGNOSES AND PROCEDURES IMPACT SEVERITY (DRGs: Severity of Illness)

CMS needs to make transparent the algorithm for determining what constitutes a specific severity level. Hospital billing and coding departments need to understand fully how diagnosis

codes map to DRG assignments to ensure that services are properly coded and billed. In the model provided by 3M, it is not apparent why some co-morbidities escalate the severity assignment and others do not. A transparent algorithm will help all stakeholders understand the benefits of using specific coding and will encourage providers to exercise greater diligence in documenting and coding services.

Removing Payment Disincentives for Technologies that Reduce Complications

In response to MedPAC's request, CMS proposed to remove the disincentives inherent in the current DRG system. Many companies develop technologies that reduce hospital complications and the current system discourages their adoption. The DRG system should not pay hospitals an added amount when a preventable complication occurs, including all nosocomial infections. We believe that all infections should be removed as complicating conditions under the DRG system. The case is particularly important for urinary tract infections (UTIs), where over 1 million Medicare patients' claims include a diagnosis of UTI. Even for infections that are less common, no patient's claim should be put into a higher paying DRG because of an infection. This provides better incentives for quality care.

CMS SHOULD SIMULTANEOUSLY IMPLEMENT COST-BASED REIMBURSEMENT AND SEVERITY ADJUSTED DRGs (HSRV Weights; DRG Weights; DRGs: Severity of Illness)

In order to maintain access to care for patients across the spectrum of severity of illness and complexity of care, it is important that CMS implement the shift to cost-based reimbursement and severity adjusted DRGs simultaneously. MDMA recommends that CMS maintain a charge-based system for FY 2007- FY 2009 and make a full change to cost based weights with severity adjustments no sooner than FY 2010. This will provide the time necessary to revise the cost report structure to support the new DRG system and assure the data incorporated are the most relevant. This also is consistent with MedPAC's recommendation to implement the reforms simultaneously to avoid creating new distortions in the IPPS.[5]

[5] Letter from Glenn M. Hackbarth, MedPAC, to Mark McClellan, CMS, April 19, 2006, at 4.

CMS SHOULD REVISE THE THRESHOLD FOR OUTLIER PAYMENTS (Cost-Based Weights: Outlier Threshold)

In addition to the cost-based weights and severity-adjusted DRGs, MedPAC recommended that CMS adjust outlier payments in light of the other payment reforms. CMS notes in the proposed rule that it has not completed a detailed analysis of this recommendation because it lacks authority under the Medicare statute to implement the changes.[6] Although CMS states that the revised DRG system would provide better recognition of cases that currently are paid as outliers,[7] it is not clear that the DRG changes alone are enough to improve the accuracy of payment for these cases. As MedPAC stated in its recent letter to CMS, "failure to adopt any of [MedPAC's] recommendations would leave some payment distortions in place, thereby continuing to favor some patients over others."[8] MDMA agrees with MedPAC that all of the proposed changes should be implemented simultaneously. Therefore, CMS should postpone implementation of the cost-based weights and severity and complexity-adjusted DRGs until Congress has granted it authority to revise the outlier payments as well.

HOSPITALS WILL NEED MORE TIME TO IMPLEMENT THE CHANGES TO THEIR BILLING SYSTEMS REQUIRED BY IPPS REFORMS (HSRV Weights; DRG Weights; DRGs: Severity of Illness)

As we learned from implementation of the Medicare Hospital Outpatient Prospective Payment System, major changes to Medicare's payment systems require hospitals to make substantial investments in new billing software, as well as training staff and physicians to appropriately document care and apply new coding and billing requirements. We anticipate that this burden will be particularly great if CMS implements all of the proposed changes to the IPPS. Under CMS' usual publication schedule for the IPPS rule, hospitals will have less than two months to develop or purchase new software, install and test that software, and retrain staff to use it. In light of the number and complexity of the changes being considered, many hospitals will need more than two months to prepare. This is another reason why CMS should postpone

[6] Id. at 20419.
[7] Id. at 20420.
[8] Letter from Glenn M. Hackbarth, MedPAC, to Mark McClellan, CMS, April 19, 2006, at 4.

implementation of the proposed changes. Hospitals simply need more time to learn about the changes and prepare to implement them.

MDMA also would like to highlight the industry's ongoing concerns about the limitations of the nearly exhausted ICD-9-CM coding system and the need to move to ICD-10-PCS as soon as possible. As we have commented in the past, expanding and improving this coding system would provide CMS with more flexibility and accuracy in its nomenclature, especially in identifying the broad range of new medical technologies being introduced. With the formal recommendation of the National Committee on Vital and Health Statistics (NCVHS) to move to ICD-10-PCS, CMS should initiate that process promptly. At the same time, we understand insurers and providers' concerns about the cost and administrative burden of implementing over 200,000 new diagnosis and procedure codes. If providers are required to begin using these codes in 2009, as contemplated by H.R. 4157, and if CMS implements the IPPS methodology reforms it is proposing in 2007 and 2008, hospitals would be required to undertake major billing system changes in each of the next three years. Rather than imposing three costly system upgrades, CMS should implement the IPPS reforms simultaneously with the ICD-10-PCS in FY 2010. Delaying implementation of the IPPS reforms to coincide with ICD-10-PCS would ensure that the new system employs the most accurate coding, as needed to meet the goal of a more accurate payment system.

CMS SHOULD IMPLEMENT RECOMMENDED DRG RECLASSIFICATIONS NOW TO PROTECT BENEFICIARY ACCESS TO ADVANCED CARE (DRGs: Carotid Artery Stents)

MDMA believes that CMS should correct existing discrepancies in DRG assignments prior to implementing the proposed changes to the IPPS. In the proposed rule, CMS declines to implement several recommended refinements to DRGs, choosing instead to address these concerns through the CSA-DRGs. For example, CMS proposes to delay reconsideration of assignment of Carotid Artery Stent (CAS) cases until the consolidated severity-adjusted DRG

system is implemented.[9] This decision, if finalized, will result in an unnecessary persistence of inadequate payment for CAS procedures for at least one year.

CMS notes that manufacturer representatives have requested that all CAS cases be assigned to DRG 533 (extracranial procedures with complications and comorbidities). Although CMS found that average charges in DRGs 533 and 534 (extracranial procedures without complications and comorbidities) were greater for cases involving CASs than for cases without stents, it did not propose to reclassify these cases into the higher-paying DRG. We urge CMS to reconsider this decision. The current National Coverage Determination (NCD) on CAS very clearly states that only those patients who are at high risk for surgery due to the presence of a detailed list of complications or comorbidities are eligible for CAS.[10] Therefore, by CMS' own characterization, all patients undergoing CAS have complications and comorbidities and should be assigned to DRG 533. We strongly recommend that CMS take the necessary steps to provide adequate payment for CAS now, while continuing to work on refining the CSA-DRGs to assign cases based on complexity as well as severity. This will ensure that when the proposed changes eventually are implemented, they are made using a foundation of correct DRG assignments.

CMS SHOULD EXPAND ITS CRITERIA FOR NEW-TECH ADD-ON PAYMENTS (New Technology)

Section 503 of the Medicare Modernization Act included a provision to expand the inpatient new technology add-on payment program to include a broader range of technologies. This legislation created a mechanism to help combat the problem of "payment lag," during which new and innovative technologies suffer inadequate payments for several years after they reach the market. Adequate payment is essential to hospital adoption of medical technologies and in turn to the companies that develop and manufacture them. This is particularly crucial for the smaller device companies that drive medical device innovation. Innovation could be impacted as many smaller companies do not have the financial resources to support the nationwide marketing, distribution, and status of larger, more well-recognized large companies in the medical industry. Adequate

[9] 71 Fed. Reg. at 24033.
[10] NCD for Percutaneous Transluminal Angioplasty, 20.7.

payment for new and innovative medical technologies through consistent and fair application of new technology add-on payment rules is essential to the success of innovative and life-saving medical technologies. CMS's narrow interpretation of the statutory criteria for granting new technology add-on payments has created a situation whereby virtually no products can qualify. In fact, the criteria are so steep and the process so opaque that many companies, especially small companies, cannot afford to undertake the process at all. This system is in direct conflict with Congressional intent to expedite access to new technologies. Therefore, MDMA requests that CMS provide a greater opportunity for devices to qualify for the New-Tech Add-On payments to ensure patients' access to new technologies, especially in light of the proposed revisions to the IPPS.

MDMA recommends that CMS widen the New-Tech Add-On criteria. The previous criteria were based on the charge-based system and now need to be revised to ensure that new technologies are accounted for within a cost-based DRG system. Given the reductions in reimbursement for many DRGs under the new payment system, it is important to maintain the opportunity for devices to qualify in order for patients to have access to new technologies. CMS should reconsider whether applicants meet the cost criteria based on the revised data set. For example, we urge the agency to reconsider the application submitted by St. Francis Medical Technologies for the X STOP Interspinous Process Decompression System, an innovative device that fills a critical treatment gap between conservative care and more invasive surgeries for patients with lumbar spinal stenosis. CMS should make a revised data set publicly available. CMS should extend the definition of "new" by one year for a period of 2 years in order that technologies may apply or reapply given the updated opportunity to qualify.

SPECIALTY HOSPITALS

MDMA appreciates CMS's desire to realign resources within the IPPS to more accurately reimburse hospitals for specific procedures, yet we are concerned that CMS is basing its recommendations primarily on MedPAC's physician-owned specialty hospital study. MDMA strongly believes that there will be a number of unintended consequences if CMS moves forward with restructuring the entire IPPS solely to address specialty hospital issues. These facilities are

not representative of most hospitals and are concentrated in certain areas where permitted by state-specific certificate of need regulations. These areas are not representative of the broad "cost of doing business" differentials across the United States. Specialty hospitals should be considered a separate entity from traditional "full service" acute care hospitals. CMS should remove specialty hospitals from the current data set for acute care DRGs and should develop a separate payment methodology for them.

CONCLUSION

MDMA appreciates CMS efforts to respond to MedPAC's recommendations in the 2007 IPPS proposed rule. However, we are concerned about the proposed rule's potential dramatic effects on hospital payments. Although MDMA supports improving the accuracy of IPPS rates, the proposed rule may have numerous unintended consequences that cannot be fully evaluated given the current lack of data, lack of transparency, and lack of reproducibility at this time. We ask that the agency delay implementation until 2010 to consider stakeholder input and continue public discussions of the proposed methodologies. CMS should maintain a charge based system until FY 2010 and then implement cost-based weights and severity adjusted DRGs that incorporate the complexity of care, particularly for device dependent DRGs.

* * * *

We thank CMS for the opportunity to comment on this proposed rule. As always, MDMA looks forward to working with the agency in the future to improve access to the best and innovative technologies that our industry has to offer.

Sincerely,

Mark Leahey
Executive Director
Medical Device Manufacturers Association

Submitter : Dr. Keith Naunheim **Date:** 06/12/2006

Organization : The Society of Thoracic Surgeons

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1488-P-1722-Attach-1.DOC

#1722

THE SOCIETY OF THORACIC SURGEONS

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June 12, 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 8011
Baltimore, MD 21244-1850

Dear Dr. McClellan:

On behalf of The Society of Thoracic Surgeons and the over 5,000 cardiothoracic surgeons we represent in the United States and abroad, we would like to provide comments on the proposed changes to the hospital inpatient prospective payments system (IPPS).

We understand that this proposed rule is largely a response to the concern raised about the growth of specialty hospitals as well as concerns raised by community hospitals about that competition. It is worth noting that data described in the March meeting of the MedPAC indicated that there has been no evidence of financial harm to community hospitals from specialty hospitals as they have been able to increase revenue sources to make up for any lost business due to competition. Also noteworthy was the finding that there has been no evidence of altered referral patterns on the part of physicians as a result of any ownership interest in specialty hospitals. Given these recent data, we are concerned that in promulgating this regulation which would dramatically shift payments from high technology surgical care to routine medical care, the "cure" may be worse than the "disease".

We want to make clear that we fully support your efforts to base hospital payments on accurate costs of services rather than on charges as is current policy. But we have concerns with several aspects of the methodology, the accuracy of the data proposed for use in attaining the cost basis for such payments, and with potential unintended consequences of this proposed rule on quality data collection and on clinical staff.

As you know, cardiothoracic surgery is performed exclusively in the inpatient setting, and hence our surgeons are inextricably linked to the hospitals in which they operate and largely dependent on the resources those hospitals choose to provide them. Outcomes of patient care are strongly influenced by those resources in terms of the skill and training of clinical staff, appropriateness of devices and equipment available to our surgeons, and by ongoing quality improvement efforts.

In 1999 CMS (then HCFA) removed the Practice Expense payment from the physician fee schedule for the specifically-trained clinical staff that our members employ and who assist them in hospitals. Since that time some hospitals may have recognized the value to patient care of these trained staff and directed resources to ensure that the cardiothoracic surgical team was maintained. According to the HHS OIG, 19% of hospitals provided full or partial support for these clinical staff. We are concerned that reducing payments for most major cardiovascular services will cause hospitals to reduce spending for these types of resources which can often make the difference in patient outcomes and incidence of complications.

Additionally, the majority of The Society of Thoracic Surgeons members participate in one of our national clinical quality improvement databases through which we have seen dramatic improvement in mortality and incidence of complications as well as more rapid adoption of new clinical best practices. In the National Cardiac Database we have participation by the nation's cardiac surgeons as well as the vast majority of hospital that perform cardiac surgery. Our practices partner with the hospitals in which they work to advance improvements in patient outcomes

through clinical data collection and feedback. This activity, which is arguably the most accurate, risk-adjusted system of measuring and improving patient outcomes is not required, funded, or even encouraged by any CMS physician payment policies. We believe that quality improvement is an important component of physicians' practices, and this is why our database participants pay nearly $100,000 to collect data and receive feedback to improve quality. We find it ludicrous that Medicare practice expense payments do not allow for quality improvement costs. However, we are quite concerned that with this new proposal, not only will participation in a multi-institutional risk adjusted clinical database not be encouraged, but it will be discouraged and jeopardized as the dramatic shift of resources away from cardiovascular care will make continued participation increasingly difficult for hospitals.

Methodology

We believe that through a few reasonable improvements in the proposed methodology, the severe impacts of this proposal could be moderated, allowing both hospitals and surgeons to continue to protect patient welfare during this shift of resources.

Cost Data

The accuracy of data from hospital cost reports is dubious at best. These cost reports have been unused and only about 15% of these cost reports are audited. Further, the data proposed for use is several years old today. We strongly urge CMS to use more recent and audited cost reports and to put in place strong definitions and requirements so that cost data will be more standardized.

Data Trimming

It appears the data trimming in the cost-to-charge cost center calculation in this proposal may have been excessive. The trimming at 1.96 standard deviations from the mean has caused the exclusion of hospitals with high markups on routine accommodations to be excluded from the calculation. Additionally this trim excluded 260 large hospitals that accounted for over 25% of the total routine accommodation charges. Though CMS chose to exclude these charges from the average CCR calculation, the charges from these hospitals have been included in calculating the DRG weights. This has resulted in a significant incongruity between the cost to charge ratios and the pool of charges to which they are applied. Research on this has shown that the DRG weight changes in the proposed rule are two to three times larger than they would have been had the correct cost-to-charge ratios been used. We recommend that CMS correct this flaw and reduce the trim to a more appropriate level.

Cost-to-Charge Ratios

The use of cost to charge ratios (CCRs) for all costs causes those high-cost items (which are typically marked up far less than routine, lower costs items) to be reduced below their true cost. This causes steep reductions in the most technologically advanced items. Further, the CCRs used in the proposal have not been adjusted for hospital volume of care. The result is that in setting the DRG weights, a small 50 bed hospital carries the same weight as a 1,000 bed center. STS recommends that the CCRs be adjusted for volume, or that CMS consider reducing charges to costs first, then setting payments based on true costs.

Hospital Specific Relative Values

The proposed hospital specific relative value (HSRV) calculation seems unnecessary and somewhat counterproductive. The current formula comparing the average charge for each DRG to the average charge for all DRGs allows the finding of a mean DRG payment for the "efficiently operated facility."

However the proposed methodology seems to simply shift resources from high cost to low cost DRGs. Creating weights for each DRG within each hospital – relative to all other DRGs – would appear to only draw high cost DRGs down and move payments for low cost DRGs up. The effect of this is to reduce the range of DRG weights which appears to create overpayment in the low intensity DRGs and underpayment in the high intensity DRGs. We do not believe such "compression" is consistent with encouraging appropriate and effective patient care, and would recommend abandoning the HSRV portion of this proposal. If true costs can be approximated through better data,

this part of the methodology would seem to be completely unnecessary. HSRVs have been studied extensively over the past 20 years, and have been largely discredited as inaccurate. This policy tends to disadvantage large, urban, teaching, and DSH hospitals. In particular, this policy disadvantages hospitals that provide cardiac surgical procedures. A Rand study found that 83 percent of hospitals that lose under the HSRV methodology provide cardiac surgical services compared to 5 percent of hospitals that do not lose under HSRV. This same research found that hospitals that lose under the HSRV do not charge more for cardiac procedures as might be thought. In fact, they charge less than the other hospitals for these services.

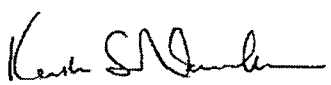
Appropriate DRG assignments
We have heard great concern regarding the area of ventricular assist devices and the proposed DRG classification. We recommend that over the period of delay or implementation, CMS continue discussions with STS and device companies to ensure appropriate classification.

Reporting of Hospital Quality Data for Annual Hospital Payment Update
The Society of Thoracic Surgeons will have numerous comments on the reporting and data collection of quality data and the incentive methodology. Our member surgeons serve in leadership roles in the NQF, AQA, and HQA, and have literally decades of experience in these areas in both the public and private sectors. However, we do not have adequate staff to review these areas and provide comments within the deadline for comment. We would be glad to meet with you to discuss these areas at any time in the process.

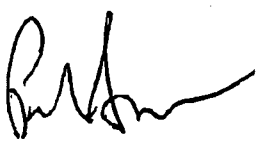
For the above stated reasons, we recommend that CMS delay the implementation of this rule one year, consider adjusting some of the methodological assumptions and calculations, and extend the comment and analysis period so stakeholders can best understand and adapt to the move to a cost based IPPS.

Thank you for consideration of our comments.

Sincerely,



Keith S. Naunheim, MD
Chairman
Council on Health Policy and Relationships



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June 12, 2006

SUBMITTED ELECTRONICALLY

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

RE: CMS-1488-P and 1488-P2 – Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

Catholic Healthcare West (CHW), on behalf of our 41 hospitals in Arizona, California and Nevada, is pleased to submit the following comments on the notice of proposed rulemaking (NPRM) for the Medicare Hospital Inpatient Prospective Payment System for Fiscal Year 2007, as published in the April 25, 2006 *Federal Register* (Vol. 71, No. 79) and 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.".

The rule, if adopted as proposed, would make the most sweeping changes to the hospital inpatient prospective payment system (IPPS) since its implementation in 1983. Some of these proposed changes would have a tremendous affect on the care our hospitals provide to Medicare beneficiaries. The major elements 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 determined Medicare's payments for hospital inpatient services. The proposed changes include a move, beginning in FY 2007, to a system of payment weights based on costs, rather than the charge-based system that has been in use since 1983, for determining the payment weights for each patient category.
2. Significant changes to refine the method for identifying the variation in patients' severity of illness within DRGs. CMS said that this 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.

4. In addition, the rule would update the payment rates, outlier threshold, quality reporting requirements and payments for medical education, among other policy changes.

Catholic Healthcare West is supportive of many of the provisions in the proposed rule, but we have significant concerns about others. The DRG changes, due to their re-distributional impact, will certainly bring potentially major destabilizing factors to bear on the financial situation of many hospitals. With 41 hospitals in our health system, CHW naturally has hospitals that stand to potentially both gain and lose significant Medicare funds as a result of the DRG changes. Regardless of those impacts, however, there are still questions with regard to the concepts and methodology CMS plans to use to create the changes, and whether the changes will ultimately create an improved payment system.

We will provide comments and recommendations on the following issues:

1. DRG Relative Value Cost Weights - HSRVcc
2. Consolidated Severity-Adjusted DRGs
3. Proposed Changes to Specific DRG Classifications – MDC 1: Intracranial Neurostimulator System for Deep Brain Stimulation, Carotid Artery Stents and Changes to the ICD-9-CM Coding System
4. FY 07 Applications for New Technology Add-On Payments – X STOP Interspinous Process Decompression System
5. Inpatient Prospective Payment System Updates
6. Increase in the Medicare Fixed-Loss Cost Outlier Payment Threshold
7. Reporting of Hospital Quality Data for Annual Hospital Payment Update
8. Value-based purchasing
9. Changes to the Area Wage Index – Occupational Mix Adjustment
10. Payment for Direct and Indirect Medical Education
11. Hospital Emergency Services Under EMTALA

In addition to our comments, we also support the comments and recommendations of the American Hospital Association, the Catholic Health Association, Premier, Inc. and the California Hospital Association.

DRG RECLASSIFICATIONS

In response to payment recommendations from the Medicare Payment Advisory Commission (MedPAC) to address the proliferation of physician-owned, limited service hospitals, the Centers for Medicare & Medicaid Services (CMS) proposed the biggest changes to the calculation of DRG relative weights since the creation of the prospective payment system (PPS). These changes would significantly redistribute payments among the DRGs and among hospitals. Specifically, CMS proposes the use of hospital-specific relative values (HSRVs) and a modified version of cost-based weights rather than charge-based weights in fiscal year 2007. CMS also proposes an alternative patient classification system called consolidated severity adjusted DRGs (CS-DRGs), with implementation likely by FY 2008.

CHW supports meaningful improvements to Medicare's inpatient PPS, and applauds CMS for its efforts to craft changes to the PPS system in an attempt to limit the incentives that spur the proliferation of physician-owned specialty hospitals. However, we are concerned that the proposed DRG changes will also harm full-service, acute care hospitals with emergency departments that serve Medicaid and uninsured patients, and that also have significant cardiac and/or orthopedic surgery services. These full-service hospitals with large heart or orthopedic programs are doing the right things by providing emergency and inpatient services for all of the people in their communities, including low income and uninsured patients. Yet they will see their reimbursement for their surgical services decline significantly under the proposed rule, thereby limiting these hospitals' ability to offset some of the losses they incur in caring for Medicaid and uninsured patients. CHW has several hospitals that would fall into this category, each of which would be essentially punished under the proposed rule for doing the right thing, even though the intention of rule is to target limited-service specialty hospitals that cherry-pick only the profitable, insured patients.

We believe that hospitals and CMS share a common goal in refining the system to create an equal opportunity for return across DRGs that will provide an equal incentive to treat all types of patients and conditions. We also believe the system should be simple, predictable, and stable over time. One of the fundamental values of a *prospective* payment system is the ability of providers to reasonably estimate payments in advance to inform their budgeting, marketing, staffing and other key management decisions. Another core feature of the PPS is clinically cohesive and meaningful DRGs that are somewhat intuitive for providers and coders to follow, and that reflect similar resource use within DRGs. And, ultimately, the inpatient PPS should foster innovation and best practice in care delivery. CHW believes that these are essential characteristics of a well-functioning PPS and it is within these policy goals that we evaluate CMS' proposal.

We would like to emphasize here that payment changes alone will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving low-income patients, practice similar forms of selection for outpatient services and drive up utilization for services. We strongly urge CMS to rigorously

examine the investment structures of physician-owned, limited-service hospitals. It is imperative that CMS continue the suspension of issuing new provider numbers to physician-owned, limited-service hospitals until the strategic plan developed has been fully implemented and Congress has had an opportunity to consider CMS' final report.

1. DRG CHANGES: HSRV WEIGHTS

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 to develop and maintain, we are concerned that the alternative methodology being proposed by CMS hasn't 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 methodology would allow very small hospitals to have equal impact on the national cost-to-charges ratios as larger hospitals. These and other methodological issues seem reason enough to invest addition time and energies in the assessment and, as appropriate further refinement of this proposed change.

2. DRG CHANGES: SEVERITY OF ILLNESS

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. 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 Consolidated Severity-Adjusted DRGs (CSA DRGs).

CHW appreciates CMS' attempts to modify DRG payments to address the proliferation of physician-owned, limited service specialty hospitals, and we support the concept of a severity-based system. However, we are concerned about the potential unintended consequences and implications of the as-yet unproven and essentially untested payment changes of the new HSRV and CSA DRG system on hospitals. **Given the obvious potential impact on hospitals' payments, we respectfully urge CMS to delay implementing either of these DRG proposals for one year, pending more thorough**

analysis to ensure that the changes truly help to create a better payment system. 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.

Being that the DRG IPPS is dependent upon accurate ICD-9-CM codes and that moving to a severity system would again utilize ICD-9-CM codes, **we believe that having a more robust coding system, like that of ICD-10 would enhance the coding and data for any severity based system.** It should also be noted here that improvement in clinical documentation on a national level is imperative and directly linked to coded data. We encourage CMS to work with the AMA and in general communicate with the physicians in the United States to collaborate with hospitals on documentation improvement skills, as this can only aid in the improvement of clinical codes and data

Another point of concern regarding the CSA-DRGs is the implication associated with the suggestion of adjusting for case-mix "creep." While not specifically saying that it would imposed 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 to prevent all hospitals from being arbitrarily penalized for the practices of a relative few.**

Therefore, consistent with the recommendations of our hospital associations, Catholic Healthcare West believes that immediate implementation of the proposed DRG changes would be premature, and we recommend the following:

- **CHW supports a one-year delay, until at least FY 2008, in implementing the proposed DRG changes, given the concerns with the HSRVcc and CSA DRG methodology. This recommendation for delay also reflects our concerns regarding the need for an appropriate lead time to modify hospital coding systems. Further, recognizing that the court mandate limits CMS' implementation flexibility with regard to the FY 2007 occupational mix adjusted wage index, requesting a one-year delay also reflects our desire to have a year to first assess the impact of the occupational mix changes to minimize the combined impact of these other potentially disruptive major policy changes on our hospitals.**

- **CHW supports moving to a DRG-weighting methodology based on hospital costs rather than charges, but believes that during the one-year delay, CMS should complete a more thorough analysis that would include a parallel pilot test of the proposed changes in order to identify any unintended consequences.**

- **If the need for a new, more effective classification system is demonstrated and developed, CHW recommends that it be implemented simultaneously with the new DRG weighting system, but not earlier than FY 2008. This change in implementation would provide better predictability and would smooth the volatility created by these two, generally offsetting DRG changes, and also should help to ensure that redistribution of hospital payments is not unduly disruptive to selected individual hospitals.**

- **Finally, CHW recommends that CMS provide a three-year transition period to implement the proposed HSRVcc policy change, given the magnitude of payment redistribution across DRGs and hospitals. Such a transition would protect hospitals from major payment disruptions.**

CHW is committed to working with CMS, in collaboration with our associations, over the next year to address these concerns and to potentially help to develop and evaluate alternatives for new DRG weights and classifications. Given our large number of hospitals and mix of hospital sizes and types across three states, CHW represents almost a microcosm of hospitals across the country. We would, therefore, be pleased to work with CMS staff to model the impact of any potential refinements to the proposed DRG changes.

3. PROPOSED CHANGES TO SPECIFIC DRG CLASSIFICATIONS

DRGs: Neurostimulators:

The Kinetra implantable dual array neurostimulator pulse generator that delivers deep brain stimulation for treatment of Parkinson's disease and essential tremor is approved for new technology add-on payment through FY 2006 only. Without this add-on payment, CHW opposes CMS' recommendation to keep the implantation of dual array implantable neurostimulators for deep brain stimulation in DRG 1 (Craniotomy Age >17 with CC) and DRG 2 (Craniotomy Age >17 without CC), as we believe that these devices will be inadequately paid in these DRGs. **CMS should recognize the higher resources associated with this technology, and reassign the full system Kinetra implants to DRG 543 (Craniotomy with Implant of Chemo Agent or Acute Complex CNS Principal Diagnosis) under MDC 1.**

DRGs: Carotid Artery Stents:

CHW opposes the proposed delay in making any changes to carotid artery stent cases. **The higher costs associated with carotid stents should be recognized within the existing DRG system.**

Changes to the ICD-9-CM Coding System:

CHW is in support of the recommended additions and revisions to ICD-9-CM for October 2006. However, we would also once again bring to the attention of CMS that ICD-9-CM has reached limitations, which restrict the collection of valuable clinical data. We support – as does AHA and AHIMA – the adoption of ICD-10 for clinical data collection in the United States. **We recommend that CMS move expeditiously to ICD-10 in order to adapt to the significant changes to IPPS, and thus reflect accurate clinical data for severity, acuity and risk or mortality, as well as quality measures.**

4. FY 07 APPLICATIONS FOR NEW TECHNOLOGY ADD-ON PAYMENTS

X STOP Interspinous Process Decompression System:

St. Francis Medical Technologies, a medical group affiliated with CHW's St. Mary Medical Center in San Francisco, submitted an application for new technology add-on payments for the X STOP Interspinous Process Decompression System for FY 2007. The X STOP device, which was developed by two spine surgeons at St. Mary Medical Center, is inserted between the spinous processes of adjacent vertebrae in order to provide a minimally-invasive alternative to conservative treatment (exercise and physical therapy) and invasive surgery (spinal fusion). It received premarket approval from the FDA on November 21, 2005. CMS believes that the device satisfies the newness and cost threshold criteria for new technology add-on payments, but invite comments as to whether the device provides substantial clinical improvement. **CHW recommends that CMS approve the X STOP system for new technology add-on payments, as physicians have reported that it achieves symptomatic relief of pain for patients with advanced spinal stenosis with minimally-invasive surgery.**

5. INPATIENT PROSPECTIVE PAYMENT SYSTEM UPDATES

CHW fully supports the proposed rule's full market basket increase of 3.4 percent if the respective hospital voluntarily reports the additional required quality measures. (See below regarding additional comments on the voluntary quality reporting option.)

6. MEDICARE FIXED-LOSS COST OUTLIER PAYMENTS

For FY 2007, the proposed rule establishes an outlier threshold equal to the inpatient PPS rate for the DRG, including indirect medical education (IME), disproportionate share hospital (DSH) and new technology payments, plus $25,530. While this increase is not a particularly sizable increase from the FY 2006 payment threshold of $23,600, we remain very concerned that the threshold is too high.

CMS projects that the threshold for FY 2007 will result in outlier payments equal to 5.1% of operating DRG payments. Statute requires that outlier payments for any year be projected to be no less than 5% or more than 6% of total operating inpatient PPS payments. However, in

recent years, CMS has not reached that level of payment to hospitals. According to an analysis by the American Hospital Association (AHA), actual outlier payments for FY 2006 are estimated to be 0.47 percentage points lower than the 5.1 percent of funds withheld from hospitals to fund outlier payments. CMS spent only 3.8 percent, or $1.15 billion less than set aside in FY 2005, and only 3.5 percent, or $1.3 billion less than the funds withheld in 2004.

In the rule, CMS proposes to use a one-year average annual rate-of-change in charges per case from the last quarter of 2004, in combination with the first quarter of 2005, to the last quarter of 2005, in combination with the first quarter of 2006, to establish an average rate of increase in charges. This results in a 7.57 percent rate of change over one year, or 15.15 percent over two years.

CHW appreciates that CMS is proposing this methodology in an effort to avoid using data from 2003 when charges may have been atypically high. However, using the proposed charge inflation methodology will only result in an inappropriately high outlier threshold and a real payment cut to hospitals.

The AHA estimates that the fixed-loss threshold necessary to achieve 5.1 percent in FY 2006 should have been set at $21,275 as compared to the $23,600 actually utilized. They further estimate that CMS underspent the funds set aside for outliers by approximately $3 billion over FYs 2004, 2005 and 2006. This amount represents a real cut in payments to hospitals that cannot be recouped. If CMS leaves the threshold at $25,530 as proposed for FY 2007, we believe that CMS will again significantly underspend by over $300 million.

CHW has analyzed the impact of the proposed $25,530 outlier threshold on payments for our hospitals. If this threshold had been in place in the 12-month period from April 2005 – March 2006, CHW hospitals would have lost approximately $3.5 million.

Therefore, CHW respectfully recommends the following with regard to the Medicare Inpatient PPS outlier payment threshold:

CHW opposes using CMS' proposed methodology to estimate the outlier threshold. Instead, CHW urges CMS to adopt the methodology proposed by the AHA for establishing the outlier threshold in its comment letter to CMS on this proposed rule. The AHA's methodology is applicable regardless of what DRG changes are made or not made in FY 2007, and incorporates both cost and charge inflation, which we agree will make the threshold calculation more accurate and reliable. The estimated fixed-loss threshold that would result in 5.1 percent outlier payments under this methodology would be $24,000. Therefore, we urge CMS to adopt the AHA's outlier methodology and lower the outlier threshold.

7. HOSPITAL QUALITY DATA

The Deficit Reduction Act of 2005 (DRA) expands quality reporting requirements for hospitals to be eligible to receive a full market basket update. The proposed rule states that

to qualify for a full market basket update, hospitals would have to pledge to submit data on all 21 measures currently part of the Hospital Quality Alliance's (HQA) public reporting for patients discharged on or after January 1. Hospitals failing to submit data for the first calendar quarter of 2006 by August 15 would receive an inpatient update equal to the market basket minus two percentage points. Hospitals that fail data validation tests for data submitted for the first three calendar quarters of 2005 would also lose the two percentage points from the market basket update.

CHW fully supports the HQA's effort to make more information on hospital quality available to the public, and we join with CMS in wanting to make it happen quickly and accurately. However, as written, the proposed rule would require hospitals to reopen files from which data have already been abstracted, renegotiate agreements with the vendors that assist them in collecting and processing the required information, and resubmit information to the clinical data warehouse. Such retroactive alterations in the data files are difficult and costly, and open the door for the introduction of many new kinds of errors in the data. **CHW recommends that CMS make the data collection prospective. This change could be accomplished by requiring that hospitals that want a full market basket update pledge to submit the relevant data for all 21 measures for patients beginning on or after July 1.**

The DRA gave the Secretary of the Department of Health and Human Services (HHS) the authority to further expand the measures that must be reported to qualify for full market basket update in future years. **We strongly urge CMS to select measures only from those used by the HQA for public reporting.** To choose different measures would thwart efforts to streamline quality reporting, add to the confusion regarding quality measurement that currently exists in health care and dilute efforts to create a single source to share solid reliable information with the public. In addition, whenever the Secretary intends to expand the set of measures linked to payment, **CMS should consider publishing the proposal at least one full year prior to the start of the fiscal year.** This lead time will enable hospitals and their vendors to put the needed data collection processes in place to be able to provide the requested data.

Further, we agree with CMS that it is critical that the collected data be validated. The process used to validate the HQA data was reviewed by the Government Accountability Office, which concluded that there was "a high overall baseline of accuracy," but recommended several changes to improve the validation process. CMS proposes to look at the validation results for data submitted on patients who were discharged during the first three calendar quarters of 2005. CMS has hired a contractor to randomly select five patient records per quarter. That contractor selects the patients, asks the hospital to send a copy of the medical record for the hospitalization of the patients that occurred during that period, and then reabstracts the same data that the hospital abstracted from the medical record. A comparison is made between the data the hospital submitted and the data the contractor abstracted, and if there is at least an 80 percent agreement, the hospital is said to have passed validation. In the proposed rule, the hospital would have to have at least 80 percent agreement across the 15 medical records that the contractor reabstracted. This methodology assumes that the contractor has correctly reabstracted the data and that discrepancies must

mean erroneous data submission on the part of the hospital. However, that is not always the case. This validation process is still in its infancy and seems to be working to correctly validate the information submitted by many, but unfortunately not all, hospitals.

Some data validation problems have actually begun with the data submission process. Hospitals and their data collection vendors submit data to the Quality Improvement Organization (QIO) data warehouse in a good-faith effort to get the information submitted in the right format, with all of the right labels and coding. An "error report" is generated that is supposed to alert the hospital if it appears data were received in a way that is inconsistent with the requirements. The hospital is supposed to receive this report in time to make any necessary corrections. However, the report can be hundreds of pages long with a multitude of meaningless notations. A significant problem in data transmission might have occurred, but the indications of it are buried in this voluminous report and may not be discovered until it is too late for the hospital to make a correction. In addition, the data collection vendors on whom the hospitals rely to format and submit the data correctly do not have access to these error reports, nor do they have any other mechanisms for checking to make sure that the data they sent was received correctly. This has inevitably led to errors not being caught in time. When these errors are then left in the database, the CMS contractors' reabstraction of the data does not match up with what is recorded for the hospital in the database, leading to the hospital failing validation.

Another common problem results when the contractor has asked for the medical record pertaining to a particular patient, but has not specified which admission it wanted. Since it is not uncommon for heart failure patients to be readmitted for care, the omission of the specifics on which admission was being reabstracted has inevitably led to the hospital copying and submitting data on one admission, and the contractor trying to make that match up with the data for a different admission – and the data simply will not match up.

There also have been many reported instances in which the contractor conducting the reabstraction of the data failed to find information that was clearly in the medical record – a simple human error, but one that should not be used to penalize the hospital.

CMS was made aware of these problems with the validation process and it has begun to work to improve the process reliability so it can be used to support payment decisions. However, in the first three calendar quarters of 2005, the validation process did not have sufficient integrity to warrant hospital payments being withheld based on the validation results. At this juncture, we firmly believe that the problems with the validation process itself need to be resolved before any payment decisions are made solely on the basis of the contractor's work. **We strongly urge CMS to review, on a case-by-case basis, any incidence where a hospital's payment would be put in jeopardy as a result of the validation process. It should allow the hospital to submit information showing that it made a good-faith effort to supply the data warehouse with accurate information so that the public could be informed about the quality of its care. If the hospital has made a good-faith effort, it should receive full payment regardless of whether the data are deemed accurate enough for public display. In addition, CMS should instruct its QIO data warehouse to accept**

any significant corrections so that the public can have a full and accurate picture of hospital quality.

