CMS-1428-P-187

Submitter : Dr. joe ladowski **Date & Time:** 07/12/2004 02:07:47

Organization : lutheran hospital of indiana

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

i agree with the proposed increase in reimbursement for lvads

Submitter : Mr. Cecil Terry **Date & Time:** 07/12/2004 03:07:22

Organization : BJC HealthCare

Category : Hospital

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

Direct GME Initial Residency Period

The following comments are directed at an issue that relates to the direct graduate medical education (DGME) payment--the initial residency period, often referred to as the preliminary year issue.
The Federal fiscal year 2005 Medicare inpatient PPS proposed rule (69 Federal Register 28196, May 18, 2004) addresses the initial residency period (IRP) determinations used, in part, to determine Medicare DGME payments (See 69 Fed. Reg. at 28310). A clarification is necessary because the CMS interpretation of the statute described in the proposed rule as ?current? violates the statute, does not reflect Congressional intent, and results in inequitable payments to teaching hospitals for residents training in certain specialties.The most recent statement of Congressional intent with regard to this issue makes clear that the CMS interpretation described in the proposed rule is a misreading of the statute and, to the extent it has been applied incorrectly, the policy needs to be clarified. As stated by conference report language accompanying section 712 of the Medicare Modernization Act of 2003 (P.L. 108-173):

?The conferees also clarify that under section 1886(h)(5)(F), the initial residency period for any residency for which the ACGME requires a preliminary or general clinical year of training is to be determined in the resident?s second year of training.?

We urge that this issue be addressed in the inpatient final rule (or in an interim final regulation), and that CMS reinterpret the statute to reflect the most recent statement of Congressional intent. This solution will ensure that any confusion regarding the policy will be removed and a consistent policy is applied for residents whose first year of training is completed in a program that provides a general clinical year.

Because our system?s large teaching Hospitals have historically called the first year of training for these more complex specialties a ?general clinical year,? instead of a ?transitional year,? they are significantly, adversely affected by not being allowed to count the full value of the FTEs training in these specialities, when, in fact, there is no difference between a ?general clinical year? and a ?transitional year.? This ?penalty for semantics? is illogical and, obviously, unfair.

CMS? reinterpretation should reflect the statute, as clarified by Congress in the MMA 2003 conference report language by clarifying that, for residents whose first year of training is completed in a program that provides a general clinical year as required by ACGME for certain specialties, an IRP should be assigned based on the specialty the resident enters in the second year of training.

CMS-1428-P-189

Submitter : Mr. Cecil Terry **Date & Time:** 07/12/2004 03:07:26

Organization : BJC HealthCare

Category : Hospital

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

Criteria for Determining Hospitals That Will Receive Increases In Their FTE Resident Caps
(Methodology and Evaluation of Applications for ?Additional Slots? Under the ?Resident Redistribution? Proposal)

On pages 28299 through 28318 of the subject Federal Register, CMS discusses the proposed criteria for hospitals to obtain ?additional slots? for their resident training programs, including the application and evaluation process. CMS is proposing that hospitals submit evaluation forms at the ?program? level. Historically, resident caps and GME reimbursement have been applied and managed at the ?hospital? level (i.e., all of the individual programs? FTEs aggregated for the determination and application of the caps). We suggest that hospitals should be allowed to submit applications for ?additional slots? based on their ?aggregate programs? for the entire hospital, especially those hospitals who are currently training a number of FTEs above their ?resident caps.? In effect, the reimbursement reductions applied to hospitals with actual GME FTEs above their caps are applied to the entire hospital and not to the individual programs. Since the payment penalty for excess FTEs is applied to the ?aggregation of all of the hospital?s programs,? hospitals should be allowed to apply for the additional slots to remedy this situation, also based on the ?aggregation of all of the hospital?s programs.?

CMS-1428-P-190

Submitter : Mr. DAVID GLYER **Date & Time:** 07/12/2004 04:07:28

Organization : COMMUNITY MEMORIAL HOSPITAL

Category : Hospital

Issue Areas/Comments

Issues 1-10

Revised MSAs

Community Memorial Hospital is a nonprofit 240 bed hospital which is located in Ventura County, California just west and north of the Los Angeles metropolitan statistical area. We serve the residents of Ventura County and surrounding areas in this fast growing suburban area. Proposed changes in the 2000 Census designations will preclude the County from being reclassified into the Los Angeles metropolitan area costing this hospital more than $1.5 million in payments per year beginning October 1st. Wages rates at Community Memorial Hospital and other County hospitals have increase more than 23% over the last two years specifically because of the need to be competitive with Los Angeles hospitals. We ask that you consider the alternate approached discussed below which more fairly respond to the competitive realities of our labor market.