8. VALUE-BASED PURCHASING

The DRA required CMS to develop a plan to implement hospital value-based purchasing (pay-for-performance) beginning in FY 2009. The plan must consider a number of issues, including measure development, data infrastructure and refinement, public reporting and incentives.

Before addressing these issues and the questions posed by CMS, 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 believe that 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. This perspective is what guides our responses to the incentive methodology questions that follow.

CHW believes that payment rewards should be based on evidence-based measures of adherence to quality improving "processes." By using evidence-based process measures (e.g., aspirin provided at arrival to patients with acute myocardial infarction; antibiotics provided one hour prior to surgery), every provider has the opportunity to succeed, thereby improving the overall quality of the system. Incentive approaches should incorporate rewards for both attainment of a certain threshold of performance and improvement in performance.

We are concerned about premature efforts to tie payments to issues that could change incentives, such as efficiency. We believe that, for now, pay-for-performance initiatives should focus solely on quality improvement. There is no common definition of efficiency of care for hospitals. Efficient over what period of time: the course of a hospitalization or a stated period? Also, efficient for whom: the hospital ... the patient ... the government ... other payers? Each answer would lead to the development of different measures of efficiency and very different conclusions about whether care was efficient. Much more work needs to be done to define what should be encouraged in terms of efficient care before it is incorporated into payment policy.

Our recommendations follow each 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 a particular 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.** Incentive approaches to payment should use a system of rewards to increase payments or reduce regulatory burden for successful providers. Because the Medicare inpatient PPS already pays less than the cost of care for more than one-third of hospitals, incentives involving penalties should not be used. Additionally, rewards should be sizeable enough to cover the costs of implementing process changes and allow for reinvestment in quality improvement efforts. However, if such penalties are adopted, they should not 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 for 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 these 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 report; and composite measures may easily accommodate the addition of individual measures being represented in a public.

Also, to be effective, incentive approaches must align hospital and physician incentives, encouraging all to work toward the same goal of improving quality and providing effective, appropriate care. Incentive approaches rewarding improvement can only be successful if

physician and hospital performance can be successfully aligned, in terms of both performance and finances.

9. OCCUPATIONAL MIX ADJUSTMENT TO THE AREA WAGE INDEX

The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 requires CMS to collect data every three years on the occupational mix of employees from hospitals subject to the inpatient PPS in order to construct an occupational mix adjustment to the wage index to control for the effect of hospitals' employment choices – such as greater use of registered nurses (RNs) versus licensed practical nurses or certified nurse aides – rather than geographic differences in the costs of labor.

CMS initially stated in the proposed rule that it would again limit the occupational mix adjustment to 10 percent because of concerns regarding the validity of the data and the potential financial impact on hospitals. However, as a result of the decision handed down by the U.S. Court of Appeals for the Second Circuit on April 3 in *Bellevue Hospital Center v. Leavitt*, CMS on May 12 released a proposed rule revising the occupational mix adjustment portion of the FY 2007 inpatient PPS proposed rule. Under the court ruling, CMS must collect new data on the occupational mix of hospital employees and fully adjust the area wage index (AWI) for FY 2007.

CHW is very concerned about the implications of this court-mandated application of the occupational mix adjustment to 100 percent of the wage index. **While we cannot precisely model the impact of this adjustment on our hospitals, CHW is extremely concerned that our California hospitals will be disproportionately harmed by this change, because we are the only state in the country with state-mandated nurse-to-patient staffing ratios.** We believe that this system is designed to benefit parts of the country that make greater use of lesser-skilled nurses and allied health professionals, and to reduce payments in areas that make greater use of registered nurses in nursing positions. Because of California's nurse staffing laws, which specifically mandate Registered Nurse (R.N.) staff-to-patient ratios, this adjustment is likely to be especially damaging to California hospitals by reducing the payments they receive for the care they provide to Medicare beneficiaries.

While we understand that CMS was – and is – under extreme time pressure due to the timing of the court's decision, we do not believe that the 30-day comment period was sufficient for hospitals to allow for a thorough review and impact analysis. CHW expects, given the deadline change for FY 2007 survey data, that the survey results will again contain many errors and will thus be unrepresentative of true labor mix. While CMS might not have time to make changes that would improve accuracy of results for FY 2007, **we would request that CMS entertain comments with regard to the implementation for FYs 2008 and 2009. Further, we strongly urge CMS to use its discretionary authority to smooth out the impact of this change on adversely affected hospitals. Such attention could take the form of a multi-year transition or the use of corridors, as CMS has used in the past. Finally, we urge CMS to publish the occupational mix adjustment changes as an interim-final rule in August with an associated comment period.**

10. IME ADJUSTMENT AND GME PAYMENTS

Exclusion of Didactic Training - The proposed rule states that resident training that occurs at non-hospital sites must be related to patient care if a hospital wishes to count that time for direct medical education (DGME) and indirect medical education (IME) payment purposes. Resident time spent in didactic activities that often occur in associated medical schools – such as educational conferences, journal clubs and seminars – would specifically be excluded. CMS noted that its statement in a previous letter on this topic "implying that didactic time spent in non-hospital settings could be counted for direct GME and IME ... was inaccurate." CMS also noted that time spent in these activities could be counted for DGME purposes if they occur in a hospital; however, the counting prohibition applies for IME payments regardless of where the educational activity occurs.

We strongly urge CMS to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare DGME and IME payments. The stated rationale for the exclusion of this time is that it not "related to patient care." This position is in stark contrast to CMS' 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."[1]

We strongly agree with CMS' 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. 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. **CHW urges CMS to withdraw this change 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 resident physicians during their residency programs.**

11. EMTALA

Definition of "Labor" – **CHW supports CMS' proposal to modify the definition of "labor" at 489.24(b) to allow, in addition to a physician, a certified nurse-midwife or other qualified medical personnel operating under their scope of practice, as defined in hospital medical staff bylaws and in state law, to certify that a woman is in false labor.** This change recognizes that licensure and scope of practice should remain under the purview of state law and regulation. Further, this change provides hospitals with the staffing flexibility needed to maintain access to and the efficiency of vital obstetrical services,

[1] September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins.

particularly in hospitals located in areas of the country that may find it difficult to attract and retain physicians, such as rural areas.

Hospitals without Dedicated Emergency Departments (ED) – Under the proposed rule, a hospital with "specialized capability" is required to accept appropriate transfers under EMTALA regardless of whether it has a dedicated ED. Guidance is still needed on the definition of specialized capability. In addition to questions related to the availability of on-call physicians and inpatient psychiatric resources, this proposed regulation calls into question application to inpatient rehabilitation facilities and long-term acute care hospitals.

CHW agrees that a physician-owned, limited-service hospital should be treated as a hospital "with specialized capability or facilities" under EMTALA, without regard to whether it has an ED. However, we believe it is unlikely this requirement will result in improved access for patients to the specialty care they need.

It is important to separate the capabilities of the practicing physicians from the capabilities of the facility in which they are practicing. While the physician expertise housed in the physician-owned, limited-service facility could be capable of meeting the needs of community hospital patients, the facility is seldom designed or operated in a manner to support this level of practice. Although physician-owned, limited-service hospitals hold themselves out as "hospitals," many of these facilities actually have a range of capabilities more similar to a hospital department or ambulatory surgical center. These hospitals often do not have emergency capabilities, as they are geared toward elective cases of minor severity. For these reasons, it generally would not be in the best interests of community hospital patients to be transferred to these facilities.

At the same time, many physician-owned, limited-service hospitals have withdrawn specialist services from the community at-large. As their physicians maintain an increasing amount of their practice at these hospitals or other sites outside the community hospital (e.g., ambulatory surgical centers), they are much less willing to accept on-call responsibility for the broader community's emergency needs. While withdrawing specialist services from on-call coverage, these same physician-owned, limited-service hospitals presume to rely on the community hospital for back-up in the event of complications requiring around-the-clock access to emergency care and inpatient admission to the community hospital. **Every physician-owned, limited-service hospital that relies on the community's emergency services capacity should be obligated to support it.**

In addition, this policy does not address the problem of patients at physician-owned, limited service hospitals who suffer from complications appearing in a hospital ED with no warning call, no medical history, no operative report, no information on the anesthesia used and, often, no ability to reach the treating surgeon for consultation. **Physician-owned, limited-service hospitals should be required to have agreements with the community hospitals they plan to rely on in the event that they do not have the capacity to treat a particular patient.**

Specifically, CHW recommends the following:

- **A physician-owned, limited-service hospital should be required to have a pre-existing agreement with the community hospital(s) it intends to rely on for emergency back-up services.**

- **The Secretary should establish the terms that must be addressed by an agreement, including:**

  - **Procedures for an appropriate transfer for patients not covered under EMTALA** (e.g., inpatient or outpatient whose condition develops into an emergency beyond the capability of the limited-service hospital and consequently needs to be transferred to a full-service hospital);
  - **Continuity of care** (e.g., telephone consultation with the receiving hospital and physician, sending the patient's medical records along when transferred, etc.); and
  - **Support for maintaining full-time emergency capacity at the community hospital, including on-call coverage** (e.g., physician-owned, limited-service hospital physicians serve in on-call panels at the community hospital, or the physician-owned, limited-service hospital provides financial support to the community hospital to maintain on-call coverage).

In closing, thank you for your review and consideration of these comments. Catholic Healthcare West would welcome the opportunity to discuss our comments with you or your staff, as well as to provide additional input as you make further refinements to the proposed rule. If you or your staff have any questions regarding these comments, please contact me at (626) 744-2268 or **shollander@chw.edu**.

Sincerely,

Susan Hollander

Susan D. Hollander
Vice President, Public Policy and Advocacy

Submitter : Ms. Ann Berkey

Date: 06/12/2006

Organization : McKesson Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See McKesson Corporation's comments on IPPS.

CMS-1488-P-1723-Attach-1.PDF

#1723

McKesson Corporation
One Post Street
San Francisco, CA 94104-5296

[redacted]

McKESSON
Empowering Healthcare

June 12, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: **CMS-1488-P**
P.O. Box 8014
Baltimore, MD 21244-8014

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

Dear Dr. McClellan:

McKesson Corporation (hereinafter "McKesson") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS') Proposed Changes to the Hospital Inpatient Prospective Payment Systems (IPPS) and Fiscal Year 2007 Rates (CMS-1488-P) Proposed Rule.

As a Fortune 16 corporation and the nation's leading healthcare services company, we provide pharmaceuticals, medical supplies and technologies that make healthcare safer while reducing costs. We touch the lives of over 100 million patients in healthcare settings that include more than 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities, 700 home care agencies, and 25,000 retail pharmacies.

We are also the nation's leading healthcare information technology (IT) company, with software and hardware technology installed in over half of the nation's hospitals with more than 200 beds. Our healthcare IT solutions provide decision support software to help determine clinical diagnosis and treatment plans for patients, electronic systems that eliminate the need for paper prescriptions and paper medical records, secure online access to patient information for physicians, and bar-code scanning technology to prevent more than 96,000 medication errors every week. McKesson is the nation's largest provider of disease management services to state Medicaid programs to reduce the cost and improve the quality of care for patients with chronic diseases. We also provide technology to support insurers' efforts to capture and utilize information that will improve patient care and expedite reimbursement.

We are drawing on our extensive experience in health information technology to share our perspective and provide comments on these proposed regulations.

McKesson supports CMS' overall goal to improve payment rate accuracy under IPPS, and we commend the agency for striving to improve the DRG system. McKesson would like to comment on two specific areas of the proposed rule: (1) the transparency of CMS' decision making, and (2) the timing for the implementation of the proposed changes. In addition, we are offering a number of suggestions for CMS to consider before issuing the final rule.

DRGs: Severity of Illness

I. Transparency of Grouper Software Assessment and Implementation

McKesson creates and designs innovative healthcare financial management tools for use in the hospital setting. We provide access to DRG grouping and pricing software in our products and require detailed information on the DRG classification methodology so that our clients can accurately predict the effects of changes to CMS' payment methodologies. As the DRG system changes, there will be a critical need for continued access to the evolving system's methodology so that we may provide our hospital clients with the tools they need to conduct their business operations efficiently.

McKesson recommends that CMS solicit a proposal from more than one vendor, as well as engage a neutral third-party evaluator, to assess grouping methodologies prior to making a decision to adopt a specific grouping methodology. Given the need for complete transparency in changes of this magnitude, we also ask that the details of the final underlying methodology for the new system be made available as soon as possible to give hospital providers and their software vendors the time required to better understand and respond to the impact of these changes on their existing data processing, billing and management systems. We urge CMS to make the actual grouper software, or grouping algorithm, public as soon as possible.

II. Implementation Timeline

In the proposed rule, CMS proposes to implement two massive changes to the payment structure in consecutive years. Under the proposed timeline, there is insufficient time for hospitals and the vendors that support them to effectively plan for and implement this new system.

A two-step process of moving to hospital-specific relative values (HSRVs) in one year (FY 2007), and then to consolidated severity-adjusted DRGs in the following year (FY 2008), will each require fundamental, structural changes to the entire suite of hospitals' financial management systems. These changes will force information system vendors to design, program, test, document, and roll-out the new interface to users twice in two successive years. Adjustments to changes of this magnitude typically require several months of software design, followed by several months of installation and training. Conducting this time-intensive process twice in two years will be unnecessarily burdensome and financially harmful to both providers and vendors. While we support the dual policy objectives of moving to HSRVs and severity-adjusted DRGs, we recommend a consolidation of the two proposed implementation timelines to a *single* timeline with a *single* implementation

deadline of no sooner than FY 2008. This extension should give providers sufficient time to analyze and understand the changes and will allow vendors to incorporate these changes into their hospital financial management systems. Such an extension will help assure the successful transition of these important DRG system changes.

Further, it is our understanding that two other large system changes are anticipated to occur in 2009 and beyond, including the migration to ICD-10. As the entire industry plans for these additional significant changes, McKesson encourages CMS to issue any and all guidance as early as possible on these possible changes, particularly if the existing three-digit DRG system is likely to be expanded to a four-digit system.

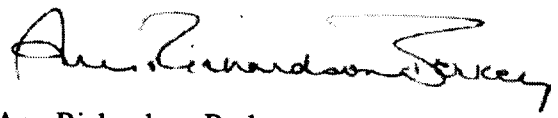
Conclusion

In summary, we recommend that CMS:

- Solicit a proposal from more than one grouping methodology vendor, as well as engage a neutral third-party evaluator, to assess grouping methodologies;
- Make available the final underlying grouper methodology for the new system; and
- Consolidate implementation of both the HSRV-related changes *and* the consolidated severity-adjusted changes to the DRG system to no sooner than FY 2008.

Thank you for the opportunity to submit these comments on the IPPS FY 2007 Proposed Rule. Should you have any questions or if we can be of further assistance, please contact me at 415-983-8494 or ann.berkey@mckesson.com.

Sincerely,



Ann Richardson Berkey
Vice President, Public Affairs

Submitter : **Dr. Alan Olson** **Date: 06/12/2006**

Organization : **Dr. Alan Olson**

Category : **Individual**

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, 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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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,

Alan G. Olson, MD

Submitter : **Dr. Peter Middleton** **Date: 06/12/2006**

Organization : **John Peter Smith Hospital-FMRP**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1725-Attach-1.DOC

#1725

Dear CMS Policy Maker:

I am a family medicine resident in a very busy HPSA. I really need my faculty to teach. Why would you interpret a rule designed to do just that as being unrelated to patient care time? Whether we are having a discussion after a patient encounter, a small group discussion regarding a difficult clinical situation, reviewing our evaluation for our care and didactic tests in a certain disease domain, or participating in lectures – we are learning about, caring for current and protecting our future patients.

My concern is that the faculty are already stretched to produce more patient visits with poor compensation and must cover four of us at a time for supervision in clinic. The hour they spend before and after clinic to discuss a specific topic that is not related to a specific individual patient will disappear with the implementation of the rule you suggest. They will not have time to sit down with us to discuss our overall performance – we will get an email.

The faculty, without support for their own development, will be likely to lose their academic edge as they work to see patients, see more patients and supervise patient care without any incentive to reflect, discuss and research our and their work.

Please help us be better physicians to our patients by supporting a competent and refreshed faculty. Rescind the interpretation of the IME and DME support rule.

Sincerely,

Submitter : Randy Redfoot **Date:** 06/12/2006

Organization : Mobile Infirmary Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attached

#1726

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 : **Mr. David Page** **Date: 06/12/2006**

Organization : **Fairview Health Services**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1488-P-1727-Attach-1.DOC

CMS-1488-P-1727-Attach-2.DOC

CMS-1488-P-1727-Attach-3.DOC

#1727

FAIRVIEW
Fairview Health Services
400 Stinson Boulevard, Minneapolis, MN 55413-2613

ELECTRONIC SUBMISSION

June 12, 2006

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

Attention: **CMS-1488-P** — Medicare Program; Changes to the Inpatient Prospective Payment System and FY 2007 Rates; Proposed Rule (71 *Federal Register 23996*), April 25, 2006.

Dear Administrator McClellan:

On behalf of Fairview Health Services ("Fairview") I welcome the opportunity to comment on the proposed rule entitled *"Medicare Program; Changes to the Inpatient Prospective Payment System and FFY 2007 Rates; Proposed Rule"* (71 Federal Register 23996), April 25, 2006. Fairview is a wholly integrated non-profit healthcare corporation operating 7 hospitals, over 50 clinics, home care and other health care providers in the state of Minnesota.

In brief, we do not oppose moving from a charge to a cost-based DRG weighting methodology, but believe that a one-year postponement is necessary to allow for further analyses to address data and computation issues and to ensure that the best possible methodology ultimately is implemented. We also support refinement of the DRGs but believe that the proposed consolidated severity-adjusted DRGs (CS-DRGs) require further examination and likely modifications before implementation. We believe that these changes should be implemented simultaneously to ensure equity and minimize payment volatility for hospitals.

We are also very concerned with the DGME and IME issues proposed. We strongly urge CMS to rescind the purported "clarification" in the proposed rule. The Agency should instead reaffirm its 1999 position defining patient care activities to include didactic activities.

HSRV Weights

We support MedPAC's recommendation to move to a cost based relative weight methodology so long as it improves the accuracy of the payment system and the methodology is sound, stable and reliable. We believe more work is needed to determine the best way to develop cost based weights and needs to consider the following issues when developing their final methodology:

- The data is not based on a provider's hospital specific cost ratio, which was the intent based on MedPAC's recommendation, but rather a national geometric mean ratio. To achieve a hospital's specific cost each hospital's charges must be matched with a PS & R crosswalk, a document submitted with the Medicare cost report per CMS 339 form. The proposed formula has all hospitals being equally weighted using the HSRVcc, this method allows small rural hospitals to carry the same weight as a large, urban hospital.
- There are only 10 categories being identified, which dilute the accuracy of the data and cannot capture the true cost of specialty service lines. Additionally, each hospital may chose to report revenue codes differently depending on where the cost is reported on the cost report. For example, revenue code 480 Cardiology could be reported on cost report line 53 EKG or as a subscript to line 37 if the hospital has a Cardiac Cath Lab. Therefore, it is impossible to make assumptions related to revenue codes across all hospitals without the assistance of the PS&R crosswalk or establish clear directions for cost report assignments for consistency purposes.
- The data that is being used is out-dated and does not include the cost of new technology that is commonly used today, such as the drug eluding stents. In order to accurately determine the DRG weights and reimbursements these costs need to be included in any analysis that is being performed
- The data contains only audited data. Hospitals that have not been audited would not be included in the data.
- The cost of organ acquisitions was included in a number of transplant DRGs causing the DRG weights to be incorrect. This needs to be corrected prior to implementation. This is very important to Fairview.

Fairview recommends the "cost-based" DRG weighting methodology be postponed for one year so CMS can determine the best way to develop a cost-based weight and make improvements to their payment system. This would also allow hospitals to conduct detailed analysis and the ability to give affirmative comments on the methodology. A one-year delay would also allow for the simultaneous implementation for cost weighting and severity refined DRG's.

DRGs: Severity of Illness

CMS also proposed moving to an entirely new patient classification system beginning in FY 2008 or earlier. The proposal is looking at expanding the DRG's

to 861, which is a consolidation of the APR-DRG system (A 3m Health Information System) that utilized 1,258 APR-DRG's.

Fairview is in favor of refining the DRGs to better reflect patient severity and complexity. We also appreciate that CMS's recognizes the need to account for patient severity in the IPPS (71 Fed. Reg. at 24026). It is important that the DRG classification system reflect those cases that involve the sickest and most complex Medicare patients. As common sites of care for these patients, ensuring that these cases are assigned to DRGs that adequately reflect the resources needed is a fundamental principle for major teaching hospitals.

We have concerns, however, about the proposed CS-DRGs because they reflect patient severity only and do not recognize service complexity. CMS agrees with these concerns, stating "a method of recognizing technologies that represent increased complexity should be included in the system." (71 Fed. Reg. 24014). We are very interested in the proposed rule statement that CMS plans to "develop criteria for determining when it is appropriate to recognize increased complexity in the structure of the DRG system and how these criteria interact with the existing statutory provisions for new technology add-on payments." (Ibid). How CMS determines these criteria and their resultant impact on the classification system will have important implications for the IPPS.

Fairview again is in favor of the severity implementation but recommends a one-year delay so CMS can consider other options submitted by the community and to allow time for testing to ensure system integrity.

Outlier Payment

The proposed rule would increase the fixed-loss cost threshold for outlier payments to be equal to a case's DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus a $25,530 outlier threshold, an increase of 8.2 percent over the FFY 2006 threshold of $23,600.

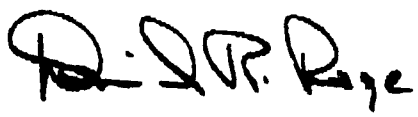
CMS proposes an increase to the threshold even though it has been estimated that outlier payments for FFY 2006 will represent only 4.71 percent of actual total DRG payments. Further, CMS estimates that outlier payments represented only 4.1 percent of total DRG payments in FFY 2005 and, according to the August 12, 2005 final rule, only 3.52 percent of total DRG payments in FFY 2004 (70 Fed. Reg. 47496). Because outlier payments were less than the 5.1 percent reduction to the standardized amount, the result is less total Medicare payments to hospitals in all three consecutive years, contrary to the intent of the outlier payment policy.

One of our hospitals relies heavily on the outlier threshold payments. This proposed change will negatively impact Fairview Health Services.

Without more recent data and better rationale, Fairview believes the FFY 2007 cost threshold remains unchanged. It is concerning that CMS continues to increase the outlier threshold when it is evident that these funds are not being fully utilized at the current thresholds.

Thank you for your considerations of our comments. If you have any questions related to these comments, you may contact Mary Edwards, Vice President of Public Policy at 612-672-2895.

Sincerely,



David Page
President and Chief Executive Officer

FAIRVIEW
Fairview Health Services
400 Stinson Boulevard, Minneapolis, MN 55413-2613

ELECTRONIC SUBMISSION

June 12, 2006

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

Attention: **CMS-1488-P** — Medicare Program; Changes to the Inpatient Prospective Payment System and FY 2007 Rates; Proposed Rule (71 *Federal Register 23996*), April 25, 2006.

Dear Administrator McClellan:

On behalf of Fairview Health Services ("Fairview") I welcome the opportunity to comment on the proposed rule entitled *"Medicare Program; Changes to the Inpatient Prospective Payment System and FFY 2007 Rates; Proposed Rule"* (71 Federal Register 23996), April 25, 2006. Fairview is a wholly integrated non-profit healthcare corporation operating 7 hospitals, over 50 clinics, home care and other health care providers in the state of Minnesota.

In brief, we do not oppose moving from a charge to a cost-based DRG weighting methodology, but believe that a one-year postponement is necessary to allow for further analyses to address data and computation issues and to ensure that the best possible methodology ultimately is implemented. We also support refinement of the DRGs but believe that the proposed consolidated severity-adjusted DRGs (CS-DRGs) require further examination and likely modifications before implementation. We believe that these changes should be implemented simultaneously to ensure equity and minimize payment volatility for hospitals.

We are also very concerned with the DGME and IME issues proposed. We strongly urge CMS to rescind the purported "clarification" in the proposed rule. The Agency should instead reaffirm its 1999 position defining patient care activities to include didactic activities.

HSRV Weights

We support MedPAC's recommendation to move to a cost based relative weight methodology so long as it improves the accuracy of the payment system and the methodology is sound, stable and reliable. We believe more work is needed to determine the best way to develop cost based weights and needs to consider the following issues when developing their final methodology:

- The data is not based on a provider's hospital specific cost ratio, which was the intent based on MedPAC's recommendation, but rather a national geometric mean ratio. To achieve a hospital's specific cost each hospital's charges must be matched with a PS & R crosswalk, a document submitted with the Medicare cost report per CMS 339 form. The proposed formula has all hospitals being equally weighted using the HSRVcc, this method allows small rural hospitals to carry the same weight as a large, urban hospital.
- There are only 10 categories being identified, which dilute the accuracy of the data and cannot capture the true cost of specialty service lines. Additionally, each hospital may chose to report revenue codes differently depending on where the cost is reported on the cost report. For example, revenue code 480 Cardiology could be reported on cost report line 53 EKG or as a subscript to line 37 if the hospital has a Cardiac Cath Lab. Therefore, it is impossible to make assumptions related to revenue codes across all hospitals without the assistance of the PS&R crosswalk or establish clear directions for cost report assignments for consistency purposes.
- The data that is being used is out-dated and does not include the cost of new technology that is commonly used today, such as the drug eluding stents. In order to accurately determine the DRG weights and reimbursements these costs need to be included in any analysis that is being performed
- The data contains only audited data. Hospitals that have not been audited would not be included in the data.
- The cost of organ acquisitions was included in a number of transplant DRGs causing the DRG weights to be incorrect. This needs to be corrected prior to implementation. This is very important to Fairview.

Fairview recommends the "cost-based" DRG weighting methodology be postponed for one year so CMS can determine the best way to develop a cost-based weight and make improvements to their payment system. This would also allow hospitals to conduct detailed analysis and the ability to give affirmative comments on the methodology. A one-year delay would also allow for the simultaneous implementation for cost weighting and severity refined DRG's.

DRGs: Severity of Illness

CMS also proposed moving to an entirely new patient classification system beginning in FY 2008 or earlier. The proposal is looking at expanding the DRG's

to 861, which is a consolidation of the APR-DRG system (A 3m Health Information System) that utilized 1,258 APR-DRG's.

Fairview is in favor of refining the DRGs to better reflect patient severity and complexity. We also appreciate that CMS's recognizes the need to account for patient severity in the IPPS (71 Fed. Reg. at 24026). It is important that the DRG classification system reflect those cases that involve the sickest and most complex Medicare patients. As common sites of care for these patients, ensuring that these cases are assigned to DRGs that adequately reflect the resources needed is a fundamental principle for major teaching hospitals.

We have concerns, however, about the proposed CS-DRGs because they reflect patient severity only and do not recognize service complexity. CMS agrees with these concerns, stating "a method of recognizing technologies that represent increased complexity should be included in the system." (71 Fed. Reg. 24014). We are very interested in the proposed rule statement that CMS plans to "develop criteria for determining when it is appropriate to recognize increased complexity in the structure of the DRG system and how these criteria interact with the existing statutory provisions for new technology add-on payments." (Ibid). How CMS determines these criteria and their resultant impact on the classification system will have important implications for the IPPS.

Fairview again is in favor of the severity implementation but recommends a one-year delay so CMS can consider other options submitted by the community and to allow time for testing to ensure system integrity.

Outlier Payment

The proposed rule would increase the fixed-loss cost threshold for outlier payments to be equal to a case's DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus a $25,530 outlier threshold, an increase of 8.2 percent over the FFY 2006 threshold of $23,600.

CMS proposes an increase to the threshold even though it has been estimated that outlier payments for FFY 2006 will represent only 4.71 percent of actual total DRG payments. Further, CMS estimates that outlier payments represented only 4.1 percent of total DRG payments in FFY 2005 and, according to the August 12, 2005 final rule, only 3.52 percent of total DRG payments in FFY 2004 (70 Fed. Reg. 47496). Because outlier payments were less than the 5.1 percent reduction to the standardized amount, the result is less total Medicare payments to hospitals in all three consecutive years, contrary to the intent of the outlier payment policy.

One of our hospitals relies heavily on the outlier threshold payments. This proposed change will negatively impact Fairview Health Services.

Without more recent data and better rationale, Fairview believes the FFY 2007 cost threshold remains unchanged. It is concerning that CMS continues to increase the outlier threshold when it is evident that these funds are not being fully utilized at the current thresholds.

Thank you for your considerations of our comments. If you have any questions related to these comments, you may contact Mary Edwards, Vice President of Public Policy at 612-672-2895.

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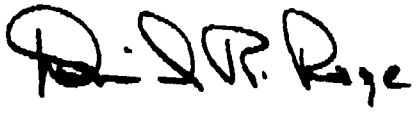

David Page
President and Chief Executive Officer

FAIRVIEW
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400 Stinson Boulevard, Minneapolis, MN 55413-2613

ELECTRONIC SUBMISSION

June 12, 2006

Mark B. McClellan, M.D. Ph.D.
Administrator
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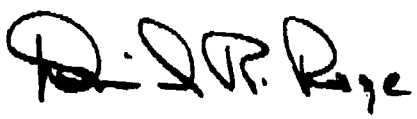

David Page
President and Chief Executive Officer

Submitter : **Dr. Manali Shendrikar** **Date: 06/12/2006**

Organization : **Santa Monica Bay Physicians**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, 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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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,

Manali Shendrikar, MD MPH

Submitter : **Date: 06/12/2006**

Organization :

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-1729-Attach-1.DOC

CMS-1488-P-1729-Attach-2.DOC

#1729

SENTARA™

VIA ELECTRONIC SUBMISSION

June 12, 2006

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

Attention: **CMS-1488—P**

Dear Administrator McClellan:

Sentara Healthcare 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). Sentara Healthcare, located in Southeastern Virginia, is a system of seven hospitals, multiple SNFs, physician practices, Home Health and Hospice. Our hospitals range from 100 to 400+ beds. This letter focuses primarily on two areas of the proposed rule: a) proposed changes to the diagnosis-related group (DRG) weighting and classification systems, and b) a clarification that would prohibit hospitals from counting much of the resident time spent in didactic activities when calculating indirect medical education (IME) and direct graduate medical education (DGME) payments.

PROPOSED CHANGES TO THE DRG WEIGHTING AND CLASSIFICATION METHODOLOGIES

We do not oppose moving from a charge to a cost-based DRG weighting methodology, but believe that a one-year postponement is necessary to ensure that the best possible methodology ultimately is implemented. However, we do believe using 2003 Cost Report data (the majority probably unaudited) to calculate cost for FFY 2007 overlooks the cost associated with new technology and artificially deflates the cost-to-charge ratios. We also support refinement of the DRGs but believe that the proposed consolidated severity-adjusted DRGs (CS-DRGs) require further examination and likely modifications before implementation. We believe that these changes should be implemented simultaneously to ensure equity and minimize payment volatility for hospitals. We do not support an effective date of October 1, 2006; there is simply not enough time for our facilities to implement the new IBM grouper and educate our coders on the severity-adjusted DRG system. Our cash flow would be severely affected.

At the DRG level, the proposed rule notes that a number of DRGs would experience payment reductions, particularly DRGs involving cardiac care. For example, cardiac procedures involving stents, both drug eluting and non drug eluting, would see payment reductions. We are concerned about such drastic reductions for these and other cardiac procedures. While the payment reductions could "potentially reduce the incentives . . . for the further development of specialty hospitals" (71 Fed. Reg. at 24006), we are concerned that the reductions significantly affect our hospitals that do significant amounts of cardiac care. Unlike many specialty hospitals, we have emergency rooms (two hospitals are designated trauma centers), treat significant numbers of Medicaid (two hospitals are DSH) and uninsured patients, and also accept complex cardiac cases. We have calculated a decrease in reimbursement of over $6 million for our large teaching hospital due to the rebasing.

DIDACTIC ACTIVITIES

We strongly urge 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 stated rationale for the exclusion of time devoted to these activities is that they are not related to patient care. 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 proposed rule 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 support CMS's 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. We urge CMS to withdraw 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 again for the opportunity to comment.

Sincerely,

Catherine Hoffler Warren, CPA
Director of Reimbursement
Sentara Healthcare

Submitter : Dr. Melissa Nothnagle **Date:** 06/12/2006

Organization : Family Medicine Residency, Memorial Hospital of RI

Category : Physician

Issue Areas/Comments

GME Payments

GME Payments

As a family medicine assistant 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.

Submitter : Mr. Thomas Golden **Date:** 06/12/2006

Organization : TruCode

Category : Health Care Industry

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

I am writing to comment on the proposed implementation of Consolidated Severity Adjusted DRGs and the proprietary nature of this new system.

CMS-1488-P-1731-Attach-1.DOC

TruCode
Alpharetta, GA • Leesburg, VA
(770) 883-8311
www.trucode.com
info@trucode.com

TruCode

#1731

Re: file code CMS-1488-P

Dear Sir or Madam,

I am writing to express my concerns regarding the perceived proprietary nature of the Consolidated Severity Adjusted DRG system that is proposed for implementation by CMS for FY 2008. In the past, the CMS Medicare Grouper has always been in the public domain, which ensured fair competition between all software vendors that support the grouper. In addition, hospitals and healthcare organizations greatly benefited from having multiple options to consider when purchasing CMS DRG grouping software.

3M currently owns the proprietary rights to the APR-DRGs. The APR-DRG grouper is required to be used by Children's hospitals and all hospitals accepting Medicare patients within the State of Maryland. Many Maryland hospitals that we have spoken with have expressed displeasure with their inability to integrate the complete APR-DRG software into their existing systems. With a sole source provider for the software, however, they have no alternatives. To also allow 3M proprietary rights to the CMS Medicare Grouper would limit the choices available to hospitals and healthcare organizations nationwide.

Additionally, please consider that to allow any single vendor proprietary rights to the CMS Medicare Grouper would put all other Encoding/Grouping software vendors such as ourselves at a distinct competitive disadvantage, and give the appearance of bias.

I ask that you please clarify if the Consolidated Severity Adjusted DRGs will be proprietary to 3M. And if so, I ask that you reconsider based upon the issues raised in this letter. Thank you.

Sincerely,

Thomas Golden

Thomas Golden
Co-owner
TruCode
703-771-1858
tgolden@trucode.com

Submitter : Mr. Dan Riley **Date:** 06/12/2006

Organization : University of Arkansas for Medical Sciences

Category : Hospital

Issue Areas/Comments

Cost-Based Weights: Outlier Threshold

Cost-Based Weights: Outlier Threshold

"Operating Payment Rates: In recent years the fixed loss threshold applied in determining outlier payments has resulted in payments below the amount withheld to fund such payments. We note that the discussion in the Federal Register regarding the proposed fixed-loss cost outlier for 2007 states that the same methodology will be used to calculate the threshold for 2007 as was used in 2006. Inasmuch as the previously used methodology has proven to be inaccurate we urge CMS to consider alternate methods for determining the amount of the outlier threshold.

GME Payments

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"GME Payments: We believe that reimbursement for direct graduate medical education (GME) and indirect medical education (IME) is sufficiently restricted by limits on increase in per resident amounts, update factors, and resident FTE caps without the further imposition of burdensome record keeping requirements with the sole apparent intent of further reducing such payments. We also find it difficult to accept the argument that training (didactic) to do patient care is not a cost related to patient care and, therefore, not a patient care activity when done as part of an approved residency training program. Accordingly, we urge CMS to withdraw the clarification regarding the exclusion of didactic training from the GME and IME calculations.

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"HSRV Weights: In principal we support a change from DRG weights based on charges to weights based on costs. Our support derives from an understanding that the intent of the change is to promote reimbursement equity by reducing bias in the system which may have resulted from disparate charging practices in the industry. Any thoughtful change which pursues the goal of improving the accuracy of the system and equalizing incentive to provide services for all conditions we believe is worthy of our support. Our only caution would be to give appropriate consideration to the comments of others regarding weight determination methodologies and refine the system where those comments have merit accordingly.

CMS-1488-P-1732-Attach-1.DOC

CMS-1488-P-1732-Attach-2.DOC

#1732

June 12, 2006

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

Reference:CMS-1488-P

Dear Dr. McClellan,

The University of Arkansas for Medical Sciences (UAMS) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule entitled "*Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year Rates; Proposed Rule*". 71 Federal Register 23996, April 25, 2006. UAMS requests that CMS consider the following:

- HSRV Weights: In principal we support a change from DRG weights based on charges to weights based on costs. Our support derives from an understanding that the intent of the change is to promote reimbursement equity by reducing bias in the system which may have resulted from disparate charging practices in the industry. Any thoughtful change which pursues the goal of improving the accuracy of the system and equalizing incentive to provide services for all conditions we believe is worthy of our support. Our only caution would be to give appropriate consideration to the comments of others regarding weight determination methodologies and refine the system where those comments have merit accordingly.

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Thank you for this opportunity to submit these comments.

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Dan Riley
Chief Financial Officer

June 12, 2006

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Dear Dr. McClellan,

The University of Arkansas for Medical Sciences (UAMS) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule entitled "*Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year Rates; Proposed Rule*". 71 Federal Register 23996, April 25, 2006. UAMS requests that CMS consider the following:

- HSRV Weights: In principal we support a change from DRG weights based on charges to weights based on costs. Our support derives from an understanding that the intent of the change is to promote reimbursement equity by reducing bias in the system which may have resulted from disparate charging practices in the industry. Any thoughtful change which pursues the goal of improving the accuracy of the system and equalizing incentive to provide services for all conditions we believe is worthy of our support. Our only caution would be to give appropriate consideration to the comments of others regarding weight determination methodologies and refine the system where those comments have merit accordingly.

- Operating Payment Rates: In recent years the fixed loss threshold applied in determining outlier payments has resulted in payments below the amount withheld to fund such payments. We note that the discussion in the Federal Register regarding the proposed fixed-loss cost outlier for 2007 states that the same methodology will be used to calculate the threshold for 2007 as was used in 2006. Inasmuch as the previously used methodology has proven to be inaccurate we urge CMS to consider alternate methods for determining the amount of the outlier threshold.