Based on the 1990 OMB/Census data, Ventura County was considered a Primary Metropolitan Statistical Area (PMSA) and an integral part of the Los Angeles Consolidated Metropolitan Statistical Area (CMSA). As such, the hospital was eligible for Medicare geographic reclassification on a countywide basis. The Medicare Geographic Classification Review Board (MGCRB) approved our reclassification for the purposes of receiving the Los Angeles wage index and the hospitals will receive the Los Angeles wage index effect October 1, 2004. Under the 2000 Census designations that CMS proposes to adopt, Ventura County is no longer a part of the Los Angeles CMSA. The new 25% out commute standards were set at a level higher than the previously used 15% minimum and therefore, Ventura County was not considered to be a part of the Los Angeles metropolitan area. Thus, according to the May 18th proposal, Ventura County hospitals would no longer be eligible for future countywide reclassifications to the Los Angles metropolitan area.

In the December 27, 2000 Federal Register the Office of Management and Budget, in the standards for defining metropolitan and micropolitan statistical areas stated the following: ??OMB believes that it should not take into account or anticipate any public or private sector non-statistical uses that may be made of the definitions. It cautions that metropolitan statistical area and micropolitan statistical area definitions should not be used to develop and implement Federal, state and local non-statistical programs and policies without full consideration of the effects of using these definitions for such purposes.?

Like the 1990 Census designations, the 2000 Census designations are not perfect building blocks for the purposes of determining areas for Medicare wage indexes. Ventura County is every bit as economically and socially integrated into the Los Angles metropolitan area today as it was during the 1990?s. Simply because of a change in one standard, the 25% out commute standard, it appears that Ventura County would no longer be eligible for a countywide reclassification to the Los Angles MSA.

We recommend that CMS implement a grandfather provision that would allow hospitals that were PMSAs under the 1990 guidelines and were successfully reclassified to a contiguous PMSA based on the 1990 standards be grandfathered and be allowed to obtain countywide reclassification even though it does not meet the more stringent 25% out commuting requirements as adopted by OMB and the Census Bureau. An alternative would be for CMS to allow counties that are included in a Combined Statistical Area (CSA) to reclassify to a contiguous metropolitan division of the CSA using the 2000 standards.

We believe that the above is appropriate public policy and acknowledges the realities of areas such as Ventura County, that are just outside major areas such as Los Angeles and must meet the competitive salary scales in order to attract and retain competent professionals to provide needed hospital services in areas just outside these major metropolitan areas throughout the United States.

CMS-1428-P-191

Submitter : Ms. Lynda Payton **Date & Time:** 07/12/2004 04:07:02

Organization : The Nebraska Medical Center

Category : Hospital

Issue Areas/Comments

Issues 1-10

DRG Reclassifications

Pancreatic Islet Cell Transplantation

The Nebraska Medical Center is certified for Kidney, Liver, Pancreas, and Small Bowel Transplants. The hospital will be conducting a clinical trial for the pancreatic islet cell transplant.

Because this is a new procedure, the hospital understands CMS' reluctance to pay for the acquisition of the islet cells as a pass through, as is currently done with the procurement and pre-transplant related costs of the other solid organs, and applauds CMS for proposing an additional pass through payment for this procedure. However, after more data has been collected, we propose that CMS pay for the acquisition and pre-transplant related costs on a pass through basis as is done with the solid organs.

If a transplanting facility is not able to harvest and process the islet cells, that facility will need to acquire an agreement with another facility to procure the islet cells. This could have a significant impact on the cost of the procedure. In addition, if a patient would need multiple infusions, this is where a majority of the cost of the procedure will be. CMS needs to keep in mind when calculating the costs of possible multiple infusions of the islet cells.

The Nebraska Medical Center has projected that the average cost of one pancreatic Islet Cell Transplant (including the pre-transplant services) is $73,000. The average payment in DRG 468 is approximately $25,000. CMS will need to ensure that the add-on payment is sufficient to cover the pre-transplant costs of the transplant. For our facility, that amount is approximately $17,000.

Issues 11-20

Post Acute Care Transfers

Post-acute Care Transfers
The Nebraska Medical Center opposes any expansion of the post-acute care transfer policy to additional DRGs. We agree with and support the following comment which was submitted by the American Hospital Association:

'The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare PPS, and penalizes hospitals for ensuring that patients receive the right care at the right time in the right place.
Last year, after an extensive analysis to identify the best method by which to expand the transfer policy, the agency adopted four specific criteria that a DRG must meet, for both of the two most recent years for which data are available, in order to be added to the post-acute care transfer policy:
1. The DRG must have at least 14,000 cases of post-acute care transfers;
2. The DRG must have at least 10 percent of its post-acute care transfers occurring before the mean length of stay for the DRG;
3. The DRG must have a length of stay of at least three days; and
4. The DRG must have at least a 7 percent decrease in length of stay over the past five years (1998-2003).