- GME Payments: We believe that reimbursement for direct graduate medical education (GME) and indirect medical education (IME) is sufficiently restricted by limits on increase in per resident amounts, update factors, and resident FTE caps without the further imposition of burdensome record keeping requirements

with the sole apparent intent of further reducing such payments. We also find it difficult to accept the argument that training (didactic) to do patient care is not a cost related to patient care and, therefore, not a patient care activity when done as part of an approved residency training program. Accordingly, we urge CMS to withdraw the clarification regarding the exclusion of didactic training from the GME and IME calculations.

Thank you for this opportunity to submit these comments.

Sincerely,

Dan Riley

Dan Riley
Chief Financial Officer

Submitter :

Date: 06/12/2006

Organization :

Category : Individual

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

I strongly belived that adopting a proprietary system that is neither transparent or accessible, and will cause an increase in $$ for software acquisition, training and services, is both 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 the cause of health care affordability.

Submitter : **Dr. Cinh Pham** **Date: 06/12/2006**

Organization : **John Peter Smith Hospital-FMRP**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1734-Attach-1.DOC

#1734

Dear CMS policy maker

I am a family medicine resident in a very busy HPSA. I really need my faculty to teach. Why would you interpret a rule designed to do just that as being un related to patient care time? Whether we are having a discussion after a patient encounter, a small group discussion regarding a difficult clinical situation, reviewing our evaluation for our care and didactic tests in a certain disease domain, or participating in lectures – we are learning about, caring for current and protecting our future patients.

My concern is that the faculty are already stretched to produce more patient visits with poor compensation and must cover four of us at a time for supervision in clinic. That hour they spend before and after clinic to discuss a specific topic that is not related to a specific individual patient will disappear with the implementation of the rule you suggest. They will not have time to sit down with us to discuss our overall performance – we will get an email.

The faculty, without support for their own development, will be likely to lose their academic edge as they work to see patients, see more patients and supervise patient care without any incentive to reflect, discuss and research our and their work.

Please help us be better physicians to our patients by supporting a competent and refreshed faculty . Rescind the interpretation of the IME and DME support rule

Sincerely,

Submitter : **Ms. Maya Bermingham** **Date: 06/12/2006**

Organization : **PhRMA**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment - PhRMA Comments CMS-1488-P

CMS-1488-P-1735-Attach-1.PDF

#1735

PhRMA

June 12, 2006

VIA E-MAIL
http://www.cms.hhs.gov/eRulemaking

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

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

Dear Dr. McClellan:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the FY 2007 hospital inpatient proposed rule published by the Centers for Medicare and Medicaid Services (CMS).[1] PhRMA is a voluntary, nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

Consistent with our commitment to research and innovation, PhRMA has long sought to ensure that Medicare beneficiaries and all patients have access to the most appropriate therapies available, both in the hospital inpatient setting and other settings. Accordingly, we believe it is critical to assure that changes to Medicare's Inpatient Prospective Payment System (IPPS) support the goal of maintaining and improving patients' access to high-quality care.

The proposed rule envisions the first significant revision of the IPPS since it was implemented in 1983. It proposes two major changes to the current Diagnosis Related Group (DRG) system that determine IPPS payments for hospital stays. The first change would base DRG relative weights on costs rather than charges, by using a new Hospital Specific Relative

[1] Medicare Program; Proposed Changes to the Hospital Inpatient Payment Systems and Fiscal Year 2007 Rates; 71 Fed. Reg. 23996 (April 25, 2006).

Value Cost Centers (HSRVcc) methodology. CMS proposes to make this change in FY 2007 (i.e., starting October 1, 2006). The second change would revamp the current DRG system to recognize severity of illness better, by adopting new "consolidated severity-adjusted DRGs." This change is proposed for FY 2008 or possibly sooner.

PhRMA shares CMS' goal of improving the accuracy of IPPS payments, which can enhance beneficiary access to new and advanced therapies. Further, we recognize the magnitude of this task, and appreciate the efforts by CMS to develop these complicated new DRG methodologies in time for publication in the proposed rule. Given the significance and complexity of these proposed changes to the DRG system, however, we are concerned that they warrant more time for a complete assessment prior to implementation. Consequently, we believe prudence dictates deferring implementation of the proposed changes until at least FY 2008. This is important to give CMS and Medicare's stakeholders an adequate opportunity to evaluate the design and likely results of the new system, to identify and fully address elements of the system that require fine-tuning prior to implementation, and to permit hospitals to make the significant changes that will be necessary to adjust to the new system without risking disruption to patient care.

Our detailed comments are set forth below. Specifically, these comments address: (1) CMS' timing for implementing a new methodology for setting DRG relative weights; (2) CMS' timing for adopting the new consolidated severity-adjusted DRGs; (3) the need to refine the new DRGs so as to recognize technologies that represent increased complexity but not necessarily greater severity of illness; and (4) the importance of maintaining Medicare beneficiaries' access to new technology through the add-on payment system.

* * *

I. HSRVcc Weights -- CMS Should Delay Implementation of a Refined DRG Weight Methodology

PhRMA suggests that CMS delay implementation of refined relative weights for at least one year to allow the agency and stakeholders sufficient time to evaluate the proposed methodology and its impact fully; identify further refinements that may be necessary to avoid unintended consequences and better advance the goal of improved payment accuracy; and adjust to anticipated changes in payment rates. The potential impact of the HSRVcc methodology is very significant. CMS estimates that on average the new HSRVcc methodology would reduce the total weights for surgical DRGs by 5.7 percent and increase the weights for medical DRGs by 6 percent, when applied to the FY2006 DRGs.[2] For individual DRGs, however, the changes may

[2] Id. at 24020.

be considerably larger; for example, Table I in the proposed rule, showing selected high-volume DRGs, lists two DRGs that would experience 30 percent payment cuts due to the HSRVcc methodology.

The extensive nature of the changes associated with the proposed HSRVcc methodology and its overall complexity raise questions about the accuracy of Medicare payment at the individual DRG level. Further independent review of the proposed methodology and CMS' calculations is critical to ensure that the new DRG weights are indeed accurate weights that appropriately reflect resource costs for inpatient therapies. Furthermore, due to the delay in releasing MedPAR data to the public and the complexity of replicating the agency's methodology, few stakeholders have been able to analyze the proposed system thoroughly and to assess the consequences of the many design choices that went into its development. An additional year will be required prior to implementation to allow for a robust stakeholder dialogue with CMS concerning an appropriate DRG weighting methodology.

Certain aspects of the HSRVcc methodological design have raised concerns and highlight the importance of delayed implementation. For example, the proposal envisions CMS calculating unweighted national geometric mean cost-to-charge ratios (CCRs),[3] instead of CCRs weighted by hospital size; small hospitals' CCRs would therefore receive the same weight as large hospitals' CCRs, although large hospitals have more claims and are more likely to use advanced technologies that often have higher CCRs. Since each hospital's CCR is given the same weight, this methodology could potentially skew payments by underestimating the costs of caring for patients who need innovative therapies. As a result, further study is important to assure that the design of the new CCRs will not inadvertently create barriers to care for these patients.

The data that CMS would use in constructing the HSRVcc weights is also a source of concern, as it could result in relative weights that lag behind current treatment patterns. Specifically, the proposed HSRVcc weighting methodology would rely on older data that does not capture the costs of many newer technologies. The cost report data CMS used in developing the relative weights was from FY 2003, which means that (under the timetable in the proposed rule) cost data from October 2002 would be used in setting IPPS payments for FY 2007. Given the concerns this raises, CMS should carefully analyze the impact of this approach on newer treatments and explore the options for using alternative data sources that capture current information on costs of inpatient care.

Hospital cost reporting should also be aligned with CMS' framework. The proposed HSRVcc methodology assumes that all hospitals consistently allocate costs to the same cost

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[3] Id. at 24010.

centers. But each hospital uses its own allocation system to assign costs to its cost centers, often resulting in cost assignments that do not reflect the departments to which charges are assigned in the MedPAR data. The accuracy of the proposed HSRVcc methodology hinges on a uniform mapping of costs and charges to cost centers, which hospitals can only achieve with further instruction from CMS. Postponing implementation of refined DRG weights by at least one year would allow CMS to develop such guidance and give hospitals lead time to make system adjustments and begin reporting costs in accordance with that guidance, which will be important to assuring that a refined weighting system fulfills its purpose of improving payment accuracy.

In addition, it appears that there could be difficulties in fully replicating CMS' results, which raises questions about the calculations that merit further evaluation, and limits the ability of stakeholders to provide detailed feedback to CMS prior to implementation of a refined relative weight system. This is important because fully-informed comments based on a careful study of the proposed system are essential to help assure that necessary refinements are identified and addressed well before a major, complex change to the inpatient payment system is put in place.

Finally, delayed implementation of a refined DRG weight methodology would also allow hospitals more time to plan for the budgetary and administrative adjustments necessitated by the new weights. Under the timetable in the proposed rule, hospitals would only have the 60-day comment period to analyze these proposed changes, and only a brief period after publication of the final rule to adjust their budgets and test and implement the system changes needed to prepare for adoption of the HSRVcc weights. Given the critical patient care responsibilities facing hospitals and the disruption associated with sudden, large-scale revisions to payment systems, a delay of at least one year is warranted to permit an orderly switchover to a refined weighting system.

II. DRGs: Severity of Illness – Concurrent FY 2008 Implementation with a Refined Weight Methodology, and Recognizing Complexity of Care Independent of Severity of Illness in DRGs

CMS' second proposal to improve IPPS payment accuracy would replace the current DRGs with "consolidated severity-adjusted DRGs."[4] The consolidated severity-adjusted DRGs are based on a DRG system called the "All Patient Refined DRG System" (the APR DRGs) designed by 3M Health Information Systems. CMS developed the consolidated severity-adjusted DRGs by starting with the APR-DRGs (1258 in total) and then consolidating many of them. The result is a more granular system than Medicare's current system (861 DRGs compared with 526 DRGs currently) that is intended to reflect severity of illness more fully.

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[4] Id. at 24011.

PhRMA agrees with CMS that severity-adjusted DRGs should not be implemented until FY 2008 (which we believe is also the earliest time appropriate for implementation of refined DRG weights). This schedule would not only allow more time to review and analyze the impact of these major changes, but would also allow hospitals and other stakeholders to plan for the impact of both of these payment changes. Consequently, we urge CMS to implement both the severity-adjusted DRGs and refined DRG weights no earlier than FY 2008.

As CMS noted in the proposed rule, the current DRG system focuses on complexity (i.e., the relative volume and types of diagnostic, therapeutic, and bed services required for the treatment of a particular illness), and payments thus reflect the relative resource use needed by patients in one DRG compared to another. As CMS also noted, this focus on complexity accords with the Medicare statute, which requires that DRG classifications and weighting factors be adjusted at least annually "to reflect changes in treatment patterns, technologies . . . , and other factors which may change the relative use of hospital resources."[5] By contrast, the basis for the severity-adjusted DRGs, the APR DRG structure, "does not currently accommodate distinctions based on complexity"; therefore, "technologies that represent increased complexity, but not necessarily greater severity of illness, are not explicitly recognized."[6] CMS therefore believes that "a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the [new DRG] system," and "plan[s] to develop criteria for determining when it is appropriate to recognized increased complexity in the structure of the DRG system and how these criteria interact with the existing statutory provisions for new technology add-on payments."[7]

PhRMA agrees with CMS that the new DRG system should include a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness. Further, we believe it is critical to develop these refinements to the consolidated severity-adjusted DRGs, and to determine how they will interact with the statutory mandate for new technology add-on payments, well before implementation of the severity-adjusted DRGs.

An example of an advanced therapy in which the complexity of patient care does not correlate well with severity of illness is Proleukin (high-dose IL-2), a therapy for patients with metastatic renal cell cancer or malignant melanoma, which is usually administered in the inpatient setting. Because patients must be in relatively good condition to receive Proleukin, such cases would map to low severity DRGs. But this potentially life-saving treatment often has severe side effects that require complex and resource-intensive management, going far beyond the resources typically associated with usual chemotherapy. Under the proposed severity-

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5 Social Security Act (SSA) § 1886(d)(4).

6 71 Fed. Reg. at 24014.

7 Id.

adjusted DRGs, patients receiving Proleukin would map to CSA-DRG 736 (chemotherapy SOI 2) or CSA-DRG 737 (chemotherapy SOI 3). These DRGs were created without considering the complexity of care (consistent with the underlying logic of the APR DRG system), and therefore fail to reflect the costs associated with managing patients who receive this therapy. As proposed, payment for patients treated with Proleukin would fall from $16,925 in 2006 (DRG 492) to $5,187 (CSA-DRG 736) or $13,529 (CSA-DRG 737) - - cuts of 69 percent and 20 percent, respectively. If these cuts were implemented, many hospitals might be unable to continue providing Proleukin, which offers the only possibility of long-term survival for patients with metastatic renal cell cancer or malignant melanoma.

Proleukin is just one example highlighting the need for CMS to develop a method of recognizing complexity in the severity-adjusted DRG system. Without such improvements, the new DRG system will underpay hospitals for cases where patients are in relatively good condition but require resource-intensive care - - which would create barriers to access for these patients, and represent a step backward from CMS' goal of improving payment accuracy.

The proposed severity-adjusted DRGs also would reverse an critical policy change that was finalized last year to create DRG 559, *Acute Ischemic Stroke with Use of a Thrombolytic Agent.* This policy change permits hospitals to be reimbursed for the additional costs of caring for more complex stroke patients in need of thrombolytic therapy. As CMS noted in last year's final rule: "We agree... that there is an increased cost in caring for these [stroke tPA] patients including increased use of the intensive care unit, more diagnostic imaging studies, and laboratory and pharmacy resources. We also agree that-(1) the data indicate that patients receiving thrombolytic therapy have increased severity; and (2) reperfusion therapy is a good means to segregate these patients into a separate DRG." (Federal Register, Vol. 70, 47288, August 12, 2005.) If finalized, the proposed severity-adjusted DRGs would reverse this DRG change by assigning stroke patients receiving reperfusion therapy to CSA-DRGs 56-58 with other less severe stroke patients resulting in an estimated weighted-average 35 percent reduction for treating thrombolytic patients compared to FY 2006.

Consequently, PhRMA urges CMS to carefully examine the proposed severity-adjusted DRGs to ensure that these and other potential problems are addressed. Most importantly, the method for recognizing complexity should be proposed for public comment and refined as necessary based on stakeholder input well before the new severity-adjusted DRGs take effect. Until an appropriate method of recognizing complexity in the new DRG system is developed, CMS should delay implementation of the severity-adjusted DRGs.

III. New Technology and the IPPS

As CMS and Congress have recognized, adequate payment for new technology is essential in supporting Medicare beneficiaries' access to state-of-the art therapies. Inadequate payment can restrict access to innovative and potentially life-saving technologies for Medicare beneficiaries. Under the current and proposed DRG payment systems, it may take several years before DRG payment rates reflect the increased costs associated with the use of new technologies. New technology add-on payments thus bridge the gap between the introduction of a new technology and its recognition in the DRG payment system, helping to ensure Medicare beneficiaries' access to high-quality care in the interim. In order to preserve patient access to innovative therapies, it is critical for CMS to adapt the add-on payment mechanism to the new DRG methodology so that access to new technology is not impaired.

In the proposed rule, CMS discussed the new technology add-on payment applications but did not explain how the changes to DRG weights and groupings will affect these payments.[8] Since add-on payments are only available if the technology is inadequately paid under the DRG system,[9] changes in the rates or definitions of DRGs would affect CMS' assessment of whether a technology is adequately reimbursed. Furthermore, CMS recognized that a method of including complexity in the severity-adjusted DRGs would "interact with the existing statutory provisions for new technology add-on payments."[10] Before implementing refined DRG weights and severity-adjusted DRGs, CMS should carefully examine -- and explain to stakeholders -- how these changes would affect new technology add-on payments. Likewise, manufacturers of new technologies used in the inpatient setting will need a full understanding of how these changes interact with add-on payments in order to prepare applications to CMS for add-on payments.

Apart from addressing the implications of refined relative weights and severity-adjusted DRGs for new technology add-on payments, CMS should also revise an unfortunate interpretation of the new technology add-on provisions that has frustrated achievement of their purpose. As PhRMA has noted previously, CMS' position that the two-to-three year period in which a new technology may qualify for add-on payments begins with FDA approval of the technology is inconsistent with the statute itself and its implementing regulations. The statute expressly requires data collection and add-on payments starting on the "date on which an inpatient hospital code is issued with respect to the . . . technology."[11] The regulations recognize that an "inpatient hospital code" means an ICD-9-CM code, and provide that a technology may be considered "new" within two to three years after the "point at which data begins to become

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8 Id. at 24068.

9 42 CFR § 412.87(b)(3).

10 71 Fed. Reg. at 24014.

11 SSA § 1886(d)(5)(k)(II), (III) (emphasis added).

available reflecting the ICD-9-CM code assigned to the new . . . technology . . . ."[12] Using the date of FDA approval instead of the date referenced in the statute and regulations can result in improper denials of add-on payments and undermine the goal of assuring Medicare beneficiaries' access to important new therapies that are inadequately reimbursed under the DRG system.

* * *

PhRMA hopes that these comments will be useful to CMS in developing the final inpatient rule for FY 2007 and in its work to improve the accuracy of IPPS payments. Again, we strongly urge CMS to delay implementation of both refined DRG weights and the severity-adjusted DRGs until at least FY 2008, to allow stakeholders sufficient time to evaluate these complex changes and provide the agency with fully-informed comments on their repercussions for patient care. Major changes to the inpatient hospital payment system would be premature, and may not be the most effective approach for improving payment accuracy, without the benefit of a robust exchange between CMS and Medicare's stakeholders. We look forward to further dialogue on these issues, and trust that CMS will not hesitate to contact us with any questions, comments or requests for additional information.

Sincerely,

Richard I. Smith
Senior Vice President for
Policy, Research, and Strategic Planning

Diane E. Bieri
Deputy General Counsel
Compliance Officer

12 42 CFR § 412.87(b)(2).

Submitter : Mrs. mary elizabeth jackson **Date:** 06/12/2006

Organization : Trinity Mother Frances Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1488-P-1736-Attach-1.DOC

#1736

TRINITY MOTHER FRANCES
HEALTH SYSTEM

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of Trinity Mother Frances Health System, Tyler, Texas, representing our 3,200 employees including over 225 physicians, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2007 inpatient prospective payment system (PPS) and occupational mix adjustment proposed rules. The rule proposes the most significant changes in the calculation of diagnosis-related group (DRG) relative weights since 1983 by creating a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc).

It also proposes refining the DRGs to account for patient severity, with implementation likely in FY 2008. In addition, the rule would update the payment rates, outlier threshold, hospital wage index, quality reporting requirements, and payments for rural hospitals and medical education, among other policies.

While we support many of the proposed rule's provisions, **we have serious concerns about the proposed changes to the DRG weights and classifications**. More time is needed to understand the significant proposed policy changes, which redistribute from $1.4 to $1.7 billion within the inpatient system. Analysis shows the impact of the proposed changes to be highly unstable, with small changes in method leading to large changes in hospital payment. And the validity of CMS' proposals versus potential alternatives to improve the DRG weights and classification system is uncertain.

Trinity Mother Frances Health System supports the following:

• **One-year Delay:** TMFHS supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology. 0000

• **Valid Cost-based Weights:** We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed.

• **A New Classification System Only if the Need Can Be Demonstrated:** TMFHS does not support a new classification system at this time, as the need for a new system is still unclear. Much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.

• **Simultaneous Adoption of Any Changes to Weights and Classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.

• **Three-year Transition:** Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.

• **Collaborative Approach to Moving Forward**: TMFHS commits to working with CMS to develop and evaluate alternatives for new weights and classifications. Our Senior Vice President, Bill Bellenfant, stands ready to come to Washington if necessary to work on these very important issues.

Further, we support the comments submitted by the American Hospital Association that further explain our concerns and recommendations on the proposed DRG weight and classification system changes, as well as our position on many other issues in the proposed rule.

Trinity Mother Frances Health System appreciates the opportunity to submit these comments. If you have any questions about our remarks, please feel free to contact Mary Elizabeth Jackson at (903) 531-4788 or Jacksom@tmfhs.org.

Sincerely,

Lindsey Bradley
President and Chief Administrative Officer

David K. Teegarden, MD
President and Chief Medical Officer

Ray Thompson
Executive Vice President and Chief Operating Officer

Steven P. Keuer, MD
Executive Vice President

Submitter : **Ms. Lisa Horning** **Date: 06/12/2006**

Organization : **HP3, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

DRGs: Severity of Illness

DRGs: Severity of Illness

See Attachment

CMS-1488-P-1737-Attach-1.DOC

CMS-1488-P-1737-Attach-2.DOC

#1737

June 12, 2006

Mark McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-1850

Attention: CMS-1488-P

Dear Dr. McClellan:

HP3, Inc. respectfully submits comments to the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.

Specifically, HP3 has three areas of comment. They are as follows:

1. HRSV Weights

HP3, Inc. currently provides services to Maryland hospitals that are reimbursed under an APR DRG reimbursement logic that is similar to what CMS is proposing in CMS-1488-P. It is HP3's expert opinion that the implementation of the HRSV weights should be linked to the implementation of the proposed severity logic for continuity and successful implementation of the APR DRG based reimbursement system.

We further recommend that the APR DRG logic and HRSV weights be implemented together no earlier than fiscal year 2008. An implementation date of fiscal year 2008 would allow for—a) the necessary education and training of hospital staff regarding APR DRG logic, b) critical information technology upgrades and system improvements, and c) understanding the APR DRG reimbursement system and the operational changes that may be necessary for hospital transition.

Lastly, under this section, the proposed regulations are unclear as to how HRSV weights will be calculated annually; how CMS will implement updates to the HRSV weights; and whether CMS anticipates any compression as the HRSV weights are implemented.

2. Licensing of 3M Grouping Logic

As stated in the proposed regulations, the APR DRG analysis was performed with the 3M APR DRG software ("3M Grouper"). It is HP3's recommendation that the 3M Grouper, necessary for filing accurate claims to CMS, be in the public domain with an open architecture so that hospitals seeking reimbursement under the APR DRG system can use external resources and services to ensure the timely and accurate filing of claims under the proposed reimbursement system.

3. Determination of Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Case Mix Index (CMI) will be impacted by the severity of illness grouping logic. From HP3's experience in Maryland, CMI will have a greater rate of change in the first few years APR DRG is in effect. This increase is partly due to the change in reimbursement logic and partly due to hospitals' increased diligence in clinical documentation and precision coding of severity of illness conditions and co morbidities. It is unclear how CMS intends to address the increased rate of change in case mix. Since the high rate of change will not be revenue neutral, how does CMS plan to regulate the rate of change? Does it anticipate putting a governor in place or will there be a cap set for each hospital?

On a hospital specific level, certain hospitals may experience a rapid decline in case mix as a result of the APR DRG implementation. It is unclear whether CMS plans to implement a mechanism to address either the possibility for rapid increase or rapid decline of CMI.

Lastly, if a hospital's case mix improvement is directly tied to its internal documentation improvement and coding accuracy, HP3 recommends that in such a situation, hospitals are entitled to the full CMI benefit of their improvement programs.

Respectfully yours,

Lisa Horning, Esq.
Vice President, Intellectual Property Management and Compliance
HP3, Inc.

HP3

Documentation, Coding & Data Solutions
For Improved Reimbursement, Compliance & Patient Care

June 12, 2006

Mark McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-1850
Attention: CMS-1488-P

Dear Dr. McClellan:

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Specifically, HP3 has four areas of comment. They are as follows:

1. HRSV Weights

HP3, Inc., a national firm specializing in coding and clinical documentation improvement, currently provides services to Maryland hospitals that are reimbursed under an APR DRG reimbursement logic that is similar to what CMS is proposing in CMS-1488-P. It is HP3's expert opinion that the implementation of the HRSV weights should be linked to the implementation of the proposed severity logic for continuity and successful implementation of the APR DRG based reimbursement system.

We further recommend that the APR DRG logic and HRSV weights be implemented together no earlier than fiscal year 2008. An implementation date of fiscal year 2008 would allow for—a) the necessary education and training of hospital staff regarding APR DRG logic, b) critical information technology upgrades and system improvements, and c) understanding the APR DRG reimbursement system and the operational changes that may be necessary for hospital transition.

Lastly, under this section, the proposed regulations are unclear as to how HRSV weights will be calculated annually; how CMS will implement updates to the HRSV weights; and whether CMS anticipates any compression as the HRSV weights are implemented.

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3. Determination of Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Case Mix Index (CMI) will be impacted by the severity of illness grouping logic. From HP3's experience in Maryland, CMI will have a greater rate of change in the first few years APR DRG is in effect. This increase is partly due to the change in reimbursement logic and partly due to hospitals' increased diligence in clinical documentation and precision coding of severity of illness conditions and co morbidities. It is unclear how CMS intends to address the increased rate of change in case mix. Since the high rate of change will not be revenue neutral, how does CMS plan to regulate the rate of change? Does it anticipate putting a governor in place or will there be a cap set for each hospital?

On a hospital specific level, certain hospitals may experience a rapid decline in case mix as a result of the APR DRG implementation. It is unclear whether CMS plans to implement a mechanism to address either the possibility for rapid increase or rapid decline of CMI.

Lastly, if a hospital's case mix improvement is directly tied to its internal documentation improvement and coding accuracy, HP3 recommends that in such a situation, hospitals are entitled to the full CMI benefit of their improvement programs.

Respectfully yours,

Lisa Horning, Esq.
Vice President, Intellectual Property Management and Compliance
HP3, Inc.

Submitter :

Date: 06/12/2006

Organization : Parma Community General Hospital

Category : Hospital

Issue Areas/Comments

Operating Payment Rates

Operating Payment Rates

June 12, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and 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; Proposed Rule

Dear Dr. McClellan:

On behalf of Parma Community General Hospital, we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule on the FY 07 Medicare Inpatient Prospective Payment System (IPPS), as published in the April 25, 2006 Federal Register. Given the complexities of CMS proposal to revise the diagnosis-related group (DRG) system and the magnitude of impact this could have on our Hospital, we are writing to urge a one-year delay in implementing these policy proposals.

CMS proposes to move from the historical charge-based DRG system to a cost-based system and to implement hospital-specific relative weights by October 1, 2006. CMS also proposes modifying the DRG classification system to account for differences in patient severity and allow for a payment amount that more closely tracks the cost of providing care. In its proposal, CMS states that it would replace the current 526 DRGs with either the proposed 861 consolidated severity-adjusted DRGs by FY 08 or a similar system that accounts for the level of patient severity, developed in response to public comments that it receives.

It has been estimated that this proposal will result in a reimbursement shift of approximately 6% from surgical DRGs to medical DRGs. This is a major shift which will have a significant impact on Parma Hospital. For example, the impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by about 10%. Other technology intensive DRGs will also be significantly reduced under the CMS proposals, including DRGs for stents by 30%, ICD implants by 23%, and pacemakers by 13%. While the increase in medical DRG reimbursement is welcomed, there simply has not been sufficient time allotted to fully analyze the impact of all those policy changes.

Parma Hospital supports meaningful improvement to Medicare payments for inpatient services and applauds the tremendous effort CMS has put forth to devise a DRG system that more accurately reflects the costs of providing inpatient services. We recognize that your agency has taken these steps to make payments fairer to hospitals and to assure beneficiary access to services in the most appropriate setting. In the proposed rule, CMS seeks input on the proposed methodologies and solicits alternatives to the consolidated severity-adjusted DRG model. While we welcome the opportunity to work with CMS and other stakeholders in ensuring that any system implemented accomplishes the stated goals, we are extremely concerned with the tight timeline provided for developing comments and the implementation dates outlined in the proposal. Restructuring the DRG system as proposed in the rule would represent the most significant policy change to the IPPS since its inception. A change of this magnitude warrants a thoughtful and thorough review by hospitals, a task not easily accomplished during a 60-day comment period, given the complexity of the proposals.

As such, we strongly urge CMS to delay implementing both the proposed DRG reclassification and the changes to the relative weights until FY 08. The additional time will allow Parma Hospital and other hospitals to more thoroughly evaluate the proposals and offer more constructive feedback to your agency.

Again, thank you for the opportunity to share our comments on the DRG provisions of the proposed IPPS rule.

Very truly yours,

Barry L. Franklin, C.P.A.
Executive Vice President/CFO

BLF:sl

Submitter : **Dr. Huong Phan** **Date: 06/12/2006**

Organization : **John Peter Smith Hospital-FMRP**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1739-Attach-1.DOC

#1739

Currently I am completing my residency in family medicine. When I became aware that CMS would stop funding payment to faculty for teaching, preparing curriculum and evaluating my performance through GME -- IME and DME support – I became alarmed.

We are in a state with a huge health care professional shortage in communities under 25,000. These communities cannot afford to support several nurse practitioners and visiting specialists when the services are delivered by a pluri-potential well trained family medicine specialist who is part of their community. The training programs, like mine, which prepare us for these types of venues are in very short supply. We need to be exceptionally well trained.

Someone at CMS will need to explain to me, how the teaching, curriculum development and evaluation process for the six required ACGME physician skill competencies is not related to patient care. Isn't this exactly what the IOM has criticized our training professions for? In fact, our program currently evaluates us in all these competencies as a continuing quality improvement process DURING patient care. Without time to discuss and reflect our experiences and outcomes we will not be serving the needs of our current and future patients.

Should indeed this come to pass, we will have faculty who will be caught in the productivity race with no time for us. We may get pop-up feed back from an Electronic Health Record in sites that have them that we have made an error or we are not following a guideline. No discussion there. What is being proposed is dangerous for our current patients and our future patients. Our patients deserve for us to have a better education than you are proposing.

Why does the American taxpayer support medical students at over $200,000 per student per year and offers the faculty of residencies less than $15,000 for teaching per resident per year? I am getting a lot more from my residency training to protect and serve my patients of the future than all of medical school combined. Please do not cut us any more – rescind the clarification of this dangerous and capricious rule.

Medical Resident

Submitter : Ms. Gail Gillenwaters **Date:** 06/12/2006

Organization : North Broward Hospital District

Category : Hospital

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

The North Broward Hospital District has reviewed the proposed 2007 Hospital Annual Payment Update rule and has the following comments:

1.The North Broward Hospital District recognizes the positive impact of implementing structure measures. However, such programs span multiple years, must be approved on an annual basis and require board approval. They also require significant financial resources, human resources, and time to develop and implement. Requiring such programs that present a challenge to fund, or risk reduction in payment, would not appear to be reasonable. For example, the phased-approach implementation of CPOE is projected to be completed by 2009 with an estimated cost of up to $2 million.

2.Electronic Medical Records development is also an extremely resource and financial intensive process, requiring a significant commitment of the entire organization. The phased-approach implementation is expected to cost up to $20 million and be completed no later than 2010.

Submitter : **Mr. John S.T. Gallagher /Dr. Richard N. Fine** **Date: 06/12/2006**

Organization : **Stony Brook University**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1488-P-1741-Attach-1.DOC

#1741

STATE UNIVERSITY OF NEW YORK
STONY BROOK
HEALTH SCIENCES CENTER

June 12, 2006

Electronically submitted

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

Ref: CMS-1488—P — Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates; Proposed Rule.

Re: DRG Reclassifications; Resident Time Spent in Non-patient Care Activities as Part of Approved Residency Programs; Outlier Payments; Hospital Quality Data

Dear Dr. McClellan:

Stony Brook University Hospital (SBUH) appreciates the opportunity to submit comments on the above-captioned Proposed Rule.[1] SBUH is a 504 bed university based hospital in Suffolk County, NY. The Hospital and Stony Brook University (SBU) provide education to over 520 residents and fellows in 57 different programs. These programs include but are not limited to Anesthesia, Dentistry, Dermatology, Emergency Medicine, Family Medicine, various General Medicine Programs (Cardiology, Endocrinology and others), Neurology, Obstetrics, Ophthalmology, Orthopedics, Pathology, Pediatrics, Preventative Medicine, Psychiatry, Radiology, Surgery and Urology.

SBUH also provide certain specialized services essential to the entire community, such as emergency and trauma care, angioplasty, cardiac surgery, burn care, and neonatal intensive care. The Hospital is a multifaceted institution, serving as Suffolk County's (population 1.5 million) only major training center for medical residents and interns. The Hospital is also the County's only Trauma Center. Because of all of these characteristics, the proposed changes would significantly impact day-to-day operations of the Hospital.

Our detailed comments related to the Proposed Rule are attached. In summary, the Hospital urges CMS to consider the following recommendations:

- SBUH supports CMS' policy goal to increase the accuracy of current IPPS payment methodologies. Such accuracy is critical to the financial stability of SBUH in the provision of care without regard to the relative profitability of IPPS payments. In order to ensure the most accurate system possible, the Hospital encourages CMS to take the

[1] 71 Federal Register 23996 (May 25, 2006). Hereinafter "Proposed Rule."

time to validate Hospital Specific Relative Value (HSRV) weighting using hospital cost data and seek further provider involvement in the process of developing the new severity-adjusted DRGs. We urge MedPAC and CMS to review and consider the analysis of the CMS proposals prepared by The Health Economics and Outcomes Research Institute (THEORI) of the Greater New York Hospital Association (GNYHA). Finally, to ensure payment accuracy, the Hospital urges CMS to instruct Medicare fiscal intermediaries to capture all diagnosis and procedures codes available under HIPAA electronic transaction standards.

- SBUH and SBU urge CMS to rescind its clarification in the Proposed Rule related 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.

- SBUH opposes raising the outlier threshold and supports the American Hospital Association's (AHA's) recommendation to utilize a methodology that incorporates both *cost* inflation and *charge* inflation in calculating the outlier threshold. SBUH believes the use of more than one indicator will make the threshold calculation more accurate and reliable. To account for the unspent outlier payments and attendant understated standardized amounts, the Hospital urges CMS to retroactively adjust IPPS payments.

- Finally, with regard to the development of pay-for-performance measures and value-based purchasing systems, CMS should ensure such metrics include quantification of the disparities in care experienced by patients of different races, ethnicities, and socioeconomic backgrounds

SBUH and SBU appreciate the opportunity to submit these comments on the Proposed Rule. If you have any questions about these comments, please contact Richard Nagy, Director of Finance for Reimbursement and Analysis at (631)444-4100.

Sincerely,

John S.T. Gallagher
CEO of Stony Brook University Hospital

Dr. Richard N. Fine
Dean of Medicine, Stony Brook University

COMMENTS ON THE FY 2007 INPATIENT PROSPECTIVE PAYMENT SYSTEM (IPPS) PROPOSED RULE

DRG Reclassifications

SBUH supports CMS' policy goal to improve the accuracy of current IPPS payment methodologies to better reflect the actual cost of providing care. Such accuracy is critical to ensuring the greatest possible efficiency in Medicare program. Moreover, such accuracy is critical to the financial stability of safety-net providers, who, because of their mission, provide care without regard to the profitability of IPPS payments.

The proposed DRG changes include a shift from a charge-based methodology to a hospital-specific, relative-value (HSRV) cost based weighting system and a new DRG system to better reflect patients' severity of illness. The Hospital encourages CMS to delay implementation while it validates HSRV weighting using hospital cost data. The Hospital and the University echo AHAs recommendation of a 1 year delay before implementing the proposed changes. Due to the significant negative impact on SBUH and SBU (loss of $2.6 million of revenue), we also recommend a 3 to 5 year phase in of the new DRG methodology. In order to compensate for the loss both the Hospital and University have to reconsider its current and future investment in certain educational and care programs. The reduction in Medical Education and DRG payments will force the hospital to either divest in Cardiac and other care areas or seek alternative funding sources. Either option will be costly and take considerable time due to commitments to students and faculty as well as financial obligation of the Hospital and University.

Furthermore, SBUH and SBU urge CMS to seek further provider involvement in the process to consolidate 1,258 All-Patient Refined (APR) DRGs to develop the proposed 861 severity-adjusted DRGs (loss of $1.8 million of revenue). The Hospital is particularly concerned about consolidations related to cardiac, obstetrics and psychiatric care services, which are critically important the services provided to Suffolk County. We urge CMS to ensure that the new severity-adjusted DRGs accurately reflect provider cost in all aspects of inpatient care. As above, SBUH and SBU recommend a delay of 1 year in the implementation and a 3 to 5 year phase in period for the proposed severity adjusted DRGs.

We urge MedPAC and CMS to review and consider the analysis of the CMS proposals prepared by The Health Economics and Outcomes Research Institute (THEORI) of the Greater New York Hospital Association (GNYHA). They conclude: *"HSRVcc methodology simply doesn't work and should be abandoned. Through a thorough empirical analysis, we have proven that the methodology significantly underpays for surgical cases and overpays for medical cases. It also greatly worsens the current inaccuracies in the IPPS... If implemented, the HSRVcc methodology would destabilize the hospital industry, cause negative ripple effects throughout the health care system and the general economy, and impair access to life-saving and enhancing services. It is unfortunate that CMS proposed the methodology without first determining whether it worked. And it was a mistake for the Medicare Payment Advisory Commission (MedPAC) and the Chairman of the House Ways & Means Committee to endorse the proposal without being assured of its efficacy. The CS DRG patient classification system should also be abandoned. It*

does not enhance IPPS payment accuracy, as shown in Figure 2, and it has many programmatic disadvantages. We believe that the best way to improve payment accuracy in the IPPS would be to change the basis for the DRG weights from charges to cost. Doing so would go a long way toward closing the current gap between the cost margins of medical and surgical cases It is not necessary or desirable to change the methodology for computing the DRG weights from the standard approach to the Hospital-Specific Relative Value ("HSRV") methodology, as MedPAC recommends."[12]

Finally, we join the American Hospital Association (AHA)[2] in raising concerns that CMS' DRG GROUPER does not use all diagnoses and procedures that affect a patient's severity of illness and/or the resources utilized. The current DRG GROUPER only considers nine diagnoses and up to six procedures. Hospitals submit claims to CMS in an electronic format. The Health Insurance Portability and Accountability Act of 1996 (HIPAA)[3] electronic transaction 837i standard allows up to 25 diagnoses and 25 procedures to be entered by providers. Many fiscal intermediaries (FIs) are ignoring or omitting the additional codes submitted by hospital providers since these additional diagnoses and procedures are not needed by the GROUPER to assign a DRG.

Capturing all diagnoses and procedures meeting the definitions of reportable secondary diagnoses and procedures will provide a more complete picture of patient complexity. As CMS considers methodologies for refining the patient classification system, the number of secondary diagnoses may be an important factor in determining differences in patient characteristics. This is particularly true of patients with many chronic illnesses that add to the complexity of treating them. To ensure payment accuracy, we urge CMS to instruct Medicare FIs to capture all diagnosis and procedures codes available under the HIPAA electronic transaction standards.

Resident Time Spent in Non-patient Care Activities as Part of Approved Residency Programs

SBUH and SBU join the Association of American Medical Colleges (AAMC) in strongly opposing CMS' proposal to eliminate time spent by resident in "didactic activities" as counting towards in a hospitals' direct Graduate Medical Education (GME) or Indirect Medical Education (IME) Full Time Equivalent (FTE) calculation.[4] The Proposed Rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the FTE 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."

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[2] Letter from Mr. Rick Pollack, Executive Vice President, American Hospital Association to Dr. Mark McClellan, Administrator, Centers for Medicare and Medicaid Services (June 12, 2006).
[3] Pub. L. No. 104-191.
[4] Letter from Jordan J. Cohen, M.D., President, the Association of American Medical Colleges to Dr. Mark McClellan, Administrator, Centers for Medicare and Medicaid Services (June 12, 2006).

This position is in stark contrast to CMS' position articulated 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."[5] The Hospital and the University concur with CMS' 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.

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 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 related 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.

Outlier Payments

SBUH joins AHA in opposing the proposed increase in the outlier threshold, given that outlier payments over the last several years consistently have been less than CMS projected.[6] The proposed approach unfairly penalizes hospitals with outlier cases, which are already reporting losses from treating these high cost patients and will only have to expend more resources to reach the higher threshold.

By statute, Medicare provides extra payments for unusually high cost cases in order to limit hospitals' financial risk from extraordinary costs, and to diminish any financial incentive to avoid Medicare patients with especially serious illnesses.[7] These outlier payments are made only if the DRG payment, plus IME and DSH payments, plus any payments for new technologies, plus some fixed-loss cost outlier threshold (set annually by CMS) is exceeded. As required by statute, CMS sets the fixed-loss cost outlier threshold at a level that ensures that outlier payments constitute between 5 to 6 percent of total operating DRG payments plus outlier payments.[8] Also required by statute, CMS reduces the average IPPS standardized amount to account for the estimated proportion of total DRG payments made to outlier cases.[9]

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[5] Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins (September 24, 1999).

[6] Letter from Mr. Rick Pollack, Executive Vice President, American Hospital Association to Dr. Mark McClellan, Administrator, Centers for Medicare and Medicaid Services (June 12, 2006).

[7] Social Security Act § 1886 (d)(5)(A).

[8] Social Security Act § 1886(d)(5)(A)(iv).

[9] Social Security Act § 1886(d)(3)(B).

In the Proposed Rule, CMS sets the FY 2007 fixed-loss cost outlier threshold at $25,530, an increase of 8 percent from the FY 2006 threshold amount of $23,600. SBUH believes the proposed increase in the outlier threshold is improper given that CMS has consistently over estimated the cost of outlier payments over the last few years and total outlier payments have accounted for less than the target amount of 5.1 percent of DRG payments. AHA estimates that CMS under spent the funds set aside for outliers by $3 billion between FYs 2004 and 2006.[10] AHA data also indicate that if CMS finalized the proposed threshold of $25,530, CMS will once again over estimate the expected cost of outlier payments and under spend by $319 million in FY 2007.[11]

An unwarranted policy that raises the outlier threshold unfairly penalizes hospitals already reporting losses from treating these high cost patients. This policy is further exacerbated because CMS does not propose to retroactively adjust outlier payments or, in the alternative, standardized amounts, to ensure that payments for FY 2005 and FY 2006 are equal to the target of 5.1 percent of total DRG payments.

SBUH opposes raising the outlier threshold and supports AHA's recommendation to utilize a methodology that incorporates both *cost* inflation and *charge* inflation in calculating the outlier threshold. We believe the use of more than one indicator will make the threshold calculation more accurate and reliable. To account for the unspent outlier payments and attendant decreases in standardized amounts, NAPH urges CMS to retroactively adjust IPPS payments.

Value-Based Purchasing

The development of future pay-for-performance measures and value-based purchasing systems should include measurement of disparities in care experienced by patients of different races, ethnicities, and socioeconomic backgrounds. Disparity in the provision of health care services has been a well-documented concern of many in the health care field for several years. SBUH believes that any comprehensive assessment of quality tied to pay-for-performance measures must include measurements of the disparity in care experienced by patients of different racial, ethnic, and socioeconomic backgrounds. Such measures should include the ability of health care providers to offer culturally and linguistically appropriate care as well as other measures of the difference in the quality of care received by patients of different backgrounds.

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[10] Proposed Rule, 70 Fed. Reg. 23470.

[11] See Letter from Mr. Rick Pollack, Executive Vice President, American Hospital Association to Dr. Mark McClellan, Administrator, Centers for Medicare and Medicaid Services (June 12, 2006).

[12] The Health Economics and Outcomes Research Institute of the Greater New York Hospital Association, Karen S. Heller, MBA et al, Analysis of the Centers for Medicare & Medicare Services' Proposals for Changing the Diagnosis-Related Group Weighting Methodology and Patient Classification System in the Inpatient Prospective Payment System (June 12, 2006).

Submitter : **Mr. John Krichbaum** **Date: 06/12/2006**

Organization : **American Burn Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Hospital Inpatient Prospective Payment System

CMS-1488-P-1742-Attach-1.DOC

#1742

June 15, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attn. CMS—1488—P
7500 Security Boulevard
Baltimore MD 21244

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

Dear Dr. McClellan:

The American Burn Association (ABA) appreciates the opportunity to comment on the Medicare Program Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates Proposed Rule. The American Burn Association represents the nation's burn surgeons, nurses, therapists, and other members of the burn team, and the nation's leading medical institutions with burn centers which provide therapeutic and surgical services for burn patients and other patients diagnosed with extensive and/or life-threatening skin diseases.

We urge CMS is to consider the following issues:

- Burn centers in the US are a critical national resource that must be protected.
- Terrorist acts, whether large in scope or isolated, are an acknowledged national danger. Burn Centers are among the first resources that would be used to treat patients injured from such acts.
- To the extent that a new or revised IPPS affects hospitals with burn centers, burn centers will be affected. The ABA asks that CMS consider the potential effect on burn centers during its future deliberations on IPPS.
- Burns and certain non-burn conditions that are referred to burn centers require highly complex care from surgeons, nurses, therapists and other members of the burn care team -- most often over a lengthy period of time, advanced technology, intensive daily care, and substantial hospital resources. These centers must be preserved and nurtured financially to meet the needs of the nation.
- Epidemiologically, specific resources within burn centers may be called upon when other major health threats occur. For example, a recent study on a potential avian flu pandemic indicated that virtually every mechanical ventilator in the nation would be required to treat these patients should such an event involve the US. Burn centers, skilled in the use of mechanical ventilators, would be a key part of that treatment protocol.

Following careful review of the Hospital Inpatient Prospective Payment Systems (HIPPS) proposed rule, the ABA would like to comment on several key proposals only. The scope of the proposed changes is of so significant a magnitude, and the time frame for review and analysis so limited, that no single organization can evaluate all of the potential effect of this proposal. Therefore, the ABA comments will focus on several key proposals only. Certain information gaps also contributed to the difficulty of evaluating the proposals. ABA comments are provided with the foregoing context in mind.

HSRV Weights

We note that, when applied to the current burn DRGs, the Hospital Specific Relative Value (HSRV) methodology is beneficial. However, given the proposed changes to the new Consolidated Severity-Adjusted DRG (CSA DRGs) system for 2008 or earlier, this potential beneficial effect may not be realized in 2007 or 2008.

The omission of HSRV relative weights for the proposed new CSA DRGs limits our ability to properly comment on behalf of burn centers and to estimate the effect of the new methodology. Relative weights are a critical piece of information that is needed in order to perform estimates and projections of the effects of the proposed system on burn centers nationwide.

Due to the compressed time frame allowed for analysis of these sweeping changes, we strongly recommend CMS consider delaying implementation of both the HSRV methodology and CSA DRGs. A reasonable delay would allow all stakeholders to more fully analyze the HSRV methodology and the clinical coherence and rationality of a CSA DRG system.

In addition, if CMS alters the HSRV methodology in a significant way in the final rule as a result of comments to this proposed rule, we believe a separate comment period (e.g., 90 days) on the changes would be necessary and appropriate. Should CMS choose to implement the HSRV system for 2007, we recommend it be applied to the current DRG system, leaving time through 2007 to further assess the CSA DRG system or its alternates. This recommendation is a modification of one of the range of alternative implementation options you suggest in the proposed rule (p. 24026, "Conclusions").[1]

DRGs: Severity of Illness

While the 3M Grouper tool allowed users to develop and test sample cases and did produce a cross-walked CSA DRG and current CMS DRG for each case, the absence of a Grouper to perform multiple test cases for a hospital's top 10 DRGs or a burn center's "burn" and "non-burn" DRGs precludes development of important projections as to the volumes of CSA DRGs that would result.

Again, the limited time available for study and analysis of the extensive nature and clinical complexity of the APR-DRG / CSA-DRG system, allowed only a very limited review of the contents of the system. Hence, we are unable to comment further on this important clinical classification system. We are very interested in the proposed system and, as stated above, advocate delay of its implementation until stakeholders have had sufficient time to focus on it. This delay will permit development of meaningful, clinical commentary from clinicians and hospitals and other stakeholders.

Coding Issues

In the FY 2006 IPPS Final rule (FR 70, 47474), CMS states it "would consider making changes to the CMS DRGs to better reflect severity of illness among patients." To accurately group patients by severity of illness and to meet CMS' goal, excellent documentation and coding is required. In the proposed rule (p. 24026), CMS indicates that increases in case mix index (CMI) can be expected as a result and further, that such increases do not represent real increases in underlying resource demands. This statement may be true when applied to current "CMS DRGs;" however, we are

[1] "Much like the approach we took last year to identify MCV conditions that represented higher severity in cardiovascular patients, we plan to examine which conditions identify more severely ill cases in selected MDCs and DRGs. We are soliciting comments as to whether it would be appropriate to adopt these types of limited changes in FY 2007 as an intermediate step to adopting consolidated severity-adjusted DRGs in FY 2008. We also encourage commenters to send suggestions regarding this method for modifying the DRGs".

unsure that the statement holds true for severity-adjusted DRGs as increases in CMI, if they do occur, may indeed reflect real increases in resource demands. We would welcome further elaboration of the CMS assertion as it pertains to severity-adjusted DRGs.

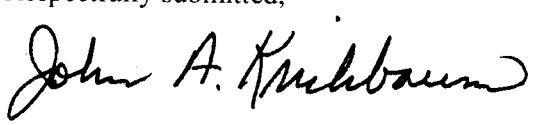
Further applicable comments can be found in the above section, "HSRV Weights."

Closing Remarks

The limited amount of time to review, analyze, and test the extremely large number and magnitude of proposed changes seems unreasonable and unlikely to yield high quality comments that will foster optimal decision-making by CMS. We suggest CMS consider a staggered phase-in of the major components and then only after additional time for analysis and comment is granted.

Thank you for the opportunity to comment on this proposed rule. The ABA looks forward to contributing its expertise to CMS in order to foster proper payment for FY2007 and in the future. If you have any questions on the issues discussed in this comment letter, please contact us. We will be happy to provide the information you require.

Respectfully submitted,



John A. Krichbaum, JD
Executive Director
American Burn Association

Submitter : Dr. Patrick Prevo **Date:** 06/12/2006

Organization : John Peter Smith Hospital-FMRP

Category : Health Care Professional or Association

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1743-Attach-1.DOC

#1743

Dear CMS Policy Maker:

I am a family medicine resident in a very busy HPSA. I really need my faculty to teach. Why would you interpret a rule designed to do just that as being unrelated to patient care time? Whether we are having a discussion after a patient encounter, a small group discussion regarding a difficult clinical situation, reviewing our evaluation for our care and didactic tests in a certain disease domain, or participating in lectures – we are learning about, caring for current and protecting our future patients.

My concern is that the faculty are already stretched to produce more patient visits with poor compensation and must cover four of us at a time for supervision in clinic. The hour they spend before and after clinic to discuss a specific topic that is not related to a specific individual patient will disappear with the implementation of the rule you suggest. They will not have time to sit down with us to discuss our overall performance – we will get an email.

The faculty, without support for their own development, will be likely to lose their academic edge as they work to see patients, see more patients and supervise patient care without any incentive to reflect, discuss and research our and their work.

Please help us be better physicians to our patients by supporting a competent and refreshed faculty. Rescind the interpretation of the IME and DME support rule.

Sincerely,

Submitter : Dr. Robert Zwolak **Date:** 06/12/2006

Organization : Society for Vascular Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

Proposed new DRG Payment Methodology

SVS fully supports changes in payment wherein the methodological underpinnings are sound, the information dispersion transparent, and the resultant reallocation more accurately reflective of true resource utilization. Having said that, we have major concerns regarding the methods and resultant changes involved in the new cAPR-DRG system.

Impact of New Methodology on Vascular Services

SVS believes the new severity of illness scoring is not appropriately targeted to shift the typical mutiply comorbid vascular patients into appropriate consolidated APR-DRGs, and it is difficult to determine exactly what SOI-based cAPR DRG category our routine patients would be assigned to. Here are some examples.

Carotid endarterectomy is the most common operation performed by vascular surgeons. (example 38.12 for 433.10). Current DRGs are 534 and 533 with FY2006 relative weights of 1.02 and 1.57 will fall to 0.966 and 1.491 in 2007. In 2008, assuming 534 transitions to 33 and 533 transitions to 34, the relative weights change to 0.981 and 1.29, representing a 3.8% reduction for with service without high severity, but a 18% reduction for the service with significant severity. Finally, in order to transition to cAPR-DRG 35, with a relative weight of 2.72, the patient would likely have to suffer septicemia, which would be highly unlikely for this disease and treatment category.

Abdominal aortic aneurysm repair (39.71) has been assigned by CMS to Other Vascular Procedures cAPR-DRG 234-236. These procedures are currently assigned to DRG 110 and 111, and they represent Major Cardiovascular Procedures performed on the largest artery in the abdomen. We believe they should be more correctly assigned to Major Abdominal and Thoracic vascular procedures cAPR-DRG 225-227.

Endovascular repair of the thoracic aorta (39.73) is apparently not recognized as a valid procedure code under the NPRM. From a clinical perspective, minimally invasive repair of the thoracic aorta represents a major step forward for patient care in terms of reduced morbidity and mortality for those who require treatment of this disorder. We recommend that 39.73 be assigned to Major Abdominal and Thoracic Procedures cAPR-DRG 225-227.

Overall, SVS is concerned about the accuracy of this system, and the difficulty associated with attempting to understand it. We believe the proposal has methodological flaws, and that to a significant extent, it is based on weak and/or inaccurate data. While we fully support movement towards improving the accuracy of payment for hospital inpatient services, we request that implementation be delayed until more accuracy and better transparency can be integrated. The changes in the current proposals will occasion major reductions for vascular and cardiovascular services the two are inextricably linked based on coexistence of disease to the extent that patients with these disorders will be significantly disadvantaged in terms of access.

Submitter : **Dr. Hetal Rana** **Date: 06/12/2006**

Organization : **John Peter Smith Hospital-FMRP**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1745-Attach-1.DOC

#1745

Dear CMS policy maker

I am a family medicine resident in a very busy HPSA. I really need my faculty to teach. Why would you interpret a rule designed to do just that as being un related to patient care time? Whether we are having a discussion after a patient encounter, a small group discussion regarding a difficult clinical situation, reviewing our evaluation for our care and didactic tests in a certain disease domain, or participating in lectures – we are learning about, caring for current and protecting our future patients.

My concern is that the faculty are already stretched to produce more patient visits with poor compensation and must cover four of us at a time for supervision in clinic. That hour they spend before and after clinic to discuss a specific topic that is not related to a specific individual patient will disappear with the implementation of the rule you suggest. They will not have time to sit down with us to discuss our overall performance – we will get an email.

The faculty, without support for their own development, will be likely to lose their academic edge as they work to see patients, see more patients and supervise patient care without any incentive to reflect, discuss and research our and their work.

Please help us be better physicians to our patients by supporting a competent and refreshed faculty . Rescind the interpretation of the IME and DME support rule

Sincerely,

Submitter : Dr. Ted Epperly **Date:** 06/12/2006

Organization : Family Medicine Residency of Idaho

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 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.

Submitter : **Dr. Shanna Shahid** **Date: 06/12/2006**

Organization : **John Peter Smith Hospital-FMRP**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1747-Attach-1.DOC

#1747

Currently I am completing my residency in family medicine. When I became aware that CMS would stop funding payment to faculty for teaching, preparing curriculum and evaluating my performance through GME -- IME and DME support – I became alarmed.

We are in a state with a huge health care professional shortage in communities under 25,000. These communities cannot afford to support several nurse practitioners and visiting specialists when the services are delivered by a pluri-potential well trained family medicine specialist who is part of their community. The training programs, like mine, which prepare us for these types of venues are in very short supply. We need to be exceptionally well trained.

Someone at CMS will need to explain to me, how the teaching, curriculum development and evaluation process for the six required ACGME physician skill competencies is not related to patient care. Isn't this exactly what the IOM has criticized our training professions for? In fact, our program currently evaluates us in all these competencies as a continuing quality improvement process DURING patient care. Without time to discuss and reflect our experiences and outcomes we will not be serving the needs of our current and future patients.

Should indeed this come to pass, we will have faculty who will be caught in the productivity race with no time for us. We may get pop-up feed back from an Electronic Health Record in sites that have them that we have made an error or we are not following a guideline. No discussion there. What is being proposed is dangerous for our current patients and our future patients. Our patients deserve for us to have a better education than you are proposing.

Why does the American taxpayer support medical students at over $200,000 per student per year and offers the faculty of residencies less than $15,000 for teaching per resident per year? I am getting a lot more from my residency training to protect and serve my patients of the future than all of medical school combined. Please do not cut us any more – rescind the clarification of this dangerous and capricious rule.

Medical Resident

Submitter : **Dr. Barry Arbuckle** **Date: 06/12/2006**

Organization : **Memorial Health Services/MemorialCare Hospitals**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-1748-Attach-1.WPD

MEMORIALCARE®

#1748

June 12, 2006

Mark B. McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P. O. Box 8010
Baltimore, MD 21244-1850

Via: Electronic Mail

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

As President and Chief Executive Officer of MemorialCare Medical Centers (MemorialCare) a five-hospital, not-for-profit health system in Los Angeles and Orange Counties, I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System (PPS) and Fiscal Year 2007 Rates; the Proposed Rule for Fiscal Year 2007".

MemorialCare is an integrated health care system founded on the traditional values of not-for-profit community service. Our projected patient days for fiscal year 2006 are 378,751 on a base of 85,657 patient discharges. With over 210,200 visits to our Emergency Departments, including one Level II trauma center, we also served our communities by performing almost 47,000 surgeries and delivering nearly 13,000 babies.

We feel it critical to our future that you address a number of important issues that will affect hospital financing in the coming year. I will give our view on the DRG (diagnosis–related group) changes, and then comment on the Graduate Medical Education Payments. Finally, I would like to discuss the proposed criteria for the reporting of hospital quality data.

DRG Changes

MemorialCare supports meaningful, appropriate improvements to Medicare's inpatient PPS. The proposed shift to cost-based weights, if executed properly, can represent such an improvement. Utilizing a cost-based methodology, as

opposed to current charge-based weights is a realistic approach. It creates a more fair and just payment system; one that hospitals may use to better accurately budget future payments. However, as noted above, any improvement must be properly vetted in order to obtain maximum benefit. The DRG changes as specifically proposed in this Rule do not meet these criteria. MemorialCare has come to this conclusion based on the following interpretation:

- **While MemorialCare supports the move to cost-based weights, we believe CMS' proposed method is flawed**. According to the American Hospital Association (AHA) and the California Hospital Association (CHA), we strongly believe that CMS erred in its data analysis, particularly related to organ acquisition costs, and treatment of certain hospital categories. Clearly, more work is needed to determine the best way to create cost-based weights. Our hospital system is willing to work with CMS in a process to develop consensus around the right way to make this change. Absent better participation from the hospital community will result in severe misinterpretation and faulty budgeting.
- **CMS has provided no analysis to validate that the proposed changes result in better payment policy.** While measuring improved payment accuracy is difficult, the large degree to which the weights fluctuate given methodological changes alone indicates the need for further analysis and study. CMS should construct a process to test the sensitivity of weights to various methodological assumptions and publicly share the result. Again, MemorialCare is willing to serve as a resource.

CMS also proposes moving to an entirely new patient classification system beginning in FY 2008 *or earlier*. Currently, Medicare uses 526 DRGs to classify all Medicare patients. CMS considered use of 3M's all patient refined DRGs (APR-DRGs) as an alternative to its current DRGs, which would increase the number of categories to 1,258. However, CMS ultimately proposed refining the APR-DRG system by consolidating APR-DRGs into fewer categories. This would result in a new DRG system with 861 consolidated severity-adjusted DRGs, or CS-DRGs. Though this appears to be a sound recommendation, creating a more equitable payment system, much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.

Specifically, MemorialCare supports the following:

- **One-year Delay:** We agree with the AHA and CHA recommendations, which support a one-year delay in the proposed DRG changes given the serious concerns with the methodology.

- **Valid Cost-based Weights:** We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed as noted in the preceding paragraph.

- **Simultaneous Adoption of Any Changes to Weights and Classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.

- **Three-year Transition:** Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.

- **Collaborative Approach to Moving Forward**: As noted above, MemorialCare commits to working with CMS to develop and evaluate alternatives for new weights and classifications.

GRADUATE MEDICAL EDUCATION (GME) PAYMENTS

Exclusion of Didactic Training. Long Beach Memorial Medical Center and Miller Children's Hospital (LBMMC/MCH), members of the MemorialCare system, both serve as Graduate Medical Education Centers. The Graduate Medical Education Department works with physicians in residency, the period of time after medical school and prior to private practice. LBMMC/MCH ensures quality education for residency programs at our two sites in podiatry, surgery, pediatrics, family practice, internal medicine, sports medicine and multiple fellowships. Our Mission is clear: To ensure quality medical education to train physicians as put forth by the Accrediting Council of Graduate Medical Education. The proposed rule states that resident training that occurs at non-hospital sites must be related to patient care if a hospital wishes to count that time for direct medical education (DGME) and indirect medical education (IME) payment purposes. Resident time spent in didactic activities that often occur in associated medical schools – such as educational conferences, journal clubs and seminars – would specifically be excluded. CMS noted that its statement in a previous letter on this topic "implying that didactic time spent in non-hospital settings could be counted for direct GME and IME ... was inaccurate." CMS also noted that time spent in these activities could be counted for DGME purposes if they occur in a hospital; however, the counting prohibition applies for IME payments regardless of where the educational activity occurs.

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We strongly urge CMS to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare DGME and IME payments. The stated rationale for the exclusion of this time is that it is not "related to patient care." This position is in stark contrast

to CMS' 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."[1]

We strongly agree with CMS' 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. In addition, it would cause a significant administrative burden to our teaching facilities to track the level of detail needed to comply with the proposed rule as LBMMC/MCH has close to 400 interns, residents, and fellows rotating to them on a yearly basis. . **We urge CMS to withdraw this change 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. There is great potential for a negative financial impact if these regulations are put into effect as proposed**

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HOSPITAL QUALITY DATA

MemorialCare values transparency in the reporting of quality outcomes. We have voluntarily participated in numerous, federal, state and local quality assessments. Further, MemorialCare is a leader in the California Hospital Assessment and Reporting Task Force (CHART). To this end, our system has used pertinent data in our efforts to improve patient safety and patient satisfaction. Our medical staff has worked collaboratively with hospital administration in our commitment to evidence-based, best practice medicine. *The Deficit Reduction Act of 2005* (DRA) expands quality-reporting requirements for hospitals to be eligible to receive a full market basket update. The proposed rule states that to qualify for their full market basket update, hospitals would have to pledge to submit data on all 21 measures currently part of the Hospital Quality Alliance's (HQA) public reporting on www.HospitalCompare.hhs.gov for patients discharged on or after January 1. Hospitals failing to submit data for the first calendar quarter of 2006 by August 15 would receive an inpatient update equal to the market basket minus two percentage points. Hospitals that fail data validation tests for data submitted for the first three calendar quarters of 2005 would also lose the two percentage points from the market basket update.

The AHA and its member hospitals fully support the HQA's effort to make more information on hospital quality available to the public, and we join with CMS in wanting to make it happen quickly and accurately. However, as written, the proposed rule would require hospitals to reopen files from which data have already been abstracted, renegotiate agreements with the vendors that assist them in collecting and processing the required information, and resubmit

[1] September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins.

information to the clinical data warehouse. Such retroactive alterations in the data files are difficult and costly, and open the door for the introduction of many new kinds of errors in the data. To require this reopening of the files makes no sense. **CMS should make the data collection prospective. This could be accomplished by requiring that hospitals that want a full market basket update pledge to submit the relevant data for all 21 measures for patients beginning on or after July 1.**

The DRA gave the Secretary of the Department of Health and Human Services (HHS) the authority to further expand the measures that must be reported to qualify for full market basket update in future years. **MemorialCare strongly urges CMS to select measures only from those used by the HQA for public reporting.** To choose different measures would thwart efforts to streamline quality reporting, add to the "babble" of quality measurement that currently exists in health care and dilute efforts to create a single source to share solid reliable information with the public. In addition, whenever the Secretary intends to expand the set of measures linked to payment, **CMS should consider publishing the proposal at least one full year prior to the start of the fiscal year.** This will enable hospitals and their vendors to put the needed data collection processes in place to be able to provide the requested data.

MemorialCare agrees with CMS that it is critical that the collected data be validated. The process used to validate the HQA data was reviewed by the Government Accountability Office, which concluded that there was "a high overall baseline of accuracy," but recommended several changes to improve the validation process. CMS proposes to look at the validation results for data submitted on patients who were discharged during the first three calendar quarters of 2005. CMS has hired a contractor to randomly select five patient records per quarter. That contractor selects the patients, asks the hospital to send a copy of the medical record for the hospitalization of the patients that occurred during that period, and then reabstracts the same data that the hospital abstracted from the medical record. A comparison is made between the data the hospital submitted and the data the contractor abstracted, and if there is at least an 80 percent agreement, the hospital is said to have passed validation. In the proposed rule, the hospital would have to have at least 80 percent agreement across the 15 medical records that the contractor reabstracted. This methodology assumes that the contractor has correctly reabstracted the data and that discrepancies must mean erroneous data submission on the part of the hospital. However, that is not always the case. This validation process is still in its infancy and seems to be working to correctly validate the information submitted by many, but unfortunately not all, hospitals. Significant problems have occurred for some hospitals of which we are aware.

Some data validation problems have actually begun with the data submission process. Hospitals and their data collection vendors submit data to the Quality Improvement Organization (QIO) data warehouse in a good-faith effort to get the

information submitted in the right format, with all of the right labels and coding. An "error report" is generated that is supposed to alert the hospital if it appears data were received in a way that is not consistent with the requirements. The hospital is supposed to receive this report in time to make any necessary corrections. However, the report can be hundreds of pages long with a multitude of meaningless notations. A significant problem in data transmission might have occurred, but the indications of it are buried in this voluminous report and may not be discovered until it is too late for the hospital to make a correction. In addition, the data collection vendors on whom the hospitals rely to format and submit the data correctly do not have access to these error reports, nor do they have any other mechanisms for checking to make sure that the data they sent was received correctly. This has inevitably led to errors not being caught in time. When these errors are then left in the database, the CMS contractors' reabstraction of the data does not match up with what is recorded for the hospital in the database, leading to the hospital failing validation.

Another common problem results when the contractor has asked for the medical record pertaining to a particular patient, but has not specified which admission it wanted. Since it is not uncommon for heart failure patients to be readmitted for care, the omission of the specifics on which admission was being reabstracted has inevitably led to the hospital copying and submitting data on one admission, and the contractor trying to make that match up with the data for a different admission – and the data simply will not match up.

There also have been many reported instances in which the contractor conducting the reabstraction of the data failed to find information that was clearly in the medical record – a simple human error, but one that should not be used to penalize the hospital.

CMS was made aware of these problems with the validation process and it has begun to work to improve the process reliability so it can be used to support payment decisions. However, in the first three calendar quarters of 2005, the validation process did not have sufficient integrity to warrant hospital payments being withheld based on the validation results. At this juncture, we firmly believe that the problems with the validation process itself need to be resolved before any payment decisions are made solely on the basis of the contractor's work. **We strongly urge CMS to review, on a case-by-case basis, any incidence where a hospital's payment would be put in jeopardy as a result of the validation process. It should allow the hospital to submit information showing that it made a good-faith effort to supply the data warehouse with accurate information so that the public could be informed about the quality of its care. If the hospital has made a good-faith effort, it should receive full payment regardless of whether the data are deemed accurate enough for public display.** In addition, CMS should instruct its QIO data warehouse to accept any significant corrections so that the public can have a full and accurate picture of hospital quality.

Thank you for the opportunity to present our views on these very important issues. The final disposition of the proposed rules will have a long lasting affect on MemorialCare and thousands of other not-for-profit hospitals. Our mission is to improve the health and well-being of individuals, families and our communities through innovation and the pursuit of excellence in all that we do. As proof of our commitment to serving our communities, MemorialCare contributed over $113,000,000 in total quantifiable community benefits in FY 2005. Any losses to our reimbursements for the care given to our Medicare patients will have a devastating affect on our ability to take care of those most in need.

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MemorialCare will be happy to work with CMS on these and any other issues discussed above, or any other topics that relate to the complexities of hospital financing.

If you have any questions concerning these comments, please feel free to contact me at (562) 933-1833, or Peter J. Mackler, Director of Government Relations and Policy at (562) 933-1836.

Sincerely.

Barry S. Arbuckle, Ph.D.
President and Chief Executive Officer
MemorialCare Medical Centers

Submitter :

Date: 06/12/2006

Organization : Surviving Sepsis Campaign

Category : Health Care Professional or Association

Issue Areas/Comments

DRGs: Severe Sepsis

DRGs: Severe Sepsis

June 12, 2006

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

RE: CMS-1488-P, DRGs: Severe Sepsis

This response to proposed rule-making is sent by the Surviving Sepsis Campaign (SSC) executive committee. The SSC is an international effort to decrease mortality in severe sepsis and is administered by the European Society of Intensive Care Medicine, the International Sepsis Forum and the Society of Critical Care Medicine. It is partially funded by unrestricted industry grants; however industry has no involvement with Campaign content or administration.

The showcase of the Surviving Sepsis Campaign is the performance improvement program that was developed in collaboration with The Institute of Health Care Improvement. The source document for this PI program is the evidence-based SSC Guideline for the Management of Severe Sepsis. The guidelines are the first internationally endorsed evidence-based guidelines and are sponsored by fifteen international organizations with interest and expertise in management of severe sepsis. The SSC performance improvement program includes sepsis change bundles which contain indicators for performance evaluation. A software program has been developed that allows bedside electronic database entry for performance evaluation after the patient satisfies the screening tool for severe sepsis.

This program is the first ever internationally deployed performance improvement program for this devastating critical illness. The program is expanding exponentially and as of this week, data is being entered or soon to be entered in over 20 countries and more than 300 hospitals and hospital systems including 40 or more hospitals in the U.S. We anticipate hundreds of hospitals in the U.S. will utilize this program by the end of the year. This will only increase.

Entry into this PI program is based on satisfying the diagnosis of severe sepsis. Emphasis on this diagnosis is important for the spread of this quality improvement program. Being able to identify these patients and to create a culture of change for better treatment of these patients is essential. We believe that the presence of a DRG for severe sepsis will assist in placing emphasis and awareness on this diagnosis for hospital quality improvement efforts. The lack of this DRG, as apparently your posting indicates your plans to be, will be counterproductive in our efforts.

At a time when the critical care world seems to be uniting to attack severe sepsis in a cohesive fashion the addition of a severe sepsis DRG coupled with coding coordination with hospital quality improvement would be a significant gain for our efforts. We encourage you to reconsider your planned decision to abandon this DRG.

Mitchell M. Levy, MD, FCCM
Executive Committee
Society of Critical Care Medicine

Julian F. Bion, MD, FRCP, FRCA
President
European Society of Intensive Care Medicine

Jean-Louis Vincent, MD, PhD, FCCM
Chairperson
International Sepsis Forum

Submitter : Dr. Barry Shefa **Date:** 06/12/2006

Organization : John Peter Smith Hospital-FMRP

Category : Health Care Professional or Association

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1750-Attach-1.DOC

Why would you interpret a rule designed to do just that as being unrelated to patient care time? Whether we are having a discussion after a patient encounter, a small group discussion regarding a difficult clinical situation, reviewing our evaluation for our care and didactic tests in a certain disease domain, or participating in lectures – we are learning about, caring for current and protecting our future patients.

#1750

My concern is that the faculty are already stretched to produce more patient visits with poor compensation and must cover four of us at a time for supervision in clinic. The hour they spend before and after clinic to discuss a specific topic that is not related to a specific individual patient will disappear with the implementation of the rule you suggest. They will not have time to sit down with us to discuss our overall performance – we will get an email.

The faculty, without support for their own development, will be likely to lose their academic edge as they work to see patients, see more patients and supervise patient care without any incentive to reflect, discuss and research our and their work.

Please help us be better physicians to our patients by supporting a competent and refreshed faculty. Rescind the interpretation of the IME and DME support rule.

Sincerely,

Submitter :

Date: 06/12/2006

Organization :

Category : Government

Issue Areas/Comments

Unadjusted Wage Index

Unadjusted Wage Index

Unadjusted Wage Index (Page 24080-24081)

We disagree with the calculation in Step 4 regarding the allocation of total overhead salaries and total overhead hours to areas of the hospital excluded from the wage index calculation (Attachment I). In the determination of the ratio of excluded area hours to revised total hours, we believe there are several flaws in this formula. There are as follows:

a) Elimination of Line 6.01 for revised Total Hours Line 6.01 (Contract I&Rs) is removed from Line 1 (Total Hours) for the denominator of the excluded %. We disagree with this calculation because contract I&R are not included in Line 1 to begin with and therefore hours are removed that are not there to begin with. In the salary portion of the wage index calculation to determine the average hourly wage, the amount reported on Line 6.01 Contract I&R is also instructed to be included in Line 9 (Contract Labor) and is therefore added to Total Salary. We propose that Line 6.01 is not removed from Total Hours.

b) Elimination of Line 13 for revised Total Hours Line 13 (Total Overhead) is removed from Line 1 (Total Hours) for the denominator of the excluded %. We disagree with this calculation because since this calculated excluded % is ultimately applied to Total Overhead salaries to determine the excluded portion of overhead, we believe this amount should remain in the denominator. We propose that Line 13 is not removed from Total Hours.

c) Costs that are included in Line 8 and 8.01 Line 8 and 8.01 amounts flow from specified lines from Worksheet A, including reclasses. However for our facilities, the related overhead for these excluded areas are also included in these reclasses. Therefore, in determining the excluded portion of overhead, the excluded % is applied to overhead that may have already been removed. We believe this is a double elimination of excluded overhead. We propose a revision in this formula to avoid this double elimination.

Submitter : Dr. Patrick Brennan
Organization : HICPAC
Category : Federal Government
Date: 06/12/2006

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Attention: CMS 1488 P
Mail Stop C4 26 05, 7
500 Security Boulevard,
Baltimore, MD 21244 1850.

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule -- CMS 1488-P-Healthcare-associated infection

Dr. McClellan:

I am writing on behalf of Health and Human Services Healthcare Infection Control Practices Advisory Committee (HICPAC) regarding the proposed rule referenced above. We see the proposed rule to eliminate enhanced payment for the occurrence of preventable HAIs in select DRGs as a means to ensure greater adherence to practices that have demonstrated efficacy in prevention of HAI.

HICPAC, in its advisory role to the Secretary of HHS, the Centers for Disease Control and Prevention and the Division of Healthcare Quality Promotion at CDC, has developed evidence based guidelines that have been widely promulgated and serve as the basis for the many national, state and local initiatives currently underway to reduce the burden of healthcare associated infections (HAI). The adoption of practices recommended in HICPAC s guidelines have had a significant impact on the incidence of HAIs in healthcare facilities in this and other countries The Committee is seen as a credible source of evidence-based advocacy for best practices in infection prevention in healthcare settings. In addition to prevention guidelines, HICPAC has been deeply involved in the effort to define the methods of surveillance, reporting and disclosure of HAIs. In April 2005 HICPAC published guidance on this subject to assist policymakers, regulators and others in the development of mandates surrounding public disclosure.

Because of its background and expertise on subjects relevant to the proposed rule HICPAC offers the following recommendations on this subject:
(please see attached for full document)

CMS-1488-P-1752-Attach-1.PDF

ATTACHMENT TO 1752

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Attention: CMS–1488–P
Mail Stop C4–26–05, 7
500 Security Boulevard,
Baltimore, MD 21244–1850.

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule -- CMS 1488-P-Healthcare-associated infection

Dr. McClellan:

I am writing on behalf of Health and Human Services' Healthcare Infection Control Practices Advisory Committee (HICPAC) regarding the proposed rule referenced above. We see the proposed rule to eliminate enhanced payment for the occurrence of preventable HAIs in select DRGs as a means to ensure greater adherence to practices that have demonstrated efficacy in prevention of HAI.