This resulted in expanding the provision from 10 DRGs in FY 2003 to 29 DRGs in FY 2004. Now, only a year later, the agency is proposing to adopt an additional set of alternative criteria that would be applied to a DRG if it failed to qualify for the transfer provision under the FY 2004 criteria. The new criteria state that the DRG only needs to have 5,000 cases of post-acute care transfers, and the percentage of transfer cases that are short-stay transfer cases is at least two standard deviations above the geometric mean length of stay across all DRGs. It also adds to the four items listed above, to state ?or contains only cases that would have been included in a DRG to which the policy applied in the prior year.?
The agency clearly is adopting the new criteria solely to capture cases currently in DRG 483 (Tracheostomy with Mechanical Ventilation) as they

also propose splitting this DRG into two new DRGs 542 and 543, based on whether or not the case had a major operating room procedure. Given the split of the DRG, cases currently subject to the policy would no longer qualify. Yet given the proposed new criteria, the transfer policy also would capture DRG 430 (Psychoses) and reduce hospital payments by an additional $25 million in FY 2005 alone.
If CMS proposed split of DRG 483 into two more specific DRGs now better accounts for variation in length of stay and cost per case, then the historically stated need for a transfer policy for these two new DRGs is no longer valid. If CMS? creation of the two new DRGs for tracheostomies with and without surgical procedures do not create less variation in length of stay and cost per case, then there is no need to split DRG 483 and no need to expand the transfer policy criteria.
The agency cannot change its rules and criteria year by year in order to ensure certain DRGs are included in the transfer policy. The AHA objects to the implementation of alternative criteria for which there is no sound policy rationale. This provision must be withdrawn in its final rule.'
(American Hospital Association Comments dated July 12, 2004 regarding CMS-1428-P)

Issues 21-30

Graduate Medical Education

CMS Evaluation of Applications for Increases in FTE Resident Caps:
As indicated in the proposed rule the Conference Report for Public Law 108-173 states that the ?Secretary shall consider giving special consideration to hospitals that train a large share of graduates from historically large medical colleges. In the proposed rule the Secretary chooses to interpret this to mean 'historically Black' medical colleges. The Nebraska Medical Center feels this is an inaccurate and arbitrary interpretation of the Conference Report. 'Historically large medical colleges' deserve special consideration as they play an important role in educating a large portion of medical students. In some cases these hospitals may be training at a level above their cap and deserve recognition for that. Evaluation Criterion Nine should recognize 'historically large medical colleges' as indicated by the Conference Report.

The Nebraska Medical Center feels that special consideration should also be given to hospitals that have consistently trained at or above their cap. By training at or above the cap these hospitals reinforce that they are dedicated to training medical students regardless of expected reimbursement and therefore deserve to be given a higher score than a hospital that is only going to increase their program due to potential reimbursement from an increased FTE cap.

Direct GME Initial Residency Period Limitation: Simultaneous Match Issue:
We appreciate CMS'recognition of the issues pertaining to residents training in a 'clinical base year' (CBY) with the intent to continue training in a specialty program. In most cases the resident either 'simultaneously matches' or signs a letter of intent to move into a specialty program after the initial CBY. Therefore supporting the CBY should not be an issue. As long as the facility can document the intent to move into a specialty program, the second year should be used to determine the Initial Residency Period. The 'Graduate Medical Education Directory' also indicates which programs require a CBY and what will be accepted as CBY. This will also help direct the Facility and Fiscal Intermediary to the proper Initial Residency Period.

Moratorium on Disallowances of Allopathic or Osteopathic Family Practice Residents Training Time in Non-hospital Settings:
Due to space contraints additional comments will be included via an attachment.

CMS-1428-P-191-Attach-1.doc

CMS-1428-P-191-Attach-1.doc

CMS-1428-P-191-Attach-1.doc

CMS-1428-P-192

Submitter : Dr. Ted Epperly **Date & Time:** 07/12/2004 05:07:37

Organization : Family Practice Residency of Idaho

Category : Physician

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

Dear Sirs:

Thanks you for the ability to respond to your May 18th proposed rule on 'proposed changes to the Hospital Inpatient Prospective Payment Systems and FY 2005 Rates'.

(full comments in attachment)

CMS-1428-P-192-Attach-1.doc

CMS-1428-P-193

Submitter : Mr. Harris Bryan Forlines **Date & Time:** 07/12/2004 06:07:55

Organization : Medical Center of Central Georgia