HICPAC, in its advisory role to the Secretary of HHS, the Centers for Disease Control and Prevention and the Division of Healthcare Quality Promotion at CDC, has developed evidence based guidelines that have been widely promulgated and serve as the basis for the many national, state and local initiatives currently underway to reduce the burden of healthcare associated infections (HAI). The adoption of practices recommended in HICPAC's guidelines have had a significant impact on the incidence of HAIs in healthcare facilities in this and other countries The Committee is seen as a credible source of evidence-based advocacy for best practices in infection prevention in healthcare settings. In addition to prevention guidelines, HICPAC has been deeply involved in the effort to define the methods of surveillance, reporting and disclosure of HAIs. In April 2005 HICPAC published guidance on this subject to assist policymakers, regulators and others in the development of mandates surrounding public disclosure.

Because of its background and expertise on subjects relevant to the proposed rule HICPAC offers the following recommendations on this subject:

1. **Adopt a rule which will enhance adherence to evidence based prevention practices:** The proposal to eliminate enhanced payment for the occurrence of preventable HAIs in select DRGs is a laudable goal. We believe the adoption of such a rule will recruit greater attention to this important issue and enhance adherence to evidence based-prevention practices.

2. **In the implementation of the rule, link process measures and patient outcomes as a basis for payment adjustments.** Because the preventable fraction of HAIs is not precisely known it is likely that facilities will be penalized for the occurrence of

infections that are beyond their control because of factors intrinsic to the patient or as yet unidentified risks. A solution to this problem is the linkage of process measures and infection outcomes. HICPAC, in its 2005 document *Guidance on Public Reporting of Healthcare-Associated Infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee* recommended such a linkage. In such an approach facilities would be penalized for infections if their performance in adherence to evidence based practices was below established thresholds.

3. **Select two DRGs which have at their core a procedure for which there are well established practices that have been proven to prevent infection during the performance of the procedure.** Evidence based guidelines developed by HICPAC serve as the basis for initiatives to reduce the incidence of central line associated bloodstream infections, ventilator associated pneumonias and surgical site infections. DRGs that will best lend themselves to implementation of the proposed rule will be those that involve procedures for which evidence based practice guidelines currently exist. Several surgical procedures as well as DRGs in which patients frequently require mechanical ventilation or the insertion of central venous catheters would be appropriate candidates for implementation. In the selection of DRGs or procedures for this purpose there should be an established link between adherence to evidence based practices and patient outcomes related to infection. HICPAC offers its services to CMS and the Secretary to assist in the selection of such DRGs and procedures.

HICPAC appreciates the opportunity to provide input on the proposed rule and welcomes the attention that this initiative provides to an important patient safety issue. We look forward to partnering with HHS and CMS in the further development of this important initiative.

Sincerely yours,

Patrick J. Brennan, MD
Chair, Healthcare Infection Control Practices Advisory Committee

Submitter : Mr. Michael Cullen

Date: 06/12/2006

Organization : South Shore Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1488-P-1753-Attach-1.WPD

#1753

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of South Shore Hospital, I appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2007 inpatient prospective payment system (PPS) and occupational mix adjustment proposed rules.

HSRV Weights

The rule proposes the most significant changes in the calculation of diagnosis-related group (DRG) relative weights since 1983 by creating a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc).

I strongly support the change from the current charge based DRG weighting system to the proposed HSRVcc system in FY07. While I understand that other parties are commenting on imperfections in the cost weighted system proposed by CMS, we should not lose sight of the greater imperfections in the current charge-based system. The proposed DRG weights under the HSRVcc methodology more closely represent the cost of providing services than the current charge-based system. Hospitals that provide more routine medical admissions as opposed to high-end, high-margin (especially cardiac) surgeries and services have been being disadvantaged for years under the current charge-based system. The move to a cost-based system should be effective in FY07 regardless of whether perfected. Even as proposed it is more reflective of the costs of providing services which should be the foundation for payment under the Medicare system.

If I can provide you with any additional information regarding our comments, please do not hesitate to contact me at (781) 340-8431.

Sincerely,
Michael R. Cullen
Senior Vice President and Chief Financial Officer

Submitter : Ms. Marisa Milton

Organization : HR Policy Association

Category : Other Association

Date: 06/12/2006

Issue Areas/Comments

Transparency of Health Care Information

Transparency of Health Care Information

See Attachment

CMS-1488-P-1754-Attach-1.DOC

#1754

HR POLICY ASSOCIATION

June 12, 2006

VIA Electronic Submission
Secretary Michael O. Leavitt
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attn: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Comments on performance-based payments and data transparency for consumers

Dear Secretary Leavitt:

HR Policy Association welcomes the opportunity to provide comments for your consideration in connection with proposed changes to the hospital inpatient prospective payment system and fiscal year 2007 rates. Our member companies greatly appreciate your efforts to advance increased transparency and we believe that Medicare should lead the way to promoting a market that recognizes and rewards high-quality, efficient, and patient-centered care.

HR Policy Association is a public policy advocacy organization representing the senior human resource executives of over 250 leading employers doing business in the United States. Collectively, our members employ over 12 percent of the U.S. private sector workforce or some 19 million Americans. Due to extreme concern over the state of our nation's health care system, HR Policy formed the Health Care Policy Roundtable – a subset of its member companies dedicated to addressing these problems.

The problems that plague our health care system are too well known. The United States spends significantly more on health care, both in terms of dollars per capita and as a percentage of Gross Domestic Product, than any of our trading partners, yet it is difficult to make the case that sufficient value is being derived to justify the enormous cost. At the same time it is large employers, the private sector, who bear a significant portion of the financial burden for this difference with our trading partners, and for that we suffer the competitive consequences. Health care purchasers face double digit increases each year with no sign of a decline in costs or more manageable inflation in the foreseeable future. As such, health care is crippling America competitively and draining our federal budget.

Unfortunately, the huge resources invested into our health care system do not provide access and high quality care for all. It is estimated that approximately 46 million Americans are without health insurance coverage. In addition to a coverage gap, there is a serious quality gap. A recent study by the RAND Corporation found that adults received recommended care only about 55 percent of the time. Clearly meaningful reform is needed. Fundamental components of the solution to these quality deficiencies lies in greater transparency and disclosure about cost and quality throughout the system, engaging consumers who have a stake in the financial as well as clinical outcome, and basing payment to doctors and hospitals on performance.

www.hrpolicy.org 1015 Fifteenth Street, NW Suite 1200 Washington DC 20005-2605 E-mail: info@hrpolicy.org Tel: 202.789.8670 Fax: 202.789.0064

We are pleased that the Department of Health and Human Services is taking attempts to address these issues through reforms within the Medicare program. Below are our comments on how these strategies would be most effective for employers as purchasers of health care benefits, as well as their employees.

I. Reduce payment updates for providers that fail to submit data

We support the Center for Medicare and Medicaid Services' (CMS') recommendation to reduce the FY 2007 annual hospital payment update by 2 percent for any hospital that does not submit data on 21 measures (8 heart attack, 4 heart failure, 7 pneumonia, 2 surgical infection prevention) for patients discharged starting January 1 through December 31, 2006.

Recommended Actions:

- CMS should go beyond "exploring the feasibility of adopting additional measures for FY 2008 update, including HCAHPS" to substantially expand measures for hospitals to obtain the FY 2008 annual update.
- Adopt measures identified by the Institute of Medicine in its *Performance Measurement: Accelerating Improvement*, *i.e.*, Hospital-CAHPS and three structural measures (computerized provide order entry, intensive care staffing with intensivists, and evidence-based hospital referral) as well as consider and adopt a number of other measures endorsed by the National Quality Forum.

II. Assess provider performance using robust measures

Medicare should evaluate the performance of each health care provider that bills Medicare, using nationally endorsed, scientifically valid, risk-adjusted, and regularly updated measures. Currently, because of the lack of well-specified and endorsed measures that meet consumers and purchasers' needs there is a great need for entities to create appropriate measures. These measures should address:

- Clinical quality (safe, timely, and effective care);
- Efficiency (prices and resource use over time);
- Equity (gender, race, ethnicity);
- Patient experience; and
- Structure or systems (*e.g.*, use of quality-enhancing health information technology).

Recommended Actions:

- Support the development, endorsement and updating of performance measures.
- Provide funding to support development of consumer-relevant measures that fill existing gaps, especially gaps in measures relating to efficiency and equity.
- Measure developers must be encouraged to create measures that are:

- reasonably scientifically acceptable;
- feasible to implement;
- relevant to consumers and purchasers; and
- reflect the continuum of care/care coordination from a patient's perspective.

III. Collect and report information that will enable informed decision-making and provider selection

Medicare should provide the public with the information on the aspects of provider performance described above. Doing so, will allow: 1) consumers to make informed decisions about their health care; 2) insurers and purchasers to make value-based contracting decisions and use differential payments as incentives; and 3) providers' improvement efforts to be supported with better information.

Recommended Actions:

- Release physician-identifiable Medicare claims data (fully protecting patient privacy), to allow for better quality and efficiency performance reporting.
- Continue to allow private-sector organizations to download granular provider performance information from the Compare websites.
- Augment hospital claims data with additional clinical data elements to better understand patient acuity.

IV. Implement financial incentives that are sensitive to the provision of high-quality, efficient, patient-centered care

Medicare should phase in a system that differentially pays providers based on nationally standardized measures.

Recommended Actions:

- Continue to rapidly expand the number and type of measures that hospitals must report to obtain annual payment update.
- Medicare payments must be sensitive to provider performance and create financial incentives to provide quality care.
- Incentives should take into account performance on quality, efficiency, and patient experience.
- Provider incentives should be budget-neutral and based on a combination of improvement and meeting thresholds.

V. Promoting effective use of HIT

Health information technology (HIT) – which includes software applications for care management, such as electronic medical records, practice management systems, and registries,

has the potential to dramatically improve the quality and efficiency of health care, however implementation has been slow.

Recommended Actions

The Secretary can spur HIT adoption and ensure that the data necessary for quality measures are captured by using conditions of participation that require hospitals to implement HIT/software applications that:

- comply with interoperability standards;
- enable standardized quality, performance, and efficiency measurement are a routine by-product of their use;
- are designed to enable the merger of their data with others for the purpose of facilitating the production of standardized quality, performance, and efficiency information; and
- tie the annual hospital payment update to the reporting of hospitals' progress toward implementation of proven HIT implementation.

Again, thank you for the opportunity to comment. Please contact me at (202) 789-8671 or mmilton@hrpolicy.org with any questions.

Sincerely,

/S/

Marisa L. Milton
Associate General Counsel and Directory, Health Care Policy

CMS-1488-P-1755

Submitter : Mr. Robert Britain
Organization : NEMA
Category : Device Association
Date: 06/12/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-1755-Attach-1.TXT

CMS-1488-P-1755-Attach-2.DOC

#1755

Setting Standards for Excellence

Robert G. Britain
Vice President, Medical Products

June 12, 2006

Mark McClellan, Administrator
Center for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator McClellan:

The National Electrical Manufacturers Association ("NEMA") hereby requests a one-year delay in the implementation of the proposed diagnosis related group ("DRG") reforms in the inpatient prospective payment system ("IPPS") update for fiscal year ("FY") 2007 ("Proposed Rule"). The Proposed Rule would make the most significant changes and produce the most unpredictable and undesirable effects to the IPPS since the 1980s. First, the proposal would move to an estimated "cost-based" system for determining the payment weights for each patient category in 2007. Second, the proposed rule would change the method for identifying the variation in patients' severity of illness that would be implemented in 2008, or potentially in 2007. Each change is significant and together are considered major modifications to the payment system. Proposing both changes in a single regulation, with implementation in 2007 and 2008, may restrict beneficiaries' access to advanced medical treatments and lead to significant unintended consequences for hospitals. NEMA is particularly concerned that CMS' proposal will unduly harm hospitals that use newer and more advanced technologies.

NEMA also requests that CMS utilize statutory authority provided to the Secretary and ensure that any quality measures allow for technological innovations and input from stakeholders. Finally, we urge CMS to adopt the necessary measures to ensure that any changes to the DRG classification system, including the proposed consolidated severity-adjusted DRG system, be provided in a non-proprietary, open-source manner, consistent with the current DRG system.

Established in 1926, NEMA is the largest U.S. trade association representing the U.S. electroindustry. The Diagnostic Imaging and Therapy Systems Division of NEMA represents over 95% of the market for X-Ray Imaging (including mammography), CT, Radiation Therapy, Magnetic Resonance, Diagnostic Ultrasound, Nuclear Medicine

Imaging and Medical Imaging Informatics equipment. NEMA appreciates the opportunity to submit these comments on the proposed rule.

DRG Weights Based on Hospital Costs

In its FY 2007 proposal, CMS analyzed hospital cost report data, departmental cost-to-charge ratios, MedPAC claims data, as well as MedPAC's suggested method for adopting hospital-specific cost relative weights. Like MedPAC, CMS believes that using charges to develop the relative weights creates bias in Medicare's payments. Accordingly, CMS is proposing to implement hospital-specific cost relative weights in FY 2007.

This effort is a continuation from the FY 2006 IPPS proposal, when MedPAC called for improved payment accuracy by basing the DRG relative weights on the estimated cost of providing care rather than on charges.[1] At that time, CMS noted it does not have access to any information that would provide a direct measure of the costs of individual discharges. Consequently, CMS stated the most straightforward way to estimate costs of an individual case was to calculate a cost-to-charge ratio for some body of claims (for example, for a hospital's radiology department), and then apply this ratio to the charges for that department. CMS noted the disadvantages to this approach as assignment of costs to departments is not uniform from hospital to hospital, given the variability of hospital accounting systems, and because cost information is often not timely available. In addition, CMS stated the application of a cost-to-charge ratio that is uniform across any body of claims may result in biased estimates of individual costs. In the end, CMS decided not to implement a change as "the accuracy of this procedure has generated some concern, and without further analysis, the extent to which accuracy of inpatient payments would be improved by adopting this method is not obvious."

Under the Proposed Rule, CMS advanced an alternative to MedPAC's approach that is thought to "achieve similar results in a more administratively feasible manner." The approach, which is proposed to go into effect on October 1, 2006, would change the basis for the weights assigned to DRGs from hospital charges to hospital costs. CMS believes this change will eliminate biases in the current DRG system that result from differential markups hospitals assign for ancillary services among the DRGs. CMS's proposed new weighting system is called the hospital-specific relative value cost center, or HSRVCC, methodology.

The proposed system is very different from MedPAC's HSRV recommendation, which would have required cost-to-charge ratios to be developed at the individual hospital level and would have involved claims matching. Instead, CMS proposes to develop hospital-specific charge relative weights at the cost c enter level to adjust for certain hospital characteristics (e.g., teaching status, disproportionate share hospital ("DSH") status, location, and size) and then scaling the weights to costs using the national cost center charge ratios developed from cost report data. CMS proposes to base HSRV weights on the following 10 hospital cost centers: Routine Days, Intensive Days;

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[1] Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule, 70 Fed. Reg. 23305, 23454 (proposed May 4, 2005).

Drugs; Supplies & Equipment; Therapeutic Services; Operating Room; Cardiology; Laboratory; Radiology; and Other Services and Charges.

While NEMA agrees there are difficulties in obtaining current cost to charge data and that certain reforms are necessary, we do not believe the best approach is one that is more "administratively feasible." In fact, CMS' proposed approach for FY 2007 is deficient in many of the ways as MedPAC's recommendations. NEMA is very concerned that CMS' attempt to modify the rate calculation methodology has not been a measured, studied, and fully transparent approach to address cost issues. Consequently, it is difficult, if not impossible, for NEMA to fully evaluate and comprehensively respond to CMS' proposal.

Without complete information on the methodology, NEMA and its members are unable to ascertain the true and complete impacts of the proposed reforms.

Moreover, by implementing the changes so quickly, CMS ignores the potential for unpredictable and potentially undesirable effects of these comprehensive changes. As such, NEMA repeats its request to delay the implementation of the proposed system in the FY 2007 proposed rule.

Severity-Adjusted DRGs

The second DRG reform is designed to better reflect severity of illness among patients. Under this reform, CMS proposes replacing the 526 current DRGs with approximately 861 consolidated proposed DRGs adjusted for patient severity. These 861 DRGs are based on the All Patient Refined Diagnosis Related Group System ("APR DRG"), which was developed by 3M and currently is used by the State of Maryland. The APR DRG system provides a mechanism for addressing high severity cases that occur in low volume through assignment of the case to one of four severity of illness subclasses.

Like the cost to charge proposal, NEMA has very serious concerns about CMS' approach to use consolidated severity adjusted DRGs. The proposal appears to be based on flawed data and questionable technical decisions and would result in payment cuts for some of the most advanced and effective medical treatments. We note that several analyses have been done that attempt to replicate CMS' work while correcting for various technical flaws. For example, the Moran Company's analysis addressed several technical flaws in the data and subsequently found that variation in its implementation could result in greater reductions than anticipated.[2] Clearly, the impact analysis is highly sensitive to changes in methodology, which raises the concern that the impact of the final rule will vary widely from the proposed rule, while providing no further opportunity for comment.

Therefore, NEMA strongly advises against implementation of the severity-adjusted DRG proposal for FY 2007. Stakeholders have not have adequate opportunity to review and comment on a full impact analysis of the DRG proposal. These changes are significant, burdensome, and the lack of a complete impact analysis has denied hospitals and stakeholders the opportunity for appropriate review and comment. As such, it is premature to implement the severity-adjusted change for FY 2007.

NEMA is committed to working with CMS on this rulemaking. However, a one-year delay in the implementation of the proposed diagnosis related reforms in the inpatient prospective payment system is necessary. The proposed changes may lead to significant unintended consequences for hospitals, restrict beneficiaries' access to advanced medical treatments, and unduly harm hospitals that use newer and more advanced technologies.

Quality Measures

Sections 1886(b)(3)(B)(viii)(V) and (VI) of the Social Security Act require that, effective for payments beginning with FY 2008, CMS add other quality measures that "reflect consensus among affected parties, and provide the Secretary with the discretion to replace any quality measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance with a measure, or the measures or indicators have been subsequently shown to not represent the best clinical practice." In the proposed rule, CMS announced plans to implement section 5001(a) of Pub. L. 109-171, including the new requirement for reporting of an expanded set of quality measures.

NEMA is concerned the full implementation of the proposed system would significantly undermine efforts to improve quality assurance. As proposed, the quality measures do not allow for stakeholder input or technological innovations that will increase patient health and reduce costs. Consequently, NEMA urges CMS to include medical technology manufacturers in the process of developing quality and cost standards. Also, CMS should include mechanisms in the standards that recognize the ability for providers to acquire new technology quickly and cost-effectively. Finally, CMS should ensure that final quality measures do not have unintended consequences of providing incentives to providers to retain older health care technologies in place at the expense of greater patient health and lower costs. Without these critical features, hospitals will not be able to dedicate resources to such important quality improvement initiatives which will lead to improved patient care. As such, NEMA requests that CMS utilize statutory authority provided to the Secretary and ensure that any quality measures allow for technological innovations and input from stakeholders.

DRG GROUPER

NEMA is concerned about the public availability of the proposed consolidated severity-adjusted DRG (CS-DRG) GROUPER logic. We note that the current DRG GROUPER program has been in the public domain since the inception of Medicare's inpatient prospective payment system. We recommend that CMS adopt the necessary measures to ensure that any changes to the DRG classification system, including the proposed CS-DRG system, be provided in a non-proprietary, open-source manner, consistent with the current DRG system. Without the new GROUPER logic, it is virtually impossible for interested parties to thoroughly analyze the impact of the proposed changes to the classification system. Further, public availability of the revised GROUPER logic will support consistent, cost-effective and rapid adoption by vendors, providers, and payers.

NEMA is also concerned with the lack of competition afforded during the Grouper development. In order to provide hospitals with the most effective and cost-

efficient technologies, NEMA stresses that CMS should allow for full and fair competition during implementation of the new billing systems.

Conclusion

NEMA is committed to working with CMS on the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. However, for the aforementioned reasons, NEMA strongly supports a one-year delay in the proposed DRG changes given the serious concerns listed. NEMA and other stakeholders are committed to working with CMS over the next year to address these concerns. NEMA supports movement to a system based on hospital costs rather than charges, but CMS' proposed method is flawed. On quality standards, NEMA requests that CMS' proposal be reformed to account for technological innovation and allow for input from advanced technology stakeholders. Finally, NEMA requests that CMS adopt the necessary measures to ensure that any changes to the DRG classification system, including the proposed CS-DRG system, be provided in a non-proprietary, open-source manner, consistent with the current DRG system.

If you have any questions, or need further information, please do not hesitate to contact me. I can be reached at (703) 841 – 3248 or by e-mail at bob_britain@nema.org

Thank you for consideration of our request.

[2] The Moran Company, Inpatient Prospective Payment System (IPPS) Analysis for FY 2007, available at www.themorancompany.com.

Sincerely,

Robert G. Britain

Submitter : Mr. Ebenezer Erzuah **Date:** 06/12/2006

Organization : E. W. Sparrow Hospital Association

Category : Hospital

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

See Attachement

CMS-1488-P-1756-Attach-1.DOC

#1756

June 6, 2006

[VIA ELECTRONIC FILING]

The Honorable Mark B. McCellan, M.D., PhD.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244 – 1850

RE: File Code CMS – 1488-P
Proposed changes to the Medicare Inpatient Prospective Payment System
Changes Dated April 25, 2006

Dear Dr. McCellan:

On behalf of Sparrow Hospital, I wish to take this opportunity to comment on the centers for Medicare & Medicaid Service's (CMS) proposed rule for the FY 2007 Inpatient prospective payment system (IPPS), published April 25, 2006 in the *Federal Register*. While the proposed rule as published has the appearance of increasing IPPS rates by 3.4 percent, the implementation of various policy changes and technical adjustments (DRG weights revision project) will result in significant payment decreases for a typical hospital like Sparrow for the period.

The adequacy of medical payments to cover the cost of services provided is crucial for ensuring the future viability of "disproportionate share" hospitals (DSH) such as Sparrow, which is also a teaching hospital and a Level 1 Trauma Center. Specifically, Sparrow Hospital has had to endure the unfavorable impact of the implementation of Section 508 (Geographic Reclassification) of the Medicare Modernization Act (MMA) for the past three years. Sparrow was only one of three (3) teaching hospitals in the State of Michigan that did not experience the favorable Medicare payment impact of Section 508. Some of the changes in the proposed rule coupled with the implementation of Ambulatory Payment Classification (APC) by the State of Michigan for Medicaid outpatient services could definitely threaten the financial viability of a DSH hospital like Sparrow.

Upon review of the proposed changes to the 2007 Medicare Inpatient Prospective Payment System (IPPS), Sparrow Hospital presents the following comments for your consideration:

HOSPITAL REDESIGNATIONS AND RECLASSIFICATIONS

(Federal Register pages 24082 - 24087)

Under section 508 of Pub. L, 108-173 a qualifying hospital based on a listed criteria could appeal the wage index classification otherwise applicable to the hospital and apply for reclassification to another area of the State in which the hospital is located (or at the discretion of the Secretary, to an area within a contiguous State). Sections 508 reclassifications are applicable for discharges occurring during the 3-year period beginning April 1, 2004 and ending March 31, 2007 and these reclassifications do not impact the wage index computation for any area or for any other hospital and cannot be affected in a budget neutral manner. The governing regulations indicate that 'if a hospital is already reclassified to a given geographic area for wage index purposes for a 3 year period, and submits an application to the same area for either the second or third year of the 3 year period, that application will not be approved"

As part of the 2006 IPPS final rule special consideration were designed to recognize the special circumstances of section 508 hospital reclassifications ending mid-year during FY 2007. Section 508 hospitals were granted flexibility within the geographic reclassification rule to allow previously approved reclassifications to continue through March 31, 2007 and new reclassifications to begin April 1, 2007.

Sparrow Hospital has applied and has been denied geographic reclassification to the Ann Arbor, Michigan CBSA for each of the last two filing cycles. The requests were made under section 1886(d) of the Act. Each rejection was based strictly on provisions under section 1886(d) where the Medicare Geographic Classification Review Board (MGCRB) considers application by hospitals for geographic reclassification for purposes of payment under the IPPS.

Sparrow Hospital would like to recommend that since any flexibility or favorable treatment to a particular group of hospitals under section 1886(d) redistributes hospital payments, because of the budget neutrality manner, all hospitals currently benefiting from Section 508 geographic reclassification should be reclassified to the wage index of their respective CBSAs.

We would also like to recommend that CMS grant a special reclassification under section 1886 of the act for "dominant hospitals" since CMS has agreed that dominant hospitals treat a disproportionately large number of sicker patients within the MSA or CBSA, as such the dominant hospital's are always in a position of competing for labor with hospitals in nearby CBSAs with higher wage indexes. Dominant hospitals (pays at least 40% of all wages in the CBSA) cannot reclassify to the adjacent higher wage index area under current geographic reclassification rules. CMS realized the unique situation of dominant hospitals and invited comments (via the 2005 proposed rules) on the concerns raised by dominant hospitals, as well as possible methods of addressing these concerns but as of now there is no special reclassification category for dominant hospitals.

DRG RECLASSIFICATIONS
(Federal Register page 24004 - 24049)

Section 1886(d) of the Act specifies that the Secretary of Health and Human Services shall establish a classification system (referred to as DRG) for inpatient discharges and adjust payments under IPPS based on appropriate weighting factors assigned to each DRG. Pursuant to this provision the CMS is proposing the most significant changes to the calculation of the DRG relative weights since the beginning of the prospective payment System. The two-step revision process would first change the manner in which weights are assigned to DRGs, and then implement a severity-adjusted DRG system. The reason given by the CMS for the revision is to improve the accuracy of payment rates for inpatient stays by assigning weights based on hospital costs rather than hospital charges.

We have observed that the proposed changes would result in a dramatic redistribution of Medicare payments among DRGs and hospitals. The calculated 2007 impact of the proposed DRG revision to Sparrow is $1 million dollars or a 1% reduction in the payment update. The case mix index for a large urban hospital that performs more complicated procedures like Sparrow will experience a significant reduction in reimbursement because of the redistribution of resource usage from surgical DRGs to medical DRGs.

Sparrow Hospital strongly opposes the CMS proposed changes because we do not believe that it accurately allocates payments rates for inpatient stays. The underlining assumptions for the proposed DRG changes is flawed because of the following reasons:

- *The development of a national cost center charge ratios from mostly un-audited and sometimes inaccurate cost reports data. This process ignores the unique cost structures among hospitals primarily based on where the hospital is located.*

- *An inconsistent pricing (mark-up) calculations between hospital ancillary departments. For example, high priced implants are priced with a much lower markup than general surgical supplies. Thus, the application of a uniform cost to charge ratio to convert charges to cost for all departments will result in the reduction of cost allocated to departments with high cost surgical implants and procedures.*

- *The lack of a CMS comprehensive impact analysis that includes a possible increase in reported case mix and changes to the outlier threshold.*

We recommend that the implementation of the revised DRGs be delayed until a comprehensive study is conducted to determine its impact on urban and disproportionate share hospitals like Sparrow that absorb a larger portion of the cost of providing health care services of the indigent and uninsured.

OPERATING PAYMENT RATES - Cost Outliers
(Federal Register pages 24149 – 24151)

For FY 2007, the CMS is proposing to use the same methodology used in 2006 to calculate the outlier threshold but unfortunately the fixed loss threshold would be increased from the 2006 amount of $23,600 to $25,530 – an 8.2 percent increase. We find the increase to the fixed loss threshold problematic because only 4.1 percent of the 5.1 percent cost outlier pool was actually paid out to providers in FY 2005. In FY 2006 CMS is projected to spend only 4.7 percent of the outlier pool.

We would recommend that the fixed outlier threshold be maintained at the current amount of $23,600, since the CMS did not spend the total allocated pool of cost outlier funds.

UPDATE FACTORS – Standardized Operating Amount
(Federal Register pages 24419 – 24420)

CMS has proposed to increase of 3.4 percent to the IPPS rate update for acute care hospitals in all areas. Providers that submit data on 10 quality indicators involving heart attack, heart failure and pneumonia will realize the full update. As required by the Deficit Reduction Act of 2005 (DRA) (Pub L, No. 109-171), hospitals that fail to report on the new and increased number of quality indicators will receive a 2-percentage point reduction in the payment update for FY 2007. Sparrow Hospital is one of the 98 percent of eligible providers that submitted the required data and thus would receive the full update in FY2006. We will also comply with the filing requirements of the enhanced quality data standards under DRA.

The increase in the payment rate is encouraging but for a number of years Medicare payments updates has not matched increases in hospital operations cost. For example for the period between 1998 to 2006, on the aggregate, hospital cost increased 37.9% but Medicare payment increased by only 19.7 percent. For Sparrow Hospital the payment shortfall resulted in a $30 million loss on services provided to Medicare patients in FY2005 alone. We believe that the continued under-funding of the Medicare program by the CMS will ultimately lead to financial difficulty for Level I Trauma and disproportionate share hospitals like Sparrow.

We strongly believe that payments for Medicare services be closely aligned with the true healthcare inflation rate. We would also like to recommend that the filing date on the 21 expanded quality measures be extended from August 15, 2006 to October 1, 2006. If the IPPS rule is finalized on August 1, 2006, providers will have only 14 days to code the records, formulate, and submit accurate data for filing or risk losing 2 percent of the payment update.

INDIRECT MEDICAL EDUCATION (IME) ADJUSTMENT
(Federal Register Page 24107 -24114)

Section 1886 (d)(5)(B) of the Act provides that prospective payment hospitals that have residents in an approved area graduate medical education (GME) program receive additional payment to reflect the higher indirect patient care cost of teaching hospitals. As a teaching hospital, Sparrow has benefited from the willingness of the Medicare Program to pay its fair share of the cost of training physicians. The future of the country's healthcare system depends on the adequate funding for medical training programs. Before the enactment of the Medicare Modernization Act of 2003, the formula multiplier was set at 1.35 for discharges occurring during FY 2003 and thereafter, this equates to a 5.5 percent IME payment adjustment. The Congress realized that graduate medical education was under funded and modified the formula as follows:

- For discharges occurring during FY 2006, the formula multiplier is 1.37 (equivalent to a 5.55 percent adjustment)
- For discharges occurring during FY 2007, the formula multiplier is 1.32 (equivalent to a 5.38 percent adjustment)

Sparrow Hospital opposes the reduction in the IME adjustment factor in light of the fact that the cost of running teaching programs keeps on increasing. Inadequate payments to teaching hospitals will jeopardize the ability of hospitals to adequately train medical residents.

Exclusion of Didactic Training – The proposed rule also states that resident training that occurs at non-hospital sites must be related to patient care if a hospital is to include the time for GME and IME on its cost report for reimbursement purposes. Residents time spent in didactic activities (educational conferences, journal clubs and seminars) that often occur at related medical schools would be specifically excluded.

The above require further complicates the CMS requirement that for a provider to include in its FTE count for IME and GME rotations to non-provider setting, the provider is required to compensate the non-provider setting for the cost incurred by the non-provider setting in teaching and supervision activities. In this ruling CMS has stated that hospitals compensate the non-provider setting for didactic time, not for time spent in the provision of patient care, since the non-provider setting is compensated for the provision of patient care. CMS is requiring providers to compensate non-provider locations for services for which it would not reimburse providers.

Sparrow Hospital recommends that the CMS increase the IME formula multiplier to 1.42 given the current precarious financial condition of most teaching hospitals. We also recommend that if the CMS is not going to be funding didactic time in a non-provider setting, then the requirement that providers pay (in cash or in kind) the non-hospital setting for didactic time should be eliminated.

HOSPITAL-ACQUIRED INFECTIONS

(Federal Register page 24100)

The CMS restated that Medicare's IPPS encourages hospitals to treat patients efficiently. Hospitals receive the same DRG payment for stays that vary in length. In many cases, complications acquired in the hospital do not generate higher payments than the hospital would have received for other cases in the same DRG. But in some cases infections acquired in the hospital and other complications, can sometimes trigger higher payments, either as payment for outliers or by assignment to a higher-paying DRG. The CMS has determined that approximately 121 sets of DRGs are split based on the presence or absence of a complication or c-morbidity (CC), and these DRGs engender higher Medicare payments.

Section 5001© of Pub. L. 109 – 171 requires the HHS secretary to identify at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis and (c) could reasonably have been prevented through the application of evidence based guidelines by October 1, 2006. Hospitals would not receive additional payments for cases in which one of the selected secondary diagnoses was present as of discharges on or after October 1, 2008. Via the proposed 2007 IPPS rule the CMS is requesting input about which conditions and which evidence-based guidelines should be selected.

We disagree with the enforcement method and penalty stated in the proposed rule. The rule, as presented, suggests that providers only create complications in a patient's medical condition with the aim of receiving higher payments from Medicare. Sparrow has an infectious control department whose mission is to identify and eliminate hospital-acquired infection.

We recommend that CMS should engage in expanded infections control demonstration projects that will collaboratively minimize and ultimately eliminate hospital-acquired infections.

TRANPARENCY OF HEALTH CARE INFORMATION

(Federal Register pages 24115 – 24116)

CMS has come to the realization that the reason health care costs are rising so quickly is that most consumers of health care – the patients – are frequently not aware of the actual cost of their care. Health insurance shields beneficiaries from the full cost of services and they do have only limited information about quality and cost of their care. The result of the above scenario is that health services consumers do not have the incentive or means to carefully shop for providers offering best value. Thus providers of care are not subject to the competitive pressures that exist in other markets for offering quality services at the best possible price. To remedy this perceived problem the HHS Department intends to launch a major health care information transparency initiative in 2006. The department intends to provide Medicare payment information as a benchmark especially for uninsured individuals, to determine whether the charges they see on a hospital's bill bear any relationship to what third-party- fee-for service payors pay to the hospital.

We disagree with the CMS on the idea of establishing a Medicare condition of participation requirement to post prices on assistance programs to the uninsured. Sparrow Hospital currently has a community financial assistance program that provides payment assistance to uninsured patients based on a wage-determined scale. It is also important for the CMS to realize that the income level of the uninsured varies by community. What is considered low income for a person living in San Francisco, CA may not be the same for a person living in Lansing, MI because of the substantial difference in the cost of living within the two cities.

Sparrow Hospital appreciates the effort made by the HHS Department to provide pricing information to consumers but we will like to recommend that the department also provide cost and reimbursement information as part of the information made available. The proper dissemination of this information would educate consumers on the total health care funding situation in the country.

Sparrow Hospital is committed to providing excellent, cost effective and compassionate care to all patients including Medicare beneficiaries in the current "margin erosion" health care environment. We believe that our recommendations, if incorporated in the final IPPS rule will lead to an appropriate and equitable allocation of health care resources. Avenues for "cost shifting" in the health care arena have shrunk to a point where inadequate Medicare payments to cover the cost of services provided to Medicare beneficiaries greatly threatens the very survival of the healthcare delivery system in the country.

If you have questions or comments about the stated issues, please contact Ebbie Erzuah at (517) 364 – 6020 [ebbie.erzuah@sparrow.org]. Thank you for your attention to these matters.

Sincerely,

Ebbie N Erzuah

Ebbie N. Erzuah
Finance Director – Government Programs
Edward W. Sparrow Hospital Association

Submitter : Dr. Nahn Ta **Date:** 06/12/2006

Organization : John Peter Smith Hospital-FMRP

Category : Health Care Professional or Association

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1757-Attach-1.DOC

#1767

Dear CMS policy maker

I am a family medicine resident in a very busy HPSA. I really need my faculty to teach. Why would you interpret a rule designed to do just that as being un related to patient care time? Whether we are having a discussion after a patient encounter, a small group discussion regarding a difficult clinical situation, reviewing our evaluation for our care and didactic tests in a certain disease domain, or participating in lectures – we are learning about, caring for current and protecting our future patients.

My concern is that the faculty are already stretched to produce more patient visits with poor compensation and must cover four of us at a time for supervision in clinic. That hour they spend before and after clinic to discuss a specific topic that is not related to a specific individual patient will disappear with the implementation of the rule you suggest. They will not have time to sit down with us to discuss our overall performance – we will get an email.

The faculty, without support for their own development, will be likely to lose their academic edge as they work to see patients, see more patients and supervise patient care without any incentive to reflect, discuss and research our and their work.

Please help us be better physicians to our patients by supporting a competent and refreshed faculty . Rescind the interpretation of the IME and DME support rule

Sincerely,

Submitter : **Mr. Richard Gundling** **Date: 06/12/2006**

Organization : **Healthcare Financial Management Association**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comment letter

CMS-1488-P-1758-Attach-1.PDF

ATTACHMENT TO 1758

June 12, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1488-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.
and
CMS–1488–P2, Medicare Program; Hospital Inpatient Prospective Payment Systems Implementation of the Fiscal Year 2007 Occupational Mix Adjustment to the Wage Index; Proposed rule.

Dear Dr. McClellan:

The Healthcare Financial Management Association (HFMA) is pleased to submit, on behalf of our many members who are involved in the financial management of hospitals, the following comments regarding the proposed Medicare inpatient prospective payment system (PPS) regulations (CMS-1488-P) and the proposed rule on the inpatient PPS implementation of the FY07 occupational mix adjustment to the wage index. The rules were published in the April 25, 2006, and May 17, 2006, *Federal Registers*, respectively.

HFMA is the professional membership organization for individuals involved in the financial management of health care. HFMA's more than 34,000 members work in a variety of healthcare settings.

The inpatient PPS FY07 rule proposes the most significant changes in the calculation of diagnosis-related group (DRG) relative weights since DRGs were adopted. It would create what is being called cost-based weights using a newly developed hospital-specific relative values cost center methodology (HSRVcc). The rule also proposes expansion of the DRG system into consolidated severity adjusted DRGs (CS-DRGs) to account for patient severity and suggests such refinements could occur in FY08, "if not before."

We have serious concerns about the proposed changes to the DRG weights and classifications. While we believe CMS and HFMA share a common goal of refinements to the Medicare payment systems that will make for fairer and more equitable payments, our experience educating healthcare professionals tells us that even with perfect changes to the DRG-based system, more time is needed to understand not only the direct financial effects of such significant

proposed policy changes, but the many ramifications of the changes throughout hospital organizations.

CMS is receiving comments from the American Hospital Association, the Federation of American Hospitals, and the Association of American Medical Colleges, based upon significant research performed on their behalf. That research and analysis addresses such concerns as the instability of the impact of the proposed changes, that small changes in methodology could lead to large changes in hospital payment, and that the validity of CMS' proposals versus potential alternatives to improve the DRG weights and classification system is uncertain. We echo those concerns and urge your attention to that research.

HFMA asks that the following be part of the final inpatient PPS rule:

- **Additional study of the need for a new classification system.** HFMA believes additional understanding of the variation within DRGs and the capabilities of a classification system that will effectively address such variation is still needed before changes of the magnitude being proposed are put in place.

- **Delay cost-based weighting by at least one year.** While we support moving to a DRG-weighting methodology based on hospital costs rather than charges, we also believe the system should be simple, predictable, and stable over time. The PPS should also provide clinically cohesive and meaningful DRGs that are somewhat intuitive for providers and coders to follow, and that reflect similar resource use within DRGs. And, ultimately, the inpatient PPS should foster innovation and best practice in care delivery. The research and analysis undertaken for AHA, FAH, and AAMC found errors, inconsistencies, and flawed HSRVcc methodology that indicate more work and time is needed to determine the best way to create cost-based weights, develop a sound methodological approach, and to understand their potential impact. In addition, there should be analysis of proposed changes to clearly show they result in an improved system.

  HFMA sees a clear need for not less than a one-year delay, regardless of version of the proposed DRG changes, given the serious concerns with the HSRVcc and CS-DRG methodology, and appropriate consideration to the substantial education and training efforts the proposed changes would require.

- **Simultaneous adoption of changes to the weights and classifications.** HFMA supports the conclusion from the research commissioned by the AHA, FAH, and AAMC that if the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system. Such implementation would provide better predictability, smooth the volatility created by the two, generally off-setting, changes and permit the training process to engage the logic of both changes.

- **A three-year transition.** When, adopted, weighting changes and refined DRGs should be implemented over a three-year transition period, given the magnitude of payment redistribution across DRGs and hospitals, and the extensive training the changes will entail.

We also have concerns about the proposed occupational mix rule. As a result of the decision handed down by the U.S. Court of Appeals for the Second Circuit on April 3 in *Bellevue Hospital Center v. Leavitt*, CMS on May 12 released a proposed rule revising the occupational mix adjustment portion of the FY07 inpatient PPS proposed rule. The court ruling requires CMS to collect new data on the occupational mix of hospital employees and fully adjust the area wage index (AWI) for FY07. Care must be taken to prevent the errors that can result from compressing a lot of work into a limited amount of time.

HFMA urges CMS to:

- Allow hospitals to turn in both calendar quarters of data in August whether they are submitting for the first time or with corrections.

- Take comments on the calculations after the initial results of the survey are tabulated and posted, and publish the occupational mix adjustment changes as an interim-final rule in August with an associated comment period.

Finally, HFMA takes this opportunity to note what appears to be an oversight in data manipulation pertaining to the wage index. CMS eliminates the critical access hospital (CAH) data from the wage index file it uses to compute the national average hourly wage (NAHW). Since CAHs have lower average hourly wages (AHWs) than the average PPS hospital, the elimination of their data produces an overstated NAHW. This artificial increase is included in the negative budget neutrality adjustment that consequently reduces payments and results in the national inpatient PPS operating payments being understated by an estimated $1.52 billion over five years (2003-2007). We call upon CMS to apply a positive budget neutrality adjustment in FY07 to compensate for the underpayments.

HFMA takes pride in its longstanding ability to provide technical expertise to Federal agencies. We hope that these comments prove useful.

We would welcome the opportunity to provide further assistance with these issues. Please do not hesitate to call on me at (202) 296-2920.

Sincerely,

Richard L. Gundling, FHFMA
Vice President

Submitter : **Date: 06/12/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

FTE Resident Count and Documentation

FTE Resident Count and Documentation

attached

CMS-1488-P-1759-Attach-1.DOC

#1759

UNC
SCHOOL OF MEDICINE
DEPARTMENT OF
PSYCHIATRY

Karon Dawkins, MD
Associate Professor
Director, ECT Service
Director, Residency Education

June 12, 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 University of North Carolina Health Care System 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

The University of North Carolina at Chapel Hill, Campus Box # 7160, Chapel Hill, North Carolina 27599-7160
Telephone: (919) 966-5477; FAX: (919) 966-5628; E-MAIL: karon_dawkins@MED.UNC.EDU

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.

All of our didactic efforts ultimately relate to patient care. Our seminar series are frequently case-based in covering diagnosis, phrenomenology, symptomatology, incidence, and management. We devote efforts to ensuring that our residents can appropriately interview - both in the elicitation of information and in the establishment of rapport - utilization patients. Psychotherapy didactics utilize current cases as examples. The relationship between didactics and clinical care is almost seamless.

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,
Karon Dawkins, M.D.

Submitter : Mrs. Margaret Van Amringe **Date:** 06/12/2006

Organization : Joint Commission on Accreditation of Healthcare Or

Category : Health Care Industry

Issue Areas/Comments

Services Outside the United States

Services Outside the United States

Services Outside the United States Section VII (24136)
We appreciate the clarifying changes made to the regulations referencing Medicare services furnished outside the Unites states, but we believe additional clarification may be necessary to avoid confusion. Specifically, the example cited in the preamble states: if a Medicare beneficiary who is in Guam needed emergency inpatient hospital services and the nearest available hospital adequately equipped was located in the Philippines, Medicare payment would be permitted for the services. That statement and the accompanying changes to the regulations raise several questions. First, does it matter that the beneficiary happens to be in Guam, or is there an expectation that the beneficiary resides in Guam? Second, does it matter if the beneficiary is in a United States Territory (i.e., Guam), or would payment be permitted for services furnished to a beneficiary who was in another foreign country? Finally, what is the applicability of these provisions to a Medicare beneficiary who maintains residence outside the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, or American Samoa? Further, we believe that CMS should evaluate the safety concerns of beneficiaries living outside the United States, but in close proximity to Joint Commission accredited hospitals in foreign countries. These beneficiaries are forced to travel great distances to reach hospitals in the US, sometimes at great risk to their health, while adequately equipped, accredited hospitals are immediately available to meet their health care needs.

Submitter : Dr. Yanping Ye **Date:** 06/12/2006

Organization : John Peter Smith Hospital-FMRP

Category : Health Care Professional or Association

Issue Areas/Comments

GME Payments

GME Payments

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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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.

CMS-1488-P-1761-Attach-1.DOC

#1761

Currently I am completing my residency in family medicine. When I became aware that CMS would stop funding payment to faculty for teaching, preparing curriculum and evaluating my performance through GME -- IME and DME support – I became alarmed.

We are in a state with a huge health care professional shortage in communities under 25,000. These communities cannot afford to support several nurse practitioners and visiting specialists when the services are delivered by a pluri-potential well trained family medicine specialist who is part of their community. The training programs, like mine, which prepare us for these types of venues are in very short supply. We need to be exceptionally well trained.

Someone at CMS will need to explain to me, how the teaching, curriculum development and evaluation process for the six required ACGME physician skill competencies is not related to patient care. Isn't this exactly what the IOM has criticized our training professions for? In fact, our program currently evaluates us in all these competencies as a continuing quality improvement process DURING patient care. Without time to discuss and reflect our experiences and outcomes we will not be serving the needs of our current and future patients.

Should indeed this come to pass, we will have faculty who will be caught in the productivity race with no time for us. We may get pop-up feed back from an Electronic Health Record in sites that have them that we have made an error or we are not following a guideline. No discussion there. What is being proposed is dangerous for our current patients and our future patients. Our patients deserve for us to have a better education than you are proposing.

Why does the American taxpayer support medical students at over $200,000 per student per year and offers the faculty of residencies less than $15,000 for teaching per resident per year? I am getting a lot more from my residency training to protect and serve my patients of the future than all of medical school combined. Please do not cut us any more – rescind the clarification of this dangerous and capricious rule.

Medical Resident

Submitter : **Ms. Laura Loeb** **Date: 06/12/2006**

Organization : **ACOS and AOAO**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GME Payments

GME Payments

Opppose exclusion of didactic time from D-GME and IME count

CMS-1488-P-1762-Attach-1.PDF

ATTACHMENT #1 TO 1762

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 443-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Attention: CMS-1488-P

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

Dear Administrator McClellan:

The American College of Osteopathic Surgeons (ACOS) and the American Osteopathic Academy of Orthopedics (AOAO) appreciate the opportunity to comment on the proposed rule for changes to hospital inpatient prospective payment systems for fiscal year 2007, as published in the April 25, 2005 *Federal Register*. Specifically, we will comment on proposed changes to graduate medical education (GME) policies, which, if finalized, would have a very negative impact on residency training and the medical care that residents provide to their patients. These proposed changes are found at Section IV(F)(5) -- Resident Time Spent in Nonpatient Care Activities as Part of Approved Residency Programs (Sections 413.9 and 413.78(a)).

In this section of the proposed rule, CMS suggests that it is clarifying "longstanding" policy that didactic activities in an approved residency program cannot be included in a hospital's direct GME (D-GME) or indirect medical education (IME) full-time equivalent resident count for training occurring in a nonhospital setting or for IME for training in a hospital setting. We agree with CMS that only "activities relating to patient care" should be included in the D-GME and IME counts for such training.

However, CMS stated very clearly in a 1999 letter attached that "patient care activities" include didactic activities and that these didactic activities could be counted for both D-GME and IME. As organizations that oversee the development of curriculum for residency programs, we strongly affirm the position of CMS in this 1999 correspondence that didactic activities that are part of an approved residency program are related to patient care and should be counted for D-GME and IME.

Educational activities are an essential component of all residency programs and have a direct bearing on patient care. What residents learn from other residents' or faculty case presentations is more often than not immediately applied to the care of their patients. Even with respect to journal clubs, residents often are requested by faculty to bring in an article that is directly related to a case on the service and that benefits patient care, the attending, and colleagues.

Procedural (skills-based) workshops often are related to specific cases. Many residency programs are requiring certification in a simulation or animal lab before a procedure is performed in the OR. There is time spent on cadaver dissections to enhance surgical skills.

Time spent with the black box (for minimally-invasive surgery) also is critical to improving the skill of the surgeon. Many programs are designing web-based, interactive training components and these are viewed as significant skills-enhancement exercises and learning experiences and can be multi-disciplinary.

It is also interesting to note that in terms of HIPAA regulations, Grand Rounds, which is basically a didactic case presentation, is considered part of the treatment of a patient and therefore, physicians are not required to de-identify the patient-specific health information.

Conferences on such topics as surgical infections, pain management, advanced cardiac life support, pediatric advanced life support, or trauma care might not be related to a direct patient, but provide very useful information that assists residents in future care of patients. Residents might attend laser seminars and courses on new techniques. Some programs might have weekly teaching conferences with one-hour lectures on appropriate clinical topics given by the residents.

All osteopathic training programs are required to teach certain core competencies by 2006. These core competencies include interpersonal and communication skills. This includes the learning of skills in developing appropriate doctor-patient relationships, learning how to collaborate with other health care professionals, and cultural sensitivity workshops.

There is also training on informatics, evidence-based medicine, and systematic practice management. Medical information is increasing and changing at an ever accelerating rate. New techniques are introduced into surgical practice nearly everyday. Findings from research studies are reported in medical journals and translated into popular literature and websites for patients to access. Therefore, it is essential for all surgeons to be trained in how to locate and critically appraise a large volume of new information quickly and efficiently.

Physicians must know how to use current evidence and practice guidelines in making patient care decisions through the integration of many concepts from research, informatics, and scholarship. They need to understand the role of external organizations, such as the National Committee for Quality Assurance and the Joint Commission on Accreditation of Healthcare

Organizations. They need to understand health plan reports, hospital data systems, Peer Review Organizations, CPT coding, evaluation and management coding, maintenance of a clinical record, and even patient accounting systems in order to provide better patient care.

This description is but the tip of the iceberg. The point being that residents spend much time on what CMS might describe as "didactic" or "scholarly" activities. However, these activities are directly related to the patient care provided by the residents. The reason that many patients are referred to a teaching hospital is because of the collaborative approach to patient care provided by the attendings and the residents. If this time were not allowed to be counted towards D-GME and IME, hospitals would ask residency programs to cutback on these activities. Such changes would result in a detriment to patient care.

If you have any questions concerning these comments, please feel free to contact Guy Beaumont, Executive Director of ACOS, at 703/684-0416, Ext. 105.

Respectfully submitted by,

James E. Hoogeboom, D.O., FACOS
President
ACOS

Robert P. Faconiero, D.O., FAOAO
President
AOAO

Attachment: 1999 CMS Correspondence

Vinson&Elkins

ATTORNEYS AT LAW

VINSON & ELKINS L.L.P.
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1001 FANNIN STREET
HOUSTON, TEXAS 77002-6760
TELEPHONE (713) 758-2222
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Writer's Phone: 713/758-3480
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E-mail: smcbride@velaw.com
Web: www.velaw.com

June 24, 1999

Ms. Rebecca Hirshorn
Health Care Financing Administration
7500 Security Blvd.
Mail Stop C4-07-07
Baltimore, Maryland 21244

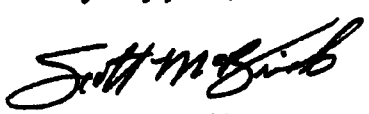
Re: Calculation of FTE Count in Nonhospital Settings

Dear Ms. Hirshorn:

This letter is to confirm our conversation of last week regarding the calculation of the full-time equivalent ("FTE") resident count in nonhospital settings for determining direct ("GME") and indirect ("IME") graduate medical education payments. Specifically, 42 C.F.R. § 413.86(f)(4)(i) states that the time residents spend in nonhospital settings may be included in the FTE count and GME payment calculations if the residents spend their time in "patient care activities." The same requirement exists for IME payment calculations under 42 C.F.R. § 412.105(f)(1)(ii)(C). Based on our conversation, it is my understanding that the Health Care Financing Administration ("HCFA") interprets the phrase "patient care activities" broadly to encompass all patient care oriented activities that relate to the residency program, including, for example, 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 students, and faculty. Accordingly, a hospital may include the entire time spent by residents in nonhospital settings in its FTE count and GME/IME payment calculations as long as the resident is involved in patient care oriented activities and other program requirements are met. If my understanding is incorrect, please notify me promptly at 713/758-3480.

Thank you for your assistance in this matter.

Very truly yours,



B. Scott McBride

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

SEP 24 1999

Mr. B. Scott McBride
Vinson & Elkins L.L.P.
2300 First City Tower
1001 Fannin Street
Houston, TX 77002-6760

Dear Mr. McBride:

This is in response to your letter regarding the calculation of full time equivalent (FTE) resident counts in nonhospital settings for determining direct (GME) and indirect (IME) graduate medical education payments. You specifically inquired about Health Care Financing Administration's (HCFA) interpretation of "patient care activities" in relation to the time residents spend in nonhospital sites.

HCFA interprets the phrase "patient care activities" broadly to include any patient care oriented activities that are part of the residency program. As you stated in your letter, 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 students, and faculty." Therefore, as long as the residents are primarily involved in patient care oriented activities and other program requirements are met, a hospital may include other educational activities as part of the entire time spent by residents in nonhospital settings and include this time in its FTE count and GME/IME payment calculations.

If you have further questions, please call Rebecca Hirshorn at 410-786-3411 or Michelle Lefkowitz at 410-786-5316 of my staff.

Sincerely,

Tzvi M. Hefter
Director
Division of Acute Care
Plan and Provider Purchasing Policy Group

Submitter : Ms. Erin Mass **Date:** 06/12/2006

Organization : The Nebraska Medical Center

Category : Hospital

Issue Areas/Comments

Cost-Based Weights: Outlier Threshold

Cost-Based Weights: Outlier Threshold

Under the Medicare inpatient prospective payment system, if the costs of a particular Medicare case exceed the relevant DRG operating and capital payment (including any disproportionate share (DSH), IME, or new technology add-on payments) plus an outlier threshold, the hospital will receive an outlier payment. This payment equals 80 percent of the case s costs above the threshold calculation.

The outlier fixed-loss cost threshold is set at a level that is intended to result in outlier payments that are between five and six percent. Outlier payments are budget-neutral. Each year the Agency reduces the inpatient standardized amount by 5.1 percent and estimates a cost threshold that should result in outlier payments that equal 5.1 percent.

The proposed rule would increase the fixed-loss cost threshold for outlier payments to be equal to a case s DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus a $25,530 outlier threshold, an increase of 8.2 percent over the FFY 2006 threshold of $23,600.

CMS proposes an increase to the threshold even though the Agency estimates that outlier payments for FFY 2006 will represent only 4.71 percent of actual total DRG payments. Further, CMS estimates that outlier payments represented only 4.1 percent of total DRG payments in FFY 2005 and, according to the August 12, 2005 final rule, only 3.52 percent of total DRG payments in FFY 2004 (70 Fed. Reg. 47496). Because outlier payments were less than the 5.1 percent reduction to the standardized amount, the result is less total Medicare payments to hospitals in all three consecutive years, contrary to the intent of the outlier payment policy.

We believe the FFY 2007 cost threshold must be reduced. CMS relies only on charge inflation to determine projected increases in per case costs, which determines outlier payment outlays.

DRGs: Severity of Illness

DRGs: Severity of Illness

CMS has proposed to move from 526 DRG s under the current payment system to 861 consolidated severity adjusted DRG s. The new DRG s represent a consolidated list of the 1,258 All Patient Refined DRG s (APR DRG s) designed by 3M Health Information Systems. This new methodology includes four severity illness subclasses where the determination of which subclass applies is based on an 18 step process that takes into account secondary diagnosis, principal diagnosis, age and procedures. This system does not allow for distinctions based on case complexity. While the implementation of this system causes fluctuations of some sort in most DRG s, certain classes of DRG s were targeted to reduce potential incentives for specialty hospitals. Unfortunately, doing so also targets teaching hospitals such as ourselves who treat a significant amount of complex cardiac cases across all payers. An analysis of these proposed changes indicates a reimbursement reduction to our cardiac service line of over $1 million annually. As with the new weighting methodology, the CS-DRG s must be carefully analyzed and assessed to ensure that they truly will improve the payment system as is the intent. Of particular concern is the fact that only illness severity is reflected while case complexity is not. CMS recognizes this fact as well, stating that a method of recognizing technologies that represent increased complexity should be included in the system. (71 Fed. Reg. 24014).

HSRV Weights

HSRV Weights

This change involves a complex methodology of accumulating relative weights for 10 cost centers for each DRG at the facility level. These are then blended to a final, single DRG weight. Costs are derived by utilizing a cost to charge ratio (CCR) for each of the 10 cost centers and then summed to obtain an overall number. We appreciate CMS s intent with this proposal, however a number of serious concerns present themselves at this point. Due to the wide reaching effects of this proposal it is imperative that all parties involved have an adequate understanding of the goal of the proposals, the underlying methodologies and the resulting impacts. Given that facilities were only allowed 60 days to review and comment on these changes, we do not feel those understandings were fully realized. We believe that more work is needed to determine the best way to develop cost based weights. This is even more important given many payers, including Medicaid, follow Medicare s payment methodology. It is our belief that this change should be postponed for at least one year to allow for additional analysis.

Submitter : **Mrs. Tamara Imm** **Date: 06/12/2006**

Organization : **Rochester General Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1488-P-1764-Attach-1.DOC

#1764

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P and P2
7500 Security Boulevard
Baltimore, Maryland 21244-8012

Re: 2007 Medicare Hospital Inpatient Proposed Rule

Dear Dr. McClellan:

Rochester General Hospital welcomes the opportunity to comment on the proposed rule related to the Medicare Prospective Payment System (PPS) for inpatients.

Rochester General Hospital is a 528 bed hospital located in Rochester, New York. Rochester General Hospital has been rated a Top 100 Heart Hospital in America for more than five years. Rochester General Hospital is the only top 100 Hospital in the Western New York region.

The availability of local, high quality cardiac care is of critical importance to the health of a community. Care of the cardiac patient requires outpatient and inpatient medical treatment as well as, in many cases, invasive procedures including cardiac catheterization, angioplasty, electrophysiology and cardiac surgical procedures. For safety reasons, New York State largely restricts the performance of these invasive procedures to tertiary hospitals with cardiac surgical programs. Rochester General Hospital is a tertiary hospital with such a program. Unfortunately, based upon the latest estimates of the impact of the 2007 Medicare Proposed Inpatient Rule, this award-winning program may be at risk.

Although we understand the premise behind the current proposed overhaul to the Diagnosis Related Group (DRG) system, it appears that there are significant reimbursement swings between hospitals. Analysis done by both HANYS and the AHA has revealed that there appears to be methodological errors and technical problems that could significantly impact payments to hospitals. Rochester General Hospital is one of the hospitals that would be impacted materially. Based upon our internal estimates, Rochester General Hospital would be forced to absorb an annual reduction in Medicare inpatient reimbursement of roughly $4.0M due to the proposed changes, in particular, to the cardiology weights. Per our analysis, by DRG, cardiac cases which previously ran at a slight profit or a minimal loss, would now run at a significant loss. Under the current proposal, every cardiac DRG would run at a loss (based upon actual Medicare cases and costs YTD March, 2006).

Although we understand the need to change the DRG system, we don't believe it was Medicare's intent to change the weights so drastically to actually result in paying less than total costs per case. If the proposed changes go through, hospitals like Rochester General Hospital may be forced to either cut or even eliminate services currently provided. Given that, please reconsider the proposed weight changes to ensure that hospitals, like Rochester General Hospital, are able to continue to provide excellent, award-winning care to its' patients.

Rochester General Hospital appreciates having the opportunity to comment on the proposed rule. If you have any questions regarding our comments, please feel free to contact me at (585) 922-1738. Thank you.

Sincerely,

Tamara C. Imm
Director of Reimbursement

Submitter : Mr. John Stewart **Date:** 06/12/2006

Organization : St Elizabeth Medical Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please keep GME payments at current levels. Any cut will negatively impact hospitals sponsoring medical residency programs--and in particular primary care programs. PCPs are in demand now and the demand will only increase in the years to come. We need to maintain current resident levels--at a minimum. Thanks for your consideration. John Stewart

Submitter : **Mrs. Donna Sollenberger** **Date: 06/12/2006**

Organization : **University of Wisconsin Hospitals**

Category : **Other Health Care Professional**

Issue Areas/Comments

IME Adjustment

IME Adjustment

June 12, 2006

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

Attention: CMS-1488 P Resident Time in Patient Activities

Dear Administrator McClellan:

The University of Wisconsin Hospital and Clinics 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. The stated rationale for the exclusion of time devoted to these activities is that they are not related to patient care 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 proposed rule 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 support the Agency s 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. We urge CMS to withdraw 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,

Donna K. Sollenberger
President and Chief Executive Officer

CMS-1488-P-1766-Attach-1.DOC

CMS-1488-P-1766-Attach-2.DOC

UWHealth

University of Wisconsin
Hospital and Clinics

#1766

June 12, 2006

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

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

Dear Administrator McClellan:

The University of Wisconsin Hospital and Clinics 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. The stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care" 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 proposed rule 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 support the Agency's 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. We urge CMS to withdraw 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,

Donna K. Sollenberger

Donna K. Sollenberger
President and Chief Executive Officer

UWHealth

University of Wisconsin
Hospital and Clinics

June 12, 2006

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

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

Dear Administrator McClellan:

The University of Wisconsin Hospital and Clinics 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).

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The proposed rule 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 support the Agency's 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. We urge CMS to withdraw 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,

Donna K. Sollenberger

Donna K. Sollenberger
President and Chief Executive Officer

Submitter : **Mr. William Mahone** **Date: 06/12/2006**

Organization : **Halifax Regional Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

June 12, 2006

Mark McClellan, M.D. Ph. D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S. W.
Washington, DC 20201

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

Dear Dr. McClellan:

I am writing as the President of a 206 bed hospital in Roanoke Rapids, NC. Our Hospital serves 75,000 people in two counties which have the lowest incomes among counties in NC. We are a full service Medical Center with 80 physicians and have remained fully accredited by the JCAHO.

Our services are 54% Medicare and 19% Medicaid. We have an exceptional operation but we have had no financial stability for the last four years. This organization lost $4m in 2004 and $2m in 2005 and currently has a 0.03% bottom line after seven months.

Your proposed changes may be the only increased revenue to allow us to maintain our current services. I can only estimate the exact manner in which you will implement the proposed changes for final form but the increased payments for our medical services are positive and important to us and the patients we serve.

We also support the comments of the Rural Referral and Sole Community Hospital Coalition, Washington, DC. Please review and accept their comments in addition to mine.

Sincerely,

William Mahone V
President
Halifax Regional Medical Center
P.O. Box 1089
250 Smith Church Road
Roanoke Rapids, NC 27879
252.535.8101

Submitter : Mr. Carl Holland **Date:** 06/12/2006

Organization : South Shore Hospital

Category : Hospital

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

South SHore Hoospital is in agreemnet with proposed DRG weight changes for 2007.

Submitter : Pattie Moore-Boyette **Date:** 06/12/2006

Organization : UNC Hospitals

Category : Hospital

Issue Areas/Comments

FTE Resident Count and Documentation

FTE Resident Count and Documentation

The University of North Carolina Health System 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 .

The activities cited in the 1999 position 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.

The proposed inpatient rule alteration exclusion, for purpose of DGME and IME payment activities held in medical school or physician s office, and other non-hospital settings, reflects a lack of understanding of the interconnectivity of graduate medical education.

The geographic location of teaching activities is ubiquitous and is often held at bedside, in conference rooms, in physician office, and other locations. The evolving merger of all of these facilities into Academic Health Centers precludes parsing out geographic sites. Conferences, such as Journal Clubs, are directed at specific patients or groups of patients. Health problems are presented in a variety of techniques, but never disconnected from the healthcare of the patient. Conferences, such as those of Morbidity and Mortality, have been major teaching activities for a century and focus on specific patients. Moreover, these conferences are sequencing into the basis of error reduction, a quality forum emphasized by CMS.

Finally, the requirement to document the time and location of all didactic efforts with the intent to exclude from the FTE count would require an alteration of the IRIS software program. The smallest increment of the very best GME programs on the market today allow rotation schedule detail down to a half day increment. 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,
Pattie Moore-Boyette
Vice-President, UNC Hospitals

Submitter : **Dr. erin mathews** **Date: 06/12/2006**

Organization : **miami valley hospital family medicine residency pr**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, 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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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,
Dr Erin Mathews

Submitter : **Dr. Charles Carter** **Date: 06/12/2006**

Organization : **University of South Carolina**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a family physician educator, 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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are

unreasonable and would add an extremely large and unnecessary administrative burden.

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,

Charles Carter, MD
University of South Carolina Department of Family Medicine

Submitter : **Dr. Paul Dake** **Date: 06/12/2006**

Organization : **McLaren Family Practice Residency Program**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a family medicine residency faculty member, 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 most 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 strongly support the Agency's 1999 position. The activities cited in the 1999 letter and 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 faculty member 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 onerous and 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 attention to these comments.

Sincerely,

Paul M. Dake, M.D.
McLaren Family Practice Residency Program
Flint, Michigan

Submitter : **Mr. Richard Fries** **Date: 06/12/2006**

Organization : **West Penn Allegheny Health System**

Category : **Health Care Provider/Association**

Issue Areas/Comments

DRG Weights

DRG Weights

attachement

#1773

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 : Jeffrey Bush **Date:** 06/12/2006

Organization : BD

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-1774-Attach-1.DOC

#1774

June 12, 2006

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

Re: ***File Code CMS-1488-P: Comments Related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates***

Dear Doctor McClellan:

Becton, Dickinson and Company (BD), a medical technology company that serves healthcare institutions, life science researchers, clinical laboratories, industry and the general public, through the manufacture and sale of medical supplies, devices, laboratory equipment and diagnostic products, submits the following comments to the Centers for Medicare and Medicaid Services (CMS) regarding the proposed changes to the Medicare hospital inpatient prospective payment systems and fiscal year 2007 rates (CMS-1488-P).

General Comments

BD shares in CMS' commitment to provide high quality healthcare at an effective cost, and we believe that we provide many products and services to Medicare beneficiaries that help the agency to meet its goals in this regard. BD also agrees with CMS that it should pay as accurately as possible for the services it purchases within the framework of the various payment systems, and we commend CMS' efforts to further refine these systems to the extent that the refinements meet the goal of improved payment accuracy based on resource use and value that beneficiaries derive from given healthcare expenditures. BD also expects to provide innovative products to Medicare beneficiaries long into the future, as we continue on our mission to helping all people live healthy lives.

To these effects, while we reiterate our position of support for payment accuracy, we also have some reservations regarding the inpatient system alterations proposed by CMS, and we are concerned that some of them may not lead to improvements in payment accuracy, and may, in fact, lead to improper incentives that deny Medicare beneficiaries access to the most effective and ultimately most efficient course of treatments. Additionally, the changes called for in this proposed rule are the most sweeping and broad-based edits to the inpatient prospective payment system since its inception, the long-term effects of these changes on patient care and hospital utilization of life-saving, long-term cost-reducing technologies are not likely to be known for some time, and the use of proprietary grouping software has limited stakeholders' ability to model and transparently verify how various scenarios will be affected. For these reasons, BD joins with hospital groups and others in urging CMS to enact a minimum of a one-year delay in the implementation of the CSA DRG and

the HSRV cost center proposals in order to allow stakeholders to more adequately assess the impact these changes will have on various industries, and most importantly on the care that Medicare beneficiaries will receive under the changes.

Related to CMS' quality initiatives, we commend the progress the agency has made on the identification and reporting of quality measures, and we continue to encourage the addition of appropriate quality measures that lead to better care for beneficiaries. We further note the agency's comments on Considerations Related to Certain Conditions, Including Hospital-Acquired Infections, and we will provide related comments on this section of the proposed rule in the context of the Deficit Reduction Act of 2005, Section 5001(c).

Proposed Changes to DRG Classifications and Relative Weights

We are aware that others are providing detailed comments and examples related to this area of the proposed rule, and, as we have participated in some of these processes, we will defer to those detailed comments rather than reiterate specifics here. However, we continue to be generally concerned about an immediate implementation of these changes as noted in our general comments above.

Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs – Value Based Purchasing – Considerations Related to Certain Conditions, Including Hospital-Acquired Infections (Section IV. B. 5. of the rule)

BD continues to be concerned about certain infections that are known to occur in association with healthcare delivery. We have long been a partner in the battle to minimize and eliminate such infections that reportedly cost our healthcare system billions of dollars annually. In the US, two prominent healthcare-associated infections (HAI's) are well-known to be MRSA (methicillin resistant staphylococcus aureus) and VRE (vancomycin resistant enterococcus). CDC reports that HAI's cause $5 billion annually in increased system costs overall. MRSA and VRE infections likely comprise a significant percentage of those costs. Given these data, we respectfully submit that two of the conditions CMS ultimately selects for inclusion in this particular quality initiative should be MRSA and VRE. We will continue our efforts to work with the agency in qualifying the existing evidence-based guidelines that support inclusion of these particular infections.

Also, we agree with and support the comments made by MedPAC that indicate the reporting of all secondary diagnoses for all admissions should be collected and that linking this information to AHRQ or other databases could provide very useful information to healthcare providers and to the agency.

Sincerely,

Jeffrey P. Bush
Director, Corporate Reimbursement
BD
1250 H. Street, Suite 1102, Washington, DC 20005

Submitter : Dr. James O'Brien **Date:** 06/12/2006

Organization : University of Louisville

Category : Academic

Issue Areas/Comments

GME Payments

GME Payments

To Whom It May Concern:

As a chair of the Department of Family and Geriatric 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. O'Brien, MD
Chair, Family and Geriatric Medicine
University of Louisville
501 E Broadway
Louisville, KY 40202

Submitter : Mrs. Laura Lavallee **Date:** 06/12/2006

Organization : Brown Family Medicine Residency Program

Category : Other Health Care Professional

Issue Areas/Comments

GME Payments

GME Payments

As a professional involved in the administration of a residency program in Family Medicine I would like to comment on the proposed rule entitled "Medicare Program; Proposed Cahnges to the Hospital Inpatient Prospetive Payment Systems and Fiscal year 2007 Rates" I strongly urge CMS to carefully consider the potential effects of the proposed rule in eliminating payment for non-patient encounter activities. Didactic and other experiences are a critical part of any residency program and are closely related to the residents continued accumulation of knowledge needed for patient care and safety. Many programs struggle to stay alive, particularly in small community hospitals and in areas that provide service to underserved patient populations. this proposed rule would place an unnecessary fiscal and administrative burden on the teaching institutions that are training our future physician workforce. I urge you to consider how impossible it would be to create a medical training environment in which the exchange of new information and discussion of best practices cannot be included in the curriculum because there is no fiscal support for it. This enviroment would be both damaging to patient care and to the continued education of our medical practitioners but also could result in the closing of smaller residency programs across the country. Please reconsider this move before you enact this policy.

Submitter : Mrs. Cathy Clark **Date:** 06/12/2006

Organization : University of Colorado Hosptial

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

About 45% of our patients in the Cardiology DRGs are Medicare patients. An Impact analysis shows a severe loss cutting into our ability to cover our cost which could impair ability to treat these patients. Our experience has been that these cost continue to escalate, not drop. These changes are coming too fast and are too severe. We also have concerns about the methodologies employee in your analysis process.

Submitter : **Ms. Annette Bar-Cohen** **Date: 06/12/2006**

Organization : **National Breast Cancer Coalition Fund**

Category : **Consumer Group**

Issue Areas/Comments

Value-Based Purchasing

Value-Based Purchasing

June 12, 2006

Secretary Michael Leavitt
Department of Health & Human Services
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P
PO Box 8011
Baltimore, MD 21244-1850

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

Dear Secretary Leavitt:

The National Breast Cancer Coalition Fund (NBCCF) appreciates this opportunity to comment on the proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. As a non-profit, advocacy organization dedicated to eradicating breast cancer, we empower and train individuals by equipping them with the tools to make informed decisions and to work beside legislative, scientific, and clinical decisionmakers.

While value-based purchasing has potential to improve the quality of care provided in hospitals, NBCCF recommends that the following be kept in mind for measure development and refinement:

' Measures used to assess health care provider performance should be nationally endorsed, consistently used, publicly reported, and meaningful to consumers.
' Measures should reflect a patient-centered, evidence-based vision of quality care addressing aspects of care such as access, information, choice, respect, accountability, and improvement.

In the public reporting of such quality data, NBCCF recommends that all information be accurate, timely, readily accessible, and disseminated in an appropriate format. There must be transparent standards of evidence that explain what level of evidence is acceptable and what happens in the absence of sufficient evidence. Providers and patients must be given time and resources to review evidence, and efforts to review and synthesize evidence must be expanded so Medicare s coverage policies reflects current scientific/medical knowledge. In addition, a national advocacy advisory panel should be established to work with advocates, health literacy specialists, economists, and the public health community to review evidence and help design effective methods for communicating health care information to consumers, providers, and insurers.

Please feel free to contact NBCCF staff member, Giselle Hicks, with any questions or concerns regarding these comments at (202) 973-0563 or ghicks@stopbreastcancer.org.

Sincerely,

Annette Bar-Cohen, MA, MPH
Director of Programs

CMS-1488-P-1778-Attach-1.DOC

#1778

NBCCF

NATIONAL BREAST CANCER COALITION FUND

grassroots advocacy in action

June 12, 2006

Secretary Michael Leavitt
Department of Health & Human Services
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P
PO Box 8011
Baltimore, MD 21244-1850

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

Dear Secretary Leavitt:

The National Breast Cancer Coalition Fund (NBCCF) appreciates this opportunity to comment on the proposed changes to the *Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.* As a non-profit, advocacy organization dedicated to eradicating breast cancer, we empower and train individuals by equipping them with the tools to make informed decisions and to work beside legislative, scientific, and clinical decisionmakers.

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Please feel free to contact NBCCF staff member, Giselle Hicks, with any questions or concerns regarding these comments at (202) 973-0563 or ghicks@stopbreastcancer.org.

Sincerely,

Annette Bar-Cohen, MA, MPH
Director of Programs

1101 17th Street, NW, Suite 1300, Washington, DC 20036 Phone: (202) 296-7477 Fax: (202) 265-6854 http://www.stopbreastcancer.org

Submitter : Mr. Scott Malaney **Date:** 06/12/2006

Organization : Blanchard Valley Health Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-1779-Attach-1.DOC

#1779

June 12, 2006

Mark McClellan, MD, PhD
Administrator
Center for Medicare and Medicaid Studies
Room 4456, Hubert Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal year 2007 Rates; Proposed Rule

Dear Dr. McClellan:

We appreciate the opportunity to respectfully submit our response to the CMS proposal stated above.

Overall the proposed change to a cost based DRG weighting Inpatient Prospective Payment System does not appear to produce a significant negative financial impact to Blanchard Valley Regional Health Center. The significant reductions in cardiology related DRG's would be primarily offset by psychoses DRG increase in the event we continue our IP psychiatry program. However, in order to effectively quantify the full financial impact analysis of this rule, we concur with the AHA and would request additional time for hospitals to review the Hospital Specific Relative Values cost center (HSRVcc) and more importantly the Consolidated Severity DRG (CS-DRG) methodologies. We have been unable to obtain the necessary guidance regarding the CS-DRG changes for accurate analysis.

In addition to our comments relating to the proposed IP DRG weight rule changes, we would like to take this opportunity to reiterate our continued opposition to the moratorium lift on specialized physician owned hospitals. Although the proposed weight changes do shift reimbursement away from facility surgical to medical DRGs, it will not dissuade physicians from pursing this alternative. We believe payment reductions are not enough to deter inappropriate physician incentives as these can be overcome by increasing utilization, avoidance of seeing low-income patients, and instead steering of financially attractive patients to their facilities.

Many physicians owned, limited services hospitals have withdrawn specialist services or limited on-call availability, negatively impacting the communities in which they practice. The result of allowing for physician owned hospitals will be to decrease hospital utilization to cover the fixed costs of facilities and technology and ultimately increase in

costs to the community employers. When our local employers are already struggling to stay competitive worldwide this will lead to more jobs leaving our communities for lower cost environments. The physician owners will prosper at the expense of the hospitals and the communities it serves. We are requesting that the suspension of new provider numbers to physician-owned, limited-service hospitals continue until the strategic plan developed has been fully implemented and Congress has an opportunity to consider the CMS final report.

We again appreciate the opportunity to provide comments to CMS regarding the proposed rule.

Respectfully submitted,

Scott Malaney
CEO of Blanchard Valley Health Association – Parent Company of Blanchard Valley Regional Health Center

Submitter : Mr. Timothy Walbert

Date: 06/12/2006

Organization : NeoPharm, Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1488-P-1780-Attach-1.DOC

#1760

June 12, 2006

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

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

Dear Administrator McClellan:

NeoPharm appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding the hospital inpatient prospective payment systems (PPS) for operating and capital-related costs and fiscal year 2007 rates, published in the Federal Register on April 25, 2006 (the Proposed Rule).[1] NeoPharm, Inc., based in Waukegan, Illinois, is a publicly traded biopharmaceutical company dedicated to the research, development and commercialization of new and innovative cancer drugs for therapeutic applications. Our lead compound, cintredekin besudotox, used to treat Glioblastoma Multiforme (GBM), the most aggressive form of brain cancer, has received fast track status by the FDA and likely will be on the market in federal fiscal year 2007.

In these comments NeoPharm is focusing on three main issues:

1. The need to have a method of incorporating new technology that represents increased complexity but is not necessarily related to the patient's severity of illness before the CSA-DRGs are implemented.
2. The need to revise the new technology add on formula to pay on a full cost basis, based on ASP+6% for drugs and biologics.
3. The appropriate DRG assignment for new ICD 9 CM procedure code 01.28.

We discuss each of these issues below.

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1 71 Fed. Reg. 23995 (April 25, 2006).

1. **A method of incorporating new technology that represents increased complexity but is not necessarily related to the patient's severity of illness must be developed before the CSA-DRGs are implemented. (DRGs Severity of Illness).**

NeoPharm recognizes the almost Herculean effort CMS staff has put forth to produce the FY07 IPPS proposed rule. Increasing payment accuracy must be a priority goal for the agency. The current DRG system, however, has been modified significantly over the last 23 years to better reflect the changes in care that Medicare patients require. These changes have included new DRGs for drug-coated stents and special DRGs for destination heart support therapy. NeoPharm is concerned that the proposed Consolidated Severity Adjusted-DRGs (CSA-DRGs) do not take into account the complexity involved in patient care (as measured by resource use) and are not structured to easily incorporate new technological advances.

NeoPharm agrees with CMS's own assessment that the consolidated severity adjusted diagnosis related group system (CSA-DRGs) "does not currently accommodate distinctions based on complexity."[2] We also agree with CMS' belief that "a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system."[3]

CMS stated that it plans "to develop criteria for determining when it is appropriate to recognize increased complexity in the structure of the DRG system and how these criteria interact with the existing statutory provisions for the new technology add on payments." CMS invited public comments on this particular issue.

NeoPharm agrees with CMS's intent to develop criteria for determining when it is important to recognize a new technology or service that increases case complexity. Any criteria developed by CMS should be transparent and predictable and the development of these criteria should follow a public notice and comment period to ensure that all stakeholders are involved.

NeoPharm also believes that the CSA-DRG system should not be adopted until a mechanism has been established to appropriately incorporate new technologies into

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2 71 Fed. Reg. 24014 (April 25, 2006

3 Ibid

the CSA-DRGs. Launching the CSA-DRGs as proposed would result in significant payment problems for many current and soon to be launched new technologies.

An analysis of cases run through the APR-DRG system as posted on the 3 M website[4] reveals that the new CSA-DRG system is going to be a step backwards in payment for many current technologies. For example, patients treated with Proleukin, who currently are grouped to DRG 492 (payment of $16,925 in 2006) would be placed in CSA-DRG 736 (payment $5,187) or CSA-DRG 737 (payment $13,529). Similarly, Gliadel wafer patients without complications and comorbidities are currently grouped to DRG 543 (current payment of $20,815) but payment would fall to $12,367 (CSA-DRG 21) under the new system.

As a developer of a soon to be launched new technology, we are very concerned that the new CSA-DRG system will be implemented without a clear mechanism for taking into account how to appropriately incorporate cases involving new technology. The result will be a lack of Medicare patient access to potentially life saving therapies as hospitals will not be able to afford losing money on every Medicare case they treat.

2. CMS Should Pay for New Technology Add On Products on a Cost Basis, which would be ASP +6% for drugs and biologics (New Technology)

In the spirit of further improving payment accuracy, NeoPharm urges CMS to revise the new technology add on formula to better reflect provider costs. The current payment formula chosen by CMS does not adequately reimburse providers for use of the new service or technology that has been granted new technology add on status.

Currently, once a new service or technology has been granted new technology add on status, "Medicare pays a marginal cost factor of 50 percent for the costs of a new medical service or technology in excess of the full DRG payment. If the actual costs of a new medical service or technology case exceed the DRG payment by more than the 50-percent marginal cost factor of the new medical service or

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4 http://www.aprdrgassign.com/

technology, Medicare payment is limited to the DRG payment plus 50 percent of the estimated costs of the new technology."5

This approach does not adequately compensate the hospitals for the new service, as in most cases they receive only half of the cost of the new technology. Given that so few technologies have met the new technology add on standard set by CMS, it would make more sense for CMS to fully compensate hospitals for those few technologies that do meet the new technology add on standards. This could be accomplished by paying on a cost basis, which could be ASP+6% for FDA approved drugs and biologicals and list price plus a percentage for devices. The use of ASP +6% for drugs and biologicals or list price plus a percentage for devices as the payment formula would ensure that providers recoup their costs, Medicare pays a fair rate, and that payment is harmonized across treatment settings.

3. DRG assignment of new ICD 9 Procedure Code 01.28: Placement of Intracerebral catheter(s) via burr hole(s).

Following the March 2006 meeting of the ICD 9 Coding and Maintenance Committee meeting, a new code was created6 called:

> 01.28 Placement of intracerebral catheter(s) via burr hole(s)
> Convection enhanced delivery
> Stereotactic placement of intracerebral catheter(s)

This procedure involves the placement of multiple catheter(s) into the brains of patients with aggressive and often fatal brain tumors. The placement of the catheter can only occur in a neurosurgical operating room making this procedure an operating room/surgical procedure. This new code should be grouped to a surgical DRG within MDC 1.

The new procedure and the drugs infused through these intracerebral catheters are highly resource intensive, complex, and unlike anything ever used before. Ideally, these cases would be grouped to their own DRG. But if these cases must initially be placed into the current DRG structure, the following DRG assignment could be considered.

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5 70 Fed. Reg. 47342 (August 12,2005)

6 http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/Downloads/icd9addendafy07.pdf

- Under the current DRG system, DRG 543, Craniotomy W/Implant Of Chemo Agent Or Acute Complex CNS Pdx would appear to be the best fit.
- Under the CSA-DRG system, the best fit would be CSA-DRG 20, Nervous System Procedures SOI4.

NeoPharm appreciates this opportunity to comment on the FY07 IPPS Proposed Rule. NeoPharm urges CMS to delay implementation of the significant changes it has proposed in this rule until CMS can identify and seek public comment upon an appropriate method of incorporating new technologies resulting in increased complexity (as measured by resource use) in any version of the CSA-DRGs. Please feel free to contact me at (847) 406-1710 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Timothy P. Walbert
Executive Vice President, Commercial Operations
NeoPharm, Inc

Submitter : Dr. Andrew Dahlgren **Date:** 06/12/2006

Organization : W.A.Foote Health System

Category : Physician

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, 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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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,

Andrew B. Dahlgren
abdahlgren@yahoo.com

Submitter : Ms. Debbie Lombardi

Date: 06/12/2006

Organization : Florida Hospital Neuroscience Institute

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#1782

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. R. Keith **Date:** 06/12/2006

Organization : Via Christi

Category : Physician

Issue Areas/Comments

GME Payments

GME Payments

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, 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, Rex Keith

Assoc. Dir. Family Medicine Via Christi

Submitter : Dr. Peter Watson **Date:** 06/12/2006

Organization : Henry Ford Hospital, Detroit

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

The Proposed Rule purports to clarify medical resident time spent in didactic activities for purposes of calculating Medicare direct medical education (DGME) and indirect medical education (IME) payments. The stated rationale for the exclusion of time devoted to these activities is that they are not related to patient care. 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.

I would urge CMS to rescind this clarification, which is a reversal of agency policy. As recently as 1999, CMS 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 CMS 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs, and serve to improve care of individual patients. Disallowing time spent on these activities is at odds with your personal goal of improving the quality of care delivered in this country.

In addition, I am concerned that the exclusion of didactic activities is particularly stringent in non-hospital training programs which cannot be counted in the calculation of either the DGME and IME calculations. This approach would penalize hospital-based residency programs for providing their students with non-hospital training experiences, exacerbating other recent CMS policy changes that disadvantage training programs conducted outside the hospital. As you know, medical care increasingly is delivered outside the hospital and many of the quality measures CMS is proposing focus on this setting. To discourage hospitals from offering training in these settings is short-sighted to say the least.

I urge CMS to withdraw 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. I recommend that you review and revise CMS policies that discourage training programs in non-hospital settings where supervising physicians volunteer their services or provide this service at a nominal cost.

As a teaching physician responsible for the education of over 13o residents, I know the importnace of sound resident education. Compromising the integrity of that education with these proposed rules would put numerous teaching programs and patients at risk. Medical education must be protected for the safety of our patients. I appreciate your consideration.

Peter Y. Watson, MD
Associate Residency Program Director
Internal Medicine
Henry Ford Hospital
Detroit, Michigan
pwatson1@hfhs.org

Submitter : **Dr. Jerrold White** **Date: 06/12/2006**

Organization : **Mercy Medical Cente-North Iowa**

Category : **Individual**

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, 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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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,

Jerrold White, M.D.

Submitter : Mrs. Jennifer Milton

Date: 06/12/2006

Organization : CHRISTUS Transplant Institute

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-1786-Attach-1.PDF

#1786

CHRISTUS
Transplant Institute

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1488-P and P2, Medicare Program; Proposed changes to the hospital inpatient Prospective Payment System and fiscal year 2007 rates: Proposed Rule.

Dear Dr. McClellan:

On behalf of CHRISTUS Transplant Institute (CTI), we appreciate the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the fiscal year (FY) 2007 inpatient prospective payment system (PPS.) This proposed rule would direct the most wide spread change in the calculation of diagnosis-related group (DRG) relative weights since 1983.

While we support CMS in its efforts to best utilize limited health care resources through the proposed revisions, we are particularly concerned about the impact on transplant centers , their patients and the communities we serve. More time is needed to understand the proposed changes and the uncertainty of the impact on transplantation in the United States. Adequate analysis and evaluation of new methods of classification and weight determination are needed.

Specifically CTI supports the following:

* Accurate weights be distributed to the transplant community prior to the publication as a final rule allowing adequate time for analysis: In a June 6th teleconference, CMS Deputy Director Marc Harstein agreed the weights for transplantation were incorrect. Examples provided to Mr. Harstein demonstrated discrepancies of published weight for renal transplant of 5.5466 with a corrected weight of 3.0102. Published for liver of 11.7482649 and corrected of 8.9649. CTI fears the transplant community will see the corrected weights only as final rule.

* A new classification system only be developed if need can be demonstrated in conjunction with the transplant community. Transplantation serves a patient population in end stage organ failure. Severity within this unique sub population of patients must be studied in depth prior to categorizing these patients into a one-size-fits-all classification

system. Complex severity classification systems have already been developed, tested and evaluated for each of the different organ transplant populations and it is uncertain if these employed systems will be utilized to classify transplant patients in the proposed system.

* Rising costs of increasing the organ donor pool should be addressed if a new classification system is to be an accurate tool for reimbursement: Transplant Centers have increased the utilization of donated organs from Expanded Criteria Donors (ECD) and Deceased Cardiac Donors (DCD.) Collaborative efforts between HRSA and the transplant community seek to continue to increase this pool of donated organs. Any transplant DRG severity classification must also consider the type of donated organ being utilized. A DCD or ECD organ has a higher incidence of delayed organ function, leading to increased length of stay and increased procedures. Thus, two organ transplant recipients with an identical CS-DRG will have a predictably different recovery (thus costs) if one received an ECD organ. This is what makes transplantation extremely unique in the field of medicine and should be addressed.

* Define specific hospital quality data that will be mandated: It is premature to note in a final rule that hospital quality data will be required without defining what this data will be and without input from the transplant community to avoid unnecessary and costly duplication of data collection and reporting. Transplant centers have been mandated to submit patient outcome data as well as organ utilization data to the Organ Procurement Transplant Network (OPTN) since the 1980's. This data is available to CMS and now transplant patients and the public at large.

* One-Year delay: CTI supports a one-year delay in implementation of a final rule. This would provide time to test proposed changes, conduct pilot studies and incorporate the input of the larger transplant community into changes in the severity system, define data requirements, address donor quality costs and determine accuracy of proposed weights.

CTI is grateful for the opportunity to submit our comments. Please feel free to contact us for any questions you may have on our comments at 210-705-6700.

Sincerely,

Pariac J. Mulgrew, M.D.
Medical Director
CHRISTUS Transplant Institute

Jennifer Milton, BSN, CCTC, MBA
Administrative Director CHRISTUS Transplant Institute

Submitter : **Mr. Thomas Bell** **Date: 06/12/2006**

Organization : **Kansas Hospital Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-1787-Attach-1.DOC

CMS-1488-P-1787-Attach-2.DOC

1787

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of the Kansas Hospital Association and its 126 member hospitals, I appreciate the opportunity to comment on the proposed changes to the Inpatient Prospective Payment System (IP PPS) and occupational mix adjustment rules effective for federal fiscal year 2007.

KHA commends CMS for attempting to bring equity to PPS resulting from the proliferation of specialty hospitals in states like Kansas. However, the redistributional effects of the proposed changes fall far short of their intended purpose. Our modeling of the financial impact of the proposed changes to Kansas PPS hospitals revealed startling results and was contrary to the CMS assumed impact on predominantly rural states like Kansas. In aggregate the impact of changes to the wage index, DRG weighting and other minor financial adjustments will result in Kansas PPS hospitals losing over $8 million in needed Medicare reimbursement. Over 40 percent of the Kansas PPS hospitals will experience a negative impact should the proposed rules be implemented. And while the balance of the PPS hospitals in the state gain to some degree or another it is not enough to offset the losses in total and only serves to exacerbate a flawed payment system.

Therefore, KHA endorses the recommendations offered to CMS from the American Hospital Association for changes to the IP PPS. Specifically, KHA endorses the following AHA recommendations:

- **One-year Delay:** The AHA supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology. The AHA and the hospital field are committed to working with CMS over the next year to address these concerns.

- **Valid Cost-based Weights:** We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed.

- **A New Classification System Only if the Need Can Be Demonstrated:** The AHA does not support a new classification system at this time, as the need for a new system is still unclear. Much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.

- **Simultaneous Adoption of Any Changes to Weights and Classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.

- **Three-year Transition:** Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.

- **Collaborative Approach to Moving Forward**: The AHA commits to working with CMS to develop and evaluate alternatives for new weights and classifications.

Critical Access Hospitals (CAH)

On November 14, 2005, CMS issued interpretive guidelines on the relocation of CAHs as a follow-up to the FY 2006 IP PPS final rule that established the "75% test" – serving 75 percent of the same population, providing 75 percent of the same services and employing 75 percent of the same staff – for necessary provider CAHs. The guidelines appear to go well beyond the regulations included in the FY 2006 rule.

We believe the guidelines created by CMS are overly prescriptive and do not provide reasonable flexibility based on natural variation in demographics, patient needs distribution patterns, normal employee and board attrition, and necessary changes in services to meet community needs. **Rural hospitals that move a few miles are clearly the same providers serving the same communities.**

Many CAHs are planning to rebuild in the near future to improve site safety and quality of care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, modernizing telecommunications to support health information technology, or making other essential upgrades. Facilities expect to relocate when they rebuild for a

multitude of reasons: to be closer to a highway, to connect to municipal water and sewer, because of seismic safety concerns, or other similar concerns. **Such improvements will undoubtedly result in higher quality care, better patient outcomes and more efficient service, yet CMS' guidelines discourage these improvements.**

CMS' guidelines will not only impose an unnecessary burden on CAHs, but will preclude many of them from securing financing for needed capital improvements. The hospitals themselves, their hospital districts and their lenders cannot risk investing in a hospital that will be unsure of its status until a year after moving. **CMS should create a preliminary approval process to give assurances to those involved in the project that the CAH relocation will be approved if it meets the assertions made in the attestation submitted to CMS.**

Again this year, almost 60 congressional representatives signed a letter to CMS showing their support for their CAHs and urging changes to these guidelines. We agree with their recommendations and reiterate our suggestion from last year that a safe harbor be established for hospitals relocating within five miles of their existing locations. These providers are not only clearly serving the same communities, but trying to improve the quality of and access to needed health care services. A safe harbor will reduce the administrative burden on not only the hospitals, but CMS and the state survey agencies as well. **We urge CMS to create a safe harbor for CAHs moving a short distance and to make provide reasonable flexibility in the interpretation of the "75% criteria".**

While the Kansas Hospital Association supports many of the proposed rule's provisions, we have serious concerns when the redistribution of reimbursement between hospitals is this dramatic and stands to be even more so if the new patient classification system being proposed is implemented. If you have any questions about our remarks, please feel free to contact me or Fred Lucky, Senior Vice President, at 785-233-7436 or flucky@kha-net.org.

Sincerely,

Thomas L. Bell
President and CEO

1787

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

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Therefore, KHA endorses the recommendations offered to CMS from the American Hospital Association for changes to the IP PPS. Specifically, KHA endorses the following AHA recommendations:

- **One-year Delay:** The AHA supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology. The AHA and the hospital field are committed to working with CMS over the next year to address these concerns.

- **Valid Cost-based Weights:** We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed.

- **A New Classification System Only if the Need Can Be Demonstrated:** The AHA does not support a new classification system at this time, as the need for a new system is still unclear. Much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.

- **Simultaneous Adoption of Any Changes to Weights and Classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.

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multitude of reasons: to be closer to a highway, to connect to municipal water and sewer, because of seismic safety concerns, or other similar concerns. **Such improvements will undoubtedly result in higher quality care, better patient outcomes and more efficient service, yet CMS' guidelines discourage these improvements.**

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While the Kansas Hospital Association supports many of the proposed rule's provisions, we have serious concerns when the redistribution of reimbursement between hospitals is this dramatic and stands to be even more so if the new patient classification system being proposed is implemented. If you have any questions about our remarks, please feel free to contact me or Fred Lucky, Senior Vice President, at 785-233-7436 or flucky@kha-net.org.

Sincerely,

Thomas L. Bell
President and CEO

Submitter : **Ms. Debbie Lombardi** **Date: 06/12/2006**

Organization : **Florida Hospital Neuroscience Institute**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-1788-Attach-1.DOC

#1788

June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1488-P-Changes to the Hospital Inpatient Prospective Payment Systems and FY 2007 Rates

Dear Dr. McClellan:

The Neuroscience Institute (NSI) at Florida Hospital (FH) is pleased to comment on the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. Florida Hospital is a seven campus, 1,797 bed system with over 40,000 Medicare discharges in 2005. Our NSI physicians treat approximately 2,400 stroke and TIA patients and perform more than 2,200 neurosurgeries per year. The NSI is certified by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) as a Primary Stroke Center.

The following comments are submitted on behalf of the NSI:

I. HSRV Weights

A. MDC 1 (Diseases and Disorders of the Nervous System)

1. Strokes

Florida Hospital believes that the proposed cost-based weighting methodology does not adequately address the unique costs encountered by facilities that are organized as primary or comprehensive stroke centers and additionally, are JCAHO certified. More specifically, neither new technology nor regulatory factors have been factored into the DRGs.

Florida has been a pacesetter in the development of stroke centers, with a 2004 Stroke Law to establish stroke systems of care with a strong focus on rapid identification and treatment of stroke victims. As of July 1, 2006, Florida law will require emergency medical services (EMS) to transport stroke patients to facilities certified as Primary or Comprehensive Stroke Centers if certain parameters are met. This rapid response system facilitates early identification of patients potentially eligible for advanced acute stroke interventions including those involving new technology.

Facilities make significant investments in additional resources and processes to operate as stroke centers and encounter additional costs (i.e., specialty staff competencies, extensive training/continuing education, and technology adoption). In addition, they would be the first to adopt new FDA approved technology (e.g., NovoSeven® for Intracerebral Hemorrhage) and incur the costs. The long term implications of expeditiously treating stroke victims are improved clinical outcomes and decreased costs to the Medicare program.

Legislative changes, such as those to be implemented in Florida, will increase the number of patients transported to the designated centers, resulting in treatment of more Medicare patients and more associated cost expenditures. It is our concern that CMS' deferment of addressing new technology in the cost-based weighting methodology and the lack of appropriate compensation disproportionately affects these institutions, particularly in larger communities.

It is our recommendation that CMS postpone implementation of new weighting methodologies and do not implement consolidated severity-adjusted DRGs until new technology is incorporated into reimbursement and a method is determined to sufficiently reimburse stroke centers for the advanced services provided.

B. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue.

1. Spinal Surgeries

The Florida Hospital Neuroscience and Orthopaedic Institutes perform over 1,300 spinal surgeries annually. The proposed HSRV weight recalibration methodology will result in an annual reimbursement decrease of 4.9 percent to the spine service line. The unexpected weight recalibrations for FY 2007 followed by a severity adjustment in 2008 will create severe operational challenges. For example, time is needed for existing vendor contracts to sunset and new contracts to be negotiated. In addition, a reassessment of planned capital equipment and technology purchases would need to be reviewed. A 60-day implementation period does not allow adequate time to address these types of operational issues.

In summary, The American Hospital Association (AHA) has highlighted numerous flaws in CMS' proposed methodology for calculating payment weights. Florida Hospital supports CMS' move towards restructuring the current DRG system. However, we are concerned that rapid introduction of the changes, prior to modifying the methodology to address issues raised by the AHA and in the absence of a reasonable adjustment period would cause undue strains on our neuroscience and spine programs.

We are proposing that CMS delay the implementation of changes to the DRG weighting methodology and that consolidated severity-adjusted DRGs are not implemented for at least one year. We are committed to providing quality care to all of our patients. Rapid introduction of changes of this magnitude is not the best option for Medicare beneficiaries.

We hope CMS will strongly consider our recommendations.

Respectfully Submitted,

Debbie Lombardi
Assistant Vice President
Florida Hospital Neuroscience Institute

Submitter : Dr. Kirby Clark **Date:** 06/12/2006

Organization : University of MN Dept of Family Medicine

Category : Individual

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' 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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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,
Kirby Clark, MD

Submitter : **Mr. Rick Barnett** **Date: 06/12/2006**

Organization : **Mercy Medical Center Redding**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

June 12, 2006

Mark B. McClellan, M.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: CMS- 1488-P Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Payment Rates; Proposed Rule (71 Federal Register 23996), April 25, 2006.

Dear Administrator McClellan:

Mercy Medical Center Redding (MMCR) respectfully submits comments regarding the proposed changes to the inpatient prospective payment system (IPPS). In addition to these comments, MMCR supports the comments and recommendations of the American Hospital Association (AHA).

" One-year Delay: MMCR supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology. AHA and the hospital field are committed to working with CMS over the next year to address these concerns.
" Valid Cost-based Weights: MMCR supports moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS proposed HSRVcc method is flawed.
" A New Classification System Only if the Need Can Be Demonstrated: MMCR does not support a new classification system at this time, as the need for a new system is still unclear. Significant work is still needed to understand the variation within DRGs and the best classification system to address that variation before CS-DRGs or any other system is selected or advanced.
" Simultaneous Adoption of Any Changes to Weights and Classifications: If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.
" Three-year Transition: Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.
" Collaborative Approach to Moving Forward: MMCR, in coordination with AHA, commits to working with CMS to develop and evaluate alternatives for new weights and classifications.
Thank you for the opportunity to provide comments on the proposed rule. If you have any questions, please contact me at 530-225-6107.

Sincerely,

Rick Barnett
President

Submitter : Mr. Steven Hand **Date:** 06/12/2006

Organization : Memorial Hermann Hospital System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1488-P-1791-Attach-1.DOC

#1791

MEMORIAL HERMANN

VIA Electronic Submission
www.cms.hhs.gov/eRulemaking

June 12, 2006

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

Attention: CMS-1488-P

Dear Dr. McClellan:

Memorial Hermann Hospital System (MHHS) submits these comments on the proposed rule entitled *"**Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.**"* published per Federal Register Vol. 71, No. 79 Tuesday, April 25, 2006, 23996 et seq. This rulemaking seeks to make significant changes to Medicare DRG Weighting and Classification system from the current Charge-Based weighting to a "Cost-Based" in FY 2007 and to a "Severity Refined" weighting system no later than FY 2008. MHHS is the largest not-for-profit community based health system operating in Houston Texas. It serves a significant percentage of Medicare patients residing in the Greater Houston area (currently over 35,000 discharges annually). The changes being proposed will not only affect traditional Medicare but will impact Managed Medicare, both traditional and Managed Medicaid as well as commercial payors that reimburse based on Medicare groupings and/or weights.

Hospital Specific Relative Value Cost Center (HSRVcc) Weighting Methodology

We have reviewed the finding and agree that the current system has become distorted and changes need to be made. However we believe that the changes proposed are so drastic that there will be unforeseen consequence for many providers. We have modeled the proposed HSRVcc DRG weighting, and found it to lower our overall Medicare Case weight (-1%). This system of converting charges to cost need to be further tested and the issue of including non-acute providers as well as only including those within (1.96

standard deviation) from the mean needs to be further explored. Our recommendation is to delay this change and move forward in FY 2008.

Consolidated Severity Adjusted DRGs (CS-DRGs)

We have reviewed this methodology based on the 3M APR-DRGs and agree that this will be a better system than the current 526 DRG system used today. However we believe that this change will take many providers by complete surprise. Many are not accustom to coding the additional item required to use the 3M product. We have modeled the CS-DRG using cost based weights and found it to increase our overall Medicare Case weight (7%). Our recommendation is to delay this change and implement in FY 2008.

Outlier Payment Threshold

We believe the FFY 2007 cost threshold must be reduced. CMS relies only on charge inflation to determine projected increases in per case costs, which determines outlier payment outlays. The American Hospital Association (AHA), and Federation of American Hospitals, conducted an analysis that incorporates both cost and charge inflation, which makes the threshold calculation more accurate and reliable. Using this methodology, the threshold should be $24,000 for FFY 2007. We urge you to review your calculations and give serious consideration to this methodology. This is described in more detail per the AHA's comment letter.

Conclusion

We believe the current system should be rolled forward for FY 2007 so that time can be allotted to test and review prior to a careful implementation of the new CS-DRG system. Since the goal of the new system is to be revenue neutral, Department of Health and Human Services loses nothing by postponing the requested additional 12-months. In addition we are concerned with how the Occupational Mix surveys will be rolled out now that the impact has moved from 10% to 100% for FY 2007. This change alone will need to be digested before we move to the proposed changes in this publication.

If you have any questions concerning these comments, please contact Steven W. Hand at steven.hand@memorialhermann.org, or 713-448-4191.

Sincerely,

Steven W. Hand, M.P.A., C.P.A., FHFMA
AVP of Government Reporting-Operations

Submitter : **Dr. jamie feldman** **Date: 06/12/2006**

Organization : **Dr. jamie feldman**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, 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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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,
Jamie Feldman, MD, PhD

Submitter : Dr. Dan Polonia

Date: 06/12/2006

Organization : Dr. Dan Polonia

Category : Physician

Issue Areas/Comments

GME Payments

GME Payments

To Whom it May Concern,
I am a family physician and would like to comment on the proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, 71 Fed.Reg 23996. I strongly urge CMS to recind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in diddactic 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 and indirect medical education payements. I truely believe that there is no residentcy experience that is not related to paitent care activities.

Again I urge CMS to rescind its clarification in the proposed rule as described above. There can be nothing more important than the proper training of well rounded family physicians to continue the vital role of taking care of our citizens.

Most Sincerely,
Dan Polonia, M.D.

Submitter : **Dr. angelika buddeberg** **Date: 06/12/2006**

Organization : **santa monica bay physicians**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

As a family physician, 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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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,

Angelika Buddeberg

Submitter :

Date: 06/12/2006

Organization :

Category : **State Government**

Issue Areas/Comments

CBSAs

CBSAs

I am commenting on the proposed changes to the hospital inpatient prospective payment systems and fiscal year 2007 rates as posted on the Federal Register on April 25, 2006 in order to address an emerging problem in our health care industry the recruitment and retention of health care professionals.

Labor-Related Share

Labor-Related Share

I am commenting on the proposed changes to the hospital inpatient prospective payment systems and fiscal year 2007 rates as posted on the Federal Register on April 25, 2006 in order to address an emerging problem in our health care industry the recruitment and retention of health care professionals.

CMS-1488-P-1795-Attach-1.PDF

CMS-1488-P-1795-Attach-2.PDF

ATTACHMENT #1 TO 1795

KATHLEEN BABINEAUX BLANCO
GOVERNOR

State of Louisiana
OFFICE OF THE GOVERNOR
Baton Rouge
70804-9004

POST OFFICE BOX 94004
(225) 342-7015

June 12, 2006

Honorable Mark McClellan
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Dear Dr. McClellan:

I am commenting on the proposed changes to the hospital inpatient prospective payment systems and fiscal year 2007 rates as posted on the Federal Register on April 25, 2006 in order to address an emerging problem in our health care industry – the recruitment and retention of health care professionals.

The aftermath of Hurricanes Katrina and Rita has put unprecedented pressure on our health care system. In our efforts to meet the challenge of restoring health care to the impacted region, our providers are struggling to attract qualified health care professionals.

Because of severe labor shortages and competition with other industries, the wages that nursing homes, hospitals and others are required to pay have increased greatly. For example, the Louisiana Nursing Home Association reports that the average starting wage for a certified nurse aide in New Orleans has risen more than 50%. In addition to the increased wages, fewer beds are operating in the region and our citizens across the health care spectrum are impacted. We have families who are trying to return to their homes and are having a difficult time finding services for their loved ones.

One way to address workforce recruitment and retention is through the delayed wage adjustment. Specifically, I am requesting that you consider utilizing the larger of 2006 or 2007 Core Based Statistical Areas (CBSAs) wage index and increase this factor by adding 0.1000 for the areas impacted by the storm for the federal fiscal year 2007 and 2008. I suggest that the impacted areas are the counties/parishes eligible for "Individual Assistance" by the 2005 FEMA-1603, FEMA-1604, FEMA-1605 and FEMA-1606. I also ask that this enhanced wage adjustment be extended for a period of two additional years if it is determined that stability has not yet returned to the health care work force.

Since this request is only intended to help the hurricane-impacted states in our recovery, I ask that this adjustment to the wage factor not reduce the Medicare Skilled Nursing Facility Program Prospective Payment System (SNF PPS) rates in the non-impacted states.

Unless this consideration is given, this adjustment could have a negative effect on the wage index for the non-impacted CBSAs. My request is not intended to draw SNF funding away from the non-impacted areas.

Let me thank you and Secretary Leavitt for your personal concern and involvement in Louisiana's rebuilding effort. The long term recovery of our region will depend upon the continued cooperation between our respective agencies. This request will not only help our providers resume critical health care services, it will provide our citizens with the health care services they need.

Sincerely,

Kathleen Babineaux Blanco

Kathleen Babineaux Blanco
Governor

ATTACHMENT #2 TO 1795

KATHLEEN BABINEAUX BLANCO
GOVERNOR

State of Louisiana
OFFICE OF THE GOVERNOR
Baton Rouge
70804-9004

POST OFFICE BOX 94004
(225) 342-7015

June 12, 2006

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Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

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Let me thank you and Secretary Leavitt for your personal concern and involvement in Louisiana's rebuilding effort. The long term recovery of our region will depend upon the continued cooperation between our respective agencies. This request will not only help our providers resume critical health care services, it will provide our citizens with the health care services they need.

Sincerely,

Kathleen Babineaux Blanco

Kathleen Babineaux Blanco
Governor

Submitter : Mr. Timothy Charles

Date: 06/12/2006

Organization : Mercy Medical Center

Category : Hospital

Issue Areas/Comments

Capital PPS

Capital PPS

On behalf of Mercy Medical Center, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2007 inpatient prospective payment system (PPS) and occupational mix adjustment proposed rules.

The rule proposes the most significant changes in the calculation of diagnosis-related group (DRG) relative weights since 1983 by creating a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc). It also proposes refining the DRGs to account for patient severity, with implementation likely in FY 2008. In addition, the rule would update the payment rates, outlier threshold, hospital wage index, quality reporting requirements, and payments for rural hospitals and medical education, among other policies.

While Mercy Medical Center supports many of the proposed rule s provisions, we have serious concerns about the proposed changes to the DRG weights and classifications.

The hospital field supports meaningful improvements to Medicare s inpatient PPS. We believe Mercy Medical Center and CMS share a common goal in refining the system to create an equal opportunity for return across DRGs, which will provide an equal incentive to treat all types of patients and conditions. However, more time is needed to understand the significant proposed policy changes, which redistribute from $1.4 to $1.7 billion within the inpatient system. Analysis shows the impact of the proposed changes to be highly unstable, with small changes in method leading to large changes in hospital payment. And the validity of CMS proposals versus potential alternatives to improve the DRG weights and classification system is uncertain. Moving forward requires thoughtful change.

Specifically, Mercy Medical Center supports the following:

"One-year Delay: Mercy Medical Center supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology. Mercy Medical Center and the hospital field are committed to working with CMS over the next year to address these concerns.
"Valid Cost-based Weights: We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS proposed HSRVcc method is flawed.
"A New Classification System only if the Need Can Be Demonstrated: Mercy Medical Center does not support a new classification system at this time, as the need for a new system is still unclear. Much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.
" Simultaneous Adoption of Any Changes to Weights and Classifications: If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.
" Three-year Transition: Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.
" Collaborative Approach to Moving Forward: Mercy Medical Center commits to working with CMS to develop and evaluate alternatives for new weights and classifications.

Mercy Medical Center appreciates the opportunity to submit these comments. If you have any questions about our remarks, please feel free to contact me at 319-398-6133.

Sincerely,

Timothy L. Charles
President & CEO

Submitter : Dr. Julia Blank

Date: 06/12/2006

Organization : Santa Monica Bay Physicians

Category : Physician

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, 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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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,

Julia Blank, MD

Submitter : Dr. Michael Baxter

Date: 06/12/2006

Organization : The Reading Hospital and Medical Center

Category : Individual

Issue Areas/Comments

GME Payments

GME Payments

I want to add my comments to those who support high quality patient care through support for graduate medical education.
To separate the two is illogical and impractical. The proposed rule change to exclude resident didactic education from DGME and IME payments will undermine the quality of our graduate medical education programs and therefore the quality of health care in our nation. In addition, since residency training programs provide the bulk of indigent patient care in many of our communities, changes that negatively impact those programs will most certainly further widen the health care gap that already exists in our society due to racial, economic and geographic disparaties. I therefore urge CMS to rescind its proposed rule change relating to the counting of didactic time for purposes of DGME and IME payments.

Submitter : Mr. Santiago Munoz
Organization : University of California
Category : Hospital
Date: 06/12/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1488-P-1799-Attach-1.PDF

CMS-1488-P-1799-Attach-2.PDF

ATTACHMENT #1 TO 1799

UNIVERSITY OF CALIFORNIA

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June 12, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Ave, SW
Washington, DC 20201

SUBJECT: **CMS-1488-P** – Proposed Medicare Hospital Inpatient Prospective Payment System Rates for Fiscal Year 2007

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Medicare Inpatient Prospective Payment System (IPPS) proposed rule for Fiscal Year (FY) 2007 issued by the Centers for Medicare & Medicaid Services (CMS). These comments are submitted on behalf of the University of California (UC) Health System and its academic medical centers (AMCs) located in Davis, Los Angeles, Irvine, San Diego, and San Francisco.

The UC Health System is California's fifth largest hospital system. It is comprised of five AMCs which share a mission of educating health professionals, conducting research, and providing high quality patient care. Annually, the medical centers provide patient care services valued at over $3.8 billion. Eight acute care hospitals in the UC Health System house 3,217 licensed acute care beds and provide a broad array of specialized services that are often not available elsewhere. UC medical center services are essential to the health and well being of Medicare beneficiaries; they include cancer centers, trauma and burn centers, geriatric and orthopedic centers of excellence, and world class primary and preventive care.

The University is extremely concerned with the decline of its Medicare payments given our role in serving extremely high-cost Medicare beneficiaries. In fiscal year 2005, the

UC Medical Centers incurred aggregate Medicare IPPS losses in excess of $30 million. UC continues to urge Congress to provide adequate Medicare payments to its hospitals and urges CMS to ensure the Congressional intent of hospital payment updates are fully implemented on a programmatic level. Further, while UC's comments address the most significant areas of concern for its AMCs, it is generally concerned with the decline in Medicare rates and urges CMS to amend the proposed rule to prevent further reductions.

Concern about adequate Medicare payments extends to the UC Health System's work to educate physicians as well. Medicare's graduate medical education payments contribute to UC's offering of more than 300 residency programs and training for nearly half of California's interns and residents. UC academic medical centers sponsor more than 300 residency training programs in all recognized specialties and subspecialties of medicine and surgery — over 3,900 resident physicians participate annually in these programs.

- **General Comments on Proposed Rule**

The UC medical centers are supportive of efforts to improve Medicare's IPPS, including refinements to the current DRGs and ensuring that DRG relative weights better reflect hospital costs. However, given the significance and complexity of the proposed changes, we believe that a one-year postponement is necessary to allow for further analyses to address data and computation issues. Further, because changes in the relative weights will likely result in the redistribution of over a billion dollars in Medicare payments among hospitals, a significant transition period should accompany the changes. This letter will raise various data and computation issues related to changes in the DRGs and the development of new relative weights. A postponement and a phase-in of these items will help ensure that the issues are addressed and the best possible methodology ultimately is implemented.

Our letter will also comment on other important issues raised in the proposed rule, including: the outlier threshold, reporting hospital quality data, "resident time in patient activities," and the reporting of pension-related expenses.

- **DRGs and DRG Relative Weights**

In response to recommendations from the Medicare Payment Advisory Commission (MedPAC), CMS has proposed the most significant changes since the inception of the IPPS, including:

1. Refining the current DRGs to more fully capture differences in severity of illness among patients;
2. Basing the DRG relative weights on the estimated costs of providing care rather than on charges; and
3. Basing the weights on the national average of hospitals' relative values in each DRG.

While UC supports the concept of improving the DRG system, a change of this significance cannot be entered into without careful analysis and consideration. While simple in concept, developing "cost based" weights to the DRG is enormously complex. For example, the method developed by MedPAC to measure the relative DRG costs is significantly different than the HSRVcc methodology that CMS is advancing. In addition, there are modifications to both of these methodologies that should also be considered.

The UC recognizes and appreciates the CMS's effort to better account for patient severity in the IPPS. A fundamental tenet of a successful IPPS is ensuring that the DRG classification system reflects those cases that involve the sickest and most complex Medicare patients. This is especially significant for the UC given our role as major teaching sites. We have concerns, however, about the proposed CS-DRGs, in part because they reflect patient severity only and do not recognize service complexity. CMS has expressed an interest in determining when it is appropriate to recognize increased complexity in the structure of the DRG system and assessing how these criteria interact with the existing statutory provisions for new technology add-on payments. The UC believes that CMS should specifically determine these criteria to fully ascertain the impact of the new classification system and the IPPS.

Given the magnitude and the possible variability of the proposed changes to the DRG system, UC believes that the implementation of any such changes should not occur on October 1, 2006, but rather should be postponed for one year. Further, UC believes that a significant transition period must accompany any final changes.

- **Outlier Threshold**

In the rule, CMS proposes establishing a fixed-loss cost outlier threshold. This threshold would equal the DRG prospective payment rate, plus any add-on payments for new technology, disproportionate-share hospital (DSH) payments, and any indirect medical education (IME) payments, plus and additional $25,530 for FY 2007. The current additional amount is $23,600. UC is concerned that the increase in the threshold is unwarranted.

The University supports the analysis conducted by the American Hospital Association that the use of more than one indicator will make the threshold calculation more accurate and reliable. Further, UC respectfully urges CMS to implement no change that would inappropriately increase the cost outlier threshold and effectively result in payment reductions to hospitals.

- **Quality Reporting**

The Deficit Reduction Act of 2005 (DRA) expands quality-reporting requirements for hospitals to receive a full market basket update. To be eligible for a full market basket update in FY 2007, CMS proposes using hospital data submissions for the first three calendar quarters of 2005 for the existing 10 quality measures. CMS also proposes

requiring hospitals to submit the full set of 21 quality measures for services retroactively, beginning in *CY 2006* to remain eligible. UC is concerned with the retroactive nature of this proposal. Hospitals would be required to reopen files from which data have already been abstracted, execute new agreements with vendors in order to collect and process the required information, and resubmit information to the clinical data warehouse. Such retroactive alterations in the data files are difficult and costly, and open the door to errors in the data.

The DRA also gave the Secretary of the Department of Health and Human Services (DHHS) the authority to expand the number of measures that must be reported to qualify for full market basket update in future years. We urge CMS to select measures that streamline nationwide quality reporting, build on quality reporting efforts to date, and work with hospitals to ensure collective development of reliable information for the public.

- **Resident Time in Patient Activities**

We strongly urge CMS to rescind a purported "clarification" in the proposed rule that will have a significant effect on UC. The proposed rule 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 stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care" 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.

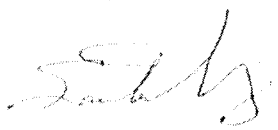
The proposed rule stands in contrast to long standing CMS policy that these activities are an integral component of the patient care activities engaged in by residents during their residency programs.

- **Medicare Wage Index**

The University is very concerned with the proposed changes to the computation of pension and other deferred compensation costs for constructing the wage index. The proposed rule indicates that, beginning in 2007, hospitals must comply with PRM, Part I, sections 2140, 2141, and 2142 and related Medicare program instructions for developing pension and other deferred compensation plan costs as wage-related costs for the wage-index. CMS has offered no rationale for moving away from the reliance on GAAP. This change would result in understated costs at publicly owned hospitals, such as the UC AMCs, that account for pension related expenses pursuant to government accounting standards. **As such, the UC AMCs request that CMS consider the unique circumstances of publicly operated hospitals and retract this change. At a minimum, CMS should offer a rationale for the proposed change and provide a full notice and comment process.**

Thank you for the opportunity to comment on the Medicare Inpatient PPS proposed rule for FY 2007. If there are questions or if I can provide any additional information or input, please contact me at 510-987-9062 or santiago.munoz@ucop.edu.

Sincerely,



Santiago Muñoz, Executive Director
Clinical Services Development

ATTACHMENT #2 TO 1799

UNIVERSITY OF CALIFORNIA

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June 12, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Ave, SW
Washington, DC 20201

SUBJECT: **CMS-1488-P** – Proposed Medicare Hospital Inpatient Prospective Payment System Rates for Fiscal Year 2007

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Medicare Inpatient Prospective Payment System (IPPS) proposed rule for Fiscal Year (FY) 2007 issued by the Centers for Medicare & Medicaid Services (CMS). These comments are submitted on behalf of the University of California (UC) Health System and its academic medical centers (AMCs) located in Davis, Los Angeles, Irvine, San Diego, and San Francisco.

The UC Health System is California's fifth largest hospital system. It is comprised of five AMCs which share a mission of educating health professionals, conducting research, and providing high quality patient care. Annually, the medical centers provide patient care services valued at over $3.8 billion. Eight acute care hospitals in the UC Health System house 3,217 licensed acute care beds and provide a broad array of specialized services that are often not available elsewhere. UC medical center services are essential to the health and well being of Medicare beneficiaries; they include cancer centers, trauma and burn centers, geriatric and orthopedic centers of excellence, and world class primary and preventive care.

The University is extremely concerned with the decline of its Medicare payments given our role in serving extremely high-cost Medicare beneficiaries. In fiscal year 2005, the

UC Medical Centers incurred aggregate Medicare IPPS losses in excess of $30 million. UC continues to urge Congress to provide adequate Medicare payments to its hospitals and urges CMS to ensure the Congressional intent of hospital payment updates are fully implemented on a programmatic level. Further, while UC's comments address the most significant areas of concern for its AMCs, it is generally concerned with the decline in Medicare rates and urges CMS to amend the proposed rule to prevent further reductions.

Concern about adequate Medicare payments extends to the UC Health System's work to educate physicians as well. Medicare's graduate medical education payments contribute to UC's offering of more than 300 residency programs and training for nearly half of California's interns and residents. UC academic medical centers sponsor more than 300 residency training programs in all recognized specialties and subspecialties of medicine and surgery — over 3,900 resident physicians participate annually in these programs.

- **General Comments on Proposed Rule**

The UC medical centers are supportive of efforts to improve Medicare's IPPS, including refinements to the current DRGs and ensuring that DRG relative weights better reflect hospital costs. However, given the significance and complexity of the proposed changes, we believe that a one-year postponement is necessary to allow for further analyses to address data and computation issues. Further, because changes in the relative weights will likely result in the redistribution of over a billion dollars in Medicare payments among hospitals, a significant transition period should accompany the changes. This letter will raise various data and computation issues related to changes in the DRGs and the development of new relative weights. A postponement and a phase-in of these items will help ensure that the issues are addressed and the best possible methodology ultimately is implemented.

Our letter will also comment on other important issues raised in the proposed rule, including: the outlier threshold, reporting hospital quality data, "resident time in patient activities," and the reporting of pension-related expenses.

- **DRGs and DRG Relative Weights**

In response to recommendations from the Medicare Payment Advisory Commission (MedPAC), CMS has proposed the most significant changes since the inception of the IPPS, including:

1. Refining the current DRGs to more fully capture differences in severity of illness among patients;
2. Basing the DRG relative weights on the estimated costs of providing care rather than on charges; and
3. Basing the weights on the national average of hospitals' relative values in each DRG.

While UC supports the concept of improving the DRG system, a change of this significance cannot be entered into without careful analysis and consideration. While simple in concept, developing "cost based" weights to the DRG is enormously complex. For example, the method developed by MedPAC to measure the relative DRG costs is significantly different than the HSRVcc methodology that CMS is advancing. In addition, there are modifications to both of these methodologies that should also be considered.

The UC recognizes and appreciates the CMS's effort to better account for patient severity in the IPPS. A fundamental tenet of a successful IPPS is ensuring that the DRG classification system reflects those cases that involve the sickest and most complex Medicare patients. This is especially significant for the UC given our role as major teaching sites. We have concerns, however, about the proposed CS-DRGs, in part because they reflect patient severity only and do not recognize service complexity. CMS has expressed an interest in determining when it is appropriate to recognize increased complexity in the structure of the DRG system and assessing how these criteria interact with the existing statutory provisions for new technology add-on payments. The UC believes that CMS should specifically determine these criteria to fully ascertain the impact of the new classification system and the IPPS.

Given the magnitude and the possible variability of the proposed changes to the DRG system, UC believes that the implementation of any such changes should not occur on October 1, 2006, but rather should be postponed for one year. Further, UC believes that a significant transition period must accompany any final changes.

- **Outlier Threshold**

In the rule, CMS proposes establishing a fixed-loss cost outlier threshold. This threshold would equal the DRG prospective payment rate, plus any add-on payments for new technology, disproportionate-share hospital (DSH) payments, and any indirect medical education (IME) payments, plus and additional $25,530 for FY 2007. The current additional amount is $23,600. UC is concerned that the increase in the threshold is unwarranted.

The University supports the analysis conducted by the American Hospital Association that the use of more than one indicator will make the threshold calculation more accurate and reliable. Further, UC respectfully urges CMS to implement no change that would inappropriately increase the cost outlier threshold and effectively result in payment reductions to hospitals.

- **Quality Reporting**

The Deficit Reduction Act of 2005 (DRA) expands quality-reporting requirements for hospitals to receive a full market basket update. To be eligible for a full market basket update in FY 2007, CMS proposes using hospital data submissions for the first three calendar quarters of 2005 for the existing 10 quality measures. CMS also proposes

requiring hospitals to submit the full set of 21 quality measures for services retroactively, beginning in *CY 2006* to remain eligible. UC is concerned with the retroactive nature of this proposal. Hospitals would be required to reopen files from which data have already been abstracted, execute new agreements with vendors in order to collect and process the required information, and resubmit information to the clinical data warehouse. Such retroactive alterations in the data files are difficult and costly, and open the door to errors in the data.

The DRA also gave the Secretary of the Department of Health and Human Services (DHHS) the authority to expand the number of measures that must be reported to qualify for full market basket update in future years. We urge CMS to select measures that streamline nationwide quality reporting, build on quality reporting efforts to date, and work with hospitals to ensure collective development of reliable information for the public.

- **Resident Time in Patient Activities**

We strongly urge CMS to rescind a purported "clarification" in the proposed rule that will have a significant effect on UC. The proposed rule 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 stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care" 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.

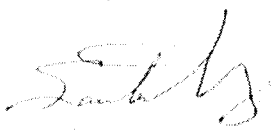
The proposed rule stands in contrast to long standing CMS policy that these activities are an integral component of the patient care activities engaged in by residents during their residency programs.

- **Medicare Wage Index**

The University is very concerned with the proposed changes to the computation of pension and other deferred compensation costs for constructing the wage index. The proposed rule indicates that, beginning in 2007, hospitals must comply with PRM, Part I, sections 2140, 2141, and 2142 and related Medicare program instructions for developing pension and other deferred compensation plan costs as wage-related costs for the wage-index. CMS has offered no rationale for moving away from the reliance on GAAP. This change would result in understated costs at publicly owned hospitals, such as the UC AMCs, that account for pension related expenses pursuant to government accounting standards. **As such, the UC AMCs request that CMS consider the unique circumstances of publicly operated hospitals and retract this change. At a minimum, CMS should offer a rationale for the proposed change and provide a full notice and comment process.**

Thank you for the opportunity to comment on the Medicare Inpatient PPS proposed rule for FY 2007. If there are questions or if I can provide any additional information or input, please contact me at 510-987-9062 or santiago.munoz@ucop.edu.

Sincerely,



Santiago Muñoz, Executive Director
Clinical Services Development

Submitter : Mrs. Mary Schore **Date:** 06/12/2006

Organization : Riverside Healthcare

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Attachment

#1800

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 : Mrs. Jacqueline Monteith **Date:** 06/12/2006

Organization : Presbyterian Health System of New Mexico

Category : Health Care Professional or Association

Issue Areas/Comments

MedPac Update Recommendation

MedPac Update Recommendation

2. The impact on the health information coding staff will be devastating!!!! Coder productivity will be impacted significantly. Coding of an inpatient record for the APR-DRG requires all conditions displayed by the patient has must be coded to thoroughly and accurately calculate the APR-DRG. Adequate time will need to be allowed for the coder to abstract all of the data from the record accurately and evaluate coding guidelines to avoid over or under coding.

Additionally, coders from Maryland as well as other institutions that are Currently utilizing the APR-DRG grouper logic have many questions. CMS and industry leaders must do a thorough evaluation of industry coding standards and guidelines to adequately anticipate all of the questions and confusion that potentially will occur. Even the AHIMA (American Health Information Management Association-the Health Information Flagship organization) has provided little comment and publication on how this will impact the Health Information Coding Professionals and Health Information Staff.

It should also be noted that vendors who provide educational resources and recommendations for educational seminars have not been allowed access to this proprietary grouper.

The Health Information Coding Staff as well as Financial Management have been working with the same system for 23 years and are comfortable and reasonably confident in the standards, guidelines and resources that are available to them. Implementing this system will impact seasoned professionals to a point of gridlock until adequate training and resources can be created and cultivated.

3. The aggressive timeframe that CMS has proposed does not allow adequate time for modifying, testing and training for updated the health information systems required to implement the APR-DRG methodology. Additionally, with the imminent ICD-10 implementation, there are going to be continued costly changes in healthcare delivery system that does not seem to have been taken into consideration.
4. Has CMS reviewed any other severity adjusted DRG systems? The APR-DRG system is a good system, but is there a competitive grouping alternative available that is public domain? Were any independent studies of the impact of this system for Hospitals, Coding and Billing Productivity, financial impact to hospitals done? Again, to implement this system and educate and change mindsets of seasoned healthcare professionals needs to be studied in detail?

This proposed rule seems to have forgotten the ideals of supporting the goal of providing affordable, quality Healthcare to the American public. It will put a continued financial burden on the ever-struggling American Healthcare System.

Submitter : Dr. Bradley Vaughn **Date:** 06/12/2006

Organization : UNC

Category : Physician

Issue Areas/Comments

FTE Resident Count and Documentation

FTE Resident Count and Documentation

I welcome 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). I 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. This ruling is a travesty and affronts every ideal of medical education, escalates inadequate training, raises the total cost of health care and makes coutless Americans suffer.

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 .

The activities cited in the 1999 position and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

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.

The proposed inpatient rule alteration exclusion, for purpose of DGME and IME payment activities held in medical school or physician s office, and other non-hospital settings, reflects a lack of understanding of the interconnectivity of graduate medical education.

The geographic location of teaching activities is ubiquitous and is often held at bedside, in conference rooms, in physician office, and other locations. The evolving merger of all of these facilities into Academic Health Centers precludes parsing out geographic sites. Conferences, such as Journal Clubs, are directed at specific patients or groups of patients. Health problems are presented in a variety of techniques, but never disconnected from the healthcare of the patient. Conferences, such as those of Morbidity and Mortality, have been major teaching activities for a century and focus on specific patients. Moreover, these conferences are sequencing into the basis of error reduction, a quality forum emphasized by CMS. Moreover, the country is badly served by capping the GME numbers for payment, as prescribed in the Balanced Budget Act of 1997.

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. This ruling represents a complete and utter lack of understanding of medical education and demonstrates how individuals who are short sighted can ultimately do major long term damage to our society. To permit this ruling to stand is sending thousands of innocent people to senseless suffering and early death.
I urge the CMS to recognize this ruling for what it truely represents to America which is a dumbing down of the medical education system, and increase in cost for American health care and an attack on all Americans.

Submitter : **Mrs. Jacqueline Monteith** **Date: 06/12/2006**

Organization : **Presbyterian Health System of New Mexico**

Category : **Health Care Professional or Association**

Issue Areas/Comments

MedPac Update Recommendation

MedPac Update Recommendation

2. The impact on the health information coding staff will be devastating!!!! Coder productivity will be impacted significantly. Coding of an inpatient record for the APR-DRG requires all conditions displayed by the patient has must be coded to thoroughly and accurately calculate the APR-DRG. Adequate time will need to be allowed for the coder to abstract all of the data from the record accurately and evaluate coding guidelines to avoid over or under coding.

Additionally, coders from Maryland as well as other institutions that are Currently utilizing the APR-DRG grouper logic have many questions. CMS and industry leaders must do a thorough evaluation of industry coding standards and guidelines to adequately anticipate all of the questions and confusion that potentially will occur. Even the AHIMA (American Health Information Management Association-the Health Information Flagship organization) has provided little comment and publication on how this will impact the Health Information Coding Professionals and Health Information Staff.

It should also be noted that vendors who provide educational resources and recommendations for educational seminars have not been allowed access to this proprietary grouper.

The Health Information Coding Staff as well as Financial Management have been working with the same system for 23 years and are comfortable and reasonably confident in the standards, guidelines and resources that are available to them. Implementing this system will impact seasoned professionals to a point of gridlock until adequate training and resources can be created and cultivated.

3. The aggressive timeframe that CMS has proposed does not allow adequate time for modifying, testing and training for updated the health information systems required to implement the APR-DRG methodology. Additionally, with the imminent ICD-10 implementation, there are going to be continued costly changes in healthcare delivery system that does not seem to have been taken into consideration.
4. Has CMS reviewed any other severity adjusted DRG systems? The APR-DRG system is a good system, but is there a competitive grouping alternative available that is public domain? Were any independent studies of the impact of this system for Hospitals, Coding and Billing Productivity, financial impact to hospitals done? Again, to implement this system and educate and change mindsets of seasoned healthcare professionals needs to be studied in detail?

This proposed rule seems to have forgotten the ideals of supporting the goal of providing affordable, quality Healthcare to the American public. It will put a continued financial burden on the ever-struggling American Healthcare System.

CMS-1488-P-1803-Attach-1.DOC

#1803

Presbyterian Health System of New Mexico's Comments on the CMS Proposed IPPS Reimbursement Change for 2007
Proposed Rule:
http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1833

Federal Register Displayed At:
http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/cms1488p.pdf

Submit Comments to:
http://www.cms.hhs.gov/erulemaking/

Presbyterian Health System of New Mexico would like to comment on the IPPS Reimbursement Change for 2007. This proposed reimbursement change seems to be taking place quietly. To our concern, this IPPS proposed rule is not being discussed in the Provider Organization Journals and Periodicals possibly due to the swiftness of the proposed ruling? There seems to be a lack of industry awareness on the impact of the electronic data workflow, the personnel workflow, financial impact and industry implementation of this ruling.

Additionally, a law was signed in February, 2006, DEFRA, that is implementing additional data collection requirements (Place of Occurrence for the upcoming implementation of the UB-04) that will greatly impact industry standards for data collection and documentation that also seems to be going by unnoticed also scheduled for 2007.

Other concerns are that CMS is proposing the IPPS Reimbursement methodology to be done by a new grouper logic that is a proprietary application of 3M's that is not traditionally or currently recognized by all healthcare mainframes and interfaces. Many upgrades would need to be made to healthcare information systems in addition to training of staff, hours of system testing and understanding of this new grouper methodology.

Here at Presbyterian, we have a mission that promotes Purpose, Vision, Values and Strategies. We pride ourselves in providing Quality Healthcare to our community and an excellent working environment for our employees. We feel if we were to begin testing today, we would be lucky to meet the current CMS proposed deadline keeping in mind the software logic has not been selected. This situation is reminiscent of what occurred in Maryland in 2005 when the state of Maryland adopted the APR-DRG grouper methodology. The healthcare providers were scrambling during the final hours leading up to the deadline to implement new software, test interfaces, train staff and understand new payment methodologies that were not yet published in public domain. Software providers that were not 3M had to wait until final hours when the 3M's grouper methodology became available to vendors and adapt the grouper methodology to work within their already up and running software applications and interfaces.

CMS's proposed modifications are intended to improve the Diagnostic Related Group (DRG) System and accuracy of payment rates for inpatients. The implementation of these changes will have an immediate and possibly devastating impact on the financial and operational components of hospitals and other provider organizations not to mention the payor community if this is allowed to quietly moving forward and adequate planning for training and testing is not provided.

Our understanding at Presbyterian is the implementation will be in a 2 step process.

The first step would assign weights to DRGs based on hospital costs, rather than hospital charges. The new DRG weights would go into effect Oct. 1, 2006 along with routine changes to the DRG methodology.

The second phase, currently scheduled for 2007, would replace the current 526 DRGs with the proposed 861 consolidated severity-adjusted DRGs based on All Patient Refined Diagnosis Related Groups (APR-DRGs).

Additional areas that appear to be impacted by the proposed rule include:

1. **3M is the proprietary vendor that has developed the APR-DRG (All Patient Refined Diagnosis Related Groups). There seems to be lack of full disclosure and transparency of the casemix grouping and severity adjustment algorithms used in the APR-DRG grouper logic. Even if a full disclosure is provided to CMS, it is unlikely this will be shared with hospitals, providers, payers, industry software vendors and industry educational resources that assist with training. This seems to have created a monopoly environment that is not allowed in any other segment of Corporate America...so why in healthcare? The current DRG module that is being used is open to all vendors and providers!!!**

2. **The impact on the health information coding staff will be devastating!!!! Coder productivity will be impacted significantly. Coding of an inpatient record for the APR-DRG requires all conditions displayed by the patient has must be coded to thoroughly and accurately calculate the APR-DRG. Adequate time will need to be allowed for the coder to abstract all of the data from the record accurately and evaluate coding guidelines to avoid over or under coding.**

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3. **The aggressive timeframe that CMS has proposed does not allow adequate time for modifying, testing and training for updated the health information systems required to implement the APR-DRG methodology. Additionally, with the imminent ICD-10 implementation, there are going to be continued costly changes in healthcare delivery system that does not seem to have been taken into consideration.**
4. **Has CMS reviewed any other severity adjusted DRG systems? The APR-DRG system is a good system, but is there a competitive grouping alternative available that is public domain? Were any independent studies of the impact of this system for Hospitals, Coding and Billing Productivity, financial impact to hospitals done? Again, to implement this system and educate and change mindsets of seasoned healthcare professionals needs to be studied in detail?**

This proposed rule seems to have forgotten the ideals of supporting the goal of providing affordable, quality Healthcare to the American public. It will put a continued financial burden on the ever-struggling American Healthcare System.

Submitter : **Helene Dujardin** **Date: 06/12/2006**

Organization : **UMDNJ-University Hospital**

Category : **Hospital**

Issue Areas/Comments

Impact Analysis

Impact Analysis

See Attached

CMS-1488-P-1804-Attach-1.DOC

#1804

PThe UNIVERSITY HOSPITAL

University of Medicine and Dentistry of New Jersey

June 12, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1488-P and P2
PO Box 8011
Baltimore, MD 21244-1850

RE: Proposed Changes to the Hospital Inpatient
Prospective Payment Systems (IPPS) and FY 2007 Rates
CMS 1488-P

Dear Dr. McClellan:

UMDNJ-University Hospital welcomes this opportunity to comment on the CMS proposed rule "Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems (IPPS) and FY 2007 Rates. These comments address the following issues:

1) More time is needed to evaluate and understand the significant proposed policy changes with regard to the DRG weighting and classification systems.

2) The "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.

DRG Weighting and Classification Systems

UH supports the recommendations of the American Hospital Association (AHA) and the Association of Academic Medical Centers (AAMC) for a one-year postponement of the DRG weighting methodology to allow thoughtful analysis and to consider potential alternatives that may be more effective. The movement to cost –based weights is a complex undertaking since the costs of hospital care cannot be identified directly but rather rely on estimates based on cost-to-charge ratios and various methodologies. Similarly the proposed consolidated severity-adjusted DRGs require further analyses and modifications to ensure that the new system is one that most accurately reflects patient severity as well as service complexity (new technology).

The proposed changes to the DRG weights and classification are significant changes to the program and should be implemented simultaneously (so that combined impact on hospitals and service lines can be assessed and managed). In addition, there should be a significant transition period (a minimum of three years) to accomplish full implementation.

Resident Time in Patient Activities

We urge CMS to rescind the "clarification" that excludes medical resident time spent in didactic activities in the calculation of DGME and IME payments. The stated rationale is that these activities are not "related to patient care." The proposed rule cites journal clubs, classroom lectures and seminars as examples of didactic activities that must be excluded when determining the FTE resident counts for all IME payments (regardless of setting) and for DGME payments when the activities occur in a non-hospital setting (physician's office or affiliated medical school).

We believe that the activities cited are an integral component of the patient care experiences of residents during their residency programs. We support the position espoused by CMS in 1999 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.

Thank you for consideration of these comments.

Sincerely,

Helene K. Dujardin
Director of Business Development
UMDNJ-University Hospital
150 Bergen Street - D209
Newark, NJ 07103

Submitter : **Date: 06/12/2006**

Organization :

Category : **Individual**

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, 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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

I urge CMS to rescind its clarification in the proposed rule relating tothe 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,

Kirsten Caine MD

Submitter : Dr. Merlin Mauk **Date:** 06/12/2006

Organization : CAFP

Category : Individual

Issue Areas/Comments

GME Payments

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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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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Sincerely,
Merlin H. Mauk, M.D.

Submitter : **Dr. Steven Shelton** **Date: 06/13/2006**

Organization : **Dr. Steven Shelton**

Category : **Physician**

Issue Areas/Comments

GME Payments

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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.

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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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,
Steve Shelton, MD.

Submitter : **Dr. Deborah Hamilton** **Date: 06/13/2006**

Organization : **The Medical Group**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, 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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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,

Deborah J Hamilton, MD

Submitter : **Dr. Andrew Wapner** **Date: 06/13/2006**

Organization : **Dr. Andrew Wapner**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a pediatrician, 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,

Andrew Wapner

Submitter : **Mr. Michael Curran** **Date: 06/13/2006**

Organization : **MedStar Health, Inc**

Category : **Hospital**

Issue Areas/Comments

DRG Weights

DRG Weights

See Attachment

DRGs: Severity of Illness

DRGs: Severity of Illness

As it related to the new patient classification system, history tells us that several years are necessary to operationalize a move from the DRG system to a severity system. More specifically, APRs will require hospitals to hire additional inpatient coders and documentation specialists from an already limited pool of qualified professionals. We have seen about a 20% increase in staffing. In addition, physicians will need specific training on the importance of complete and accurate documentation of all conditions impacting the resources utilized to care for the patient under this new system. Based on our Maryland experience, we believe CMS and hospitals will need several years to expand their data set to include additional diagnoses and to have better coding to calibrate weights. Currently CMS captures only 9, which we believe is not sufficient for recognizing the severity of a patient. In Maryland 52% of records exceeded 9 diagnoses in the first year of implementing APRs.

GENERAL

GENERAL

Thank you for giving us the opportunity to allow MedStar to submit comments on the above referenced proposed rule. You may be aware that MedStar is uniquely positioned to comment on this proposal since we have hospitals in Maryland and DC. Our hospitals in Maryland have experience with the components of the proposed regulations. Because of that experience we would like to share several issues for your consideration. They relate to the new DRG weights, the new patient classification system and the timing of implementation. we would recommend the following:

(1) iterative weight logic needs be implemented at the same time as the severity system to not cause significant inequities in payments;

(2) iterative weight logic should be further reviewed and developed to ensure true costs are being captured;

(3) Implementation of the APR system should be delayed for 18 months after approval;

Thank you again for allowing us the opportunity to comment on this very important proposed regulation. We would be happy to share with you any additional information on our Maryland experience. Please call me at 410-772-6630 should you have any questions about our comments or require more detail.

HSRV Weights

HSRV Weights

As it relates to the new DRG weights, we would caution CMS against implementation of the weights without a severity system. Our experience tells us that implementing separately causes inequities in payments amongst classes of providers (i.e. Rural/Urban, Teaching/Non-Teaching, etc.). Our thoughts on this matter are shared by the Maryland s Health Services Cost Review Commission (HSCRC) who implemented a similar methodology in 2006. The HSCRC commissioned a study by Dr. Grace Carter prior to approving their iterative weight logic. I would recommend that you obtain that 16 page report from HSCRC for your consideration. In summary, Dr. Carter concluded that it is not the best policy to implement iterative weights without a system that adequately captures severity. Other researchers, which she has referenced in her report, have concluded this as well.

We also believe, based on our experience, that the proposed iterative weight structure may be limiting because of its ten groupings to attempt to arrive at costs and hospitals various markup structures within these groupings. In the report noted above Dr. Carter reinforces that unless you can adequately account for markup differences, iterative weight methodology may not be the best approach. In addition, the American Hospital Association has referenced technical weaknesses as it relates to the calculation of iterative weights which we concur is something that needs to be addressed.

Submitter : **Dr. Michele Thieman** **Date: 06/13/2006**

Organization : **Broadway Family Medicine**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, 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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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. Moreover, as a family physician, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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,

Michele Thieman, MD

Submitter : **Dr. Daniel Pound** **Date: 06/13/2006**

Organization : **University of California San Francisco**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a faculty member 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.

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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.

Submitter : **Dr. Gerald Yorioka** **Date: 06/13/2006**

Organization : **Washington Academy of Family Physicians**

Category : **Physician**

Issue Areas/Comments

GME Payments

GME Payments

As a family physician, 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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count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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,
Gerald N. Yorioka, M.D. (President, Washington Academy of Family Physicians)

Submitter : Mr. Brett Baker **Date:** 06/13/2006

Organization : American College of Physicians

Category : Physician

Issue Areas/Comments

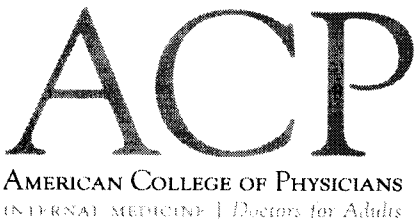
GENERAL

GENERAL

See attached comment letter from the American College of Physicians, representing 119,000 internists and medical students, that addresses: cost-based payments; severity of illness adjustments; and GME/IME payments.

CMS-1488-P-1814-Attach-1.DOC

#1814



June 12, 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 8011
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. McClellan:

The American College of Physicians (ACP), representing over 119,000 doctors of internal medicine and medical students, is pleased to submit comments on the proposed rule "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." ACP supports the efforts of the Centers for Medicare and Medicaid Services (CMS) through this rule to make the inpatient hospital payment system more accurate. Nonetheless, the College is concerned about the following two specific aspects of this proposed rule:

1. The timing of these significant changes to the payment system.

The change from a charge-based to a cost-based payment system beginning in fiscal year 2007 represents one of the most significant changes made in the hospital inpatient payment system in a number of years. The resulting change in the DRG (Diagnosis Related Groups) weights and related payments will have a major effect on revenue received for the different procedures performed in each facility and on total revenue received by a facility based upon its setting. In addition, it will affect how hospitals prioritize and employ resources – a result that will also directly affect the physicians that provide services within the facility.

The effects on the hospital and staff resulting from the proposed change to a cost-based payment system are further confounded by CMS' plans to implement a severity-adjusted DRG payment system by no later than 2008. As you are aware, both the Medicare Payment Advisory Commission (MedPAC) and Chairman Bill Thomas of the House Ways and Means Committee support the implementation of this change at the same time as the cost-based payment implementation. The College supports this approach. The addition of a

severity-adjustment to the payment system, while furthering the goal of more accurate payment, represents an additional major change to the payment system.

Changes of this magnitude require time for inpatient hospital settings to adjust to in a manner that ensures the continued quality of the care they provide and maintains their financial solvency. The College believes that the 60 day period between the publication of this proposed rule and the final day that CMS will accept comments is too limited, plus the brief time period between publication of the final rule and the start of the 2007 fiscal year, will be insufficient for facilities to process, question, plan and adapt to this new payment system.

The ACP specifically requests that CMS provide the hospital and general provider community with additional lead-time to understand the effects of the proposed changes to the inpatient hospital payment system, to question and potentially improve the methodology proposed by CMS to effect these changes, and to adapt to these proposed changes. Furthermore, the College recommends a transition or phase-in to the new cost-based, severity-adjusted payment system. Finally, it encourages CMS to publish an interim final rule rather than a final rule, which will allow all interested parties an extended opportunity to provide further comments after publication of the final rule.

2. The "clarification" provided in the rule regarding the exclusion of time spent in "nonpatient care activities" for purposes of calculating Medicare direct medical education (DGME) and indirect medical education (IME) payments.

The proposed rule excludes medical resident time spent in didactic activities in the calculation of Medicare direct DGME and IME payments. The 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]. The College supports 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.

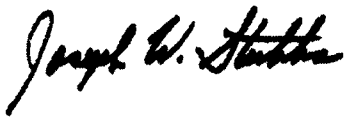
Furthermore, the current language financially penalizes hospital-based residency programs for providing their students with non-hospital training experiences – since time spent in didactic activities in non-hospital settings cannot be included within either DGME or IME calculations. The College believes that residents considering general internal medicine practices should have the opportunity to receive related training and experience within the non-hospital setting as part of their residency training. The current proposed rule provides a disincentive for the hospital-

based residency program to provide this experience. This is particularly poor public policy given the current impending shortage of primary care physicians.

The College strongly urges 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 both activities are an integral part of medical residency training and should be included within the DGME and IME calculations.

ACP appreciates the opportunity to comment on the 2007 Hospital Inpatient Proposed Rule. Please contact Neil Kirschner, Ph.D., Senior Associate in the College's Department of Regulatory and Insurer Affairs, if you have any questions.

Sincerely,



Joseph W. Stubbs, MD, FACP
Chair, Medical Service Committee

Submitter : **Mr. Marvin Eichorn** **Date: 06/13/2006**

Organization : **Mountain States Health Alliance**

Category : **Hospital**

Issue Areas/Comments

DRG Weights

DRG Weights

June 12, 2006

Center for Medicare & Medicaid Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS-1488-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and fiscal year 2007 Rates; Proposed Rule

Dear Sirs:

Mountain States Health Alliance (MSHA), on behalf of our six member hospitals, appreciates the opportunity to submit comments to the Center for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2007 inpatient prospective payment system (PPS) proposed rule.

The rule proposes the most significant changes in the calculation of diagnostic-related group (DRG) relative weights since 1983 through the creation of a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc). It also proposes refining the DRGs to account for patient severity, with implementation likely in FY 2008 or sooner. In addition to these sweeping changes, the rule would update the payment rates, outlier threshold, hospital wage index, quality reporting requirements, and payments for medical education, among other policies.

While MSHA supports many of the rule s provisions, we have serious concerns about the proposed changes to the DRG weights and classifications. More time is needed to understand the significant proposed policy changes, which national organizations estimate will redistribute from $1.4 to $1.7 billion within the inpatient system. In addition to needing the additional time to understand the system, time is also needed in order to fully update and educate internal staff members, Medical Records personnel and physicians on the documentation ramifications and changes necessary to ensure that all diagnoses, procedures and conditions are properly captured to enable accurate DRG classification reporting resulting in the continued uninterrupted equitable reimbursement for our member facilities. Given the potential significance on provider operations of applying the new occupational mix adjustment to 100% of the wage index for the first time in FY 2007, providers will need additional time to ascertain, isolate and adjust to that impact alone without the complicating factor of any DRG weight & classification changes added to the mix. Analysis from national organizations shows the impact of the proposed changes to be highly unstable, with small changes in methodology creating large changes in provider payments. The validity of CMS proposals versus potential alternatives to improve the DRG weights and classification is highly uncertain. Moving forward requires thoughtful change with due consideration of the various alternatives available.

Specifically, MSHA supports the following:

" A One-year Delay: MSHA supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology.

" Valid Cost-based Weights: MSHA supports moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS proposed HSRVcc method is flawed in many ways.

" A New Classification System Only if the Need Can Be Demonstrated: MSHA does not support a new classification system at this time, as the need for a new system is still unclear. Any new system should continue to recognize the provider resources expended in treating any given patient classification. Much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system is selected or advanced.

" Simultaneous Adoption of Any Changes to Weights and Classifications: If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and to smooth the volatility created by these two, generally off-setting changes.

" Three or Four-year

Submitter : **Dr. Jeff Levine** **Date: 06/13/2006**

Organization : **Atlantic Health System**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GME Payments

GME Payments

As a director of medical education, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services 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.

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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. Moreover, as a director of medical education, I believe this policy would require additional staff that would be responsible for sitting in on each of these didactic sessions and keep count of patient care time. Such documentation requirements are unreasonable and would add an extremely large and unnecessary administrative burden.

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 Levine, PhD
Director, Division of Academic Affairs
Atlantic Health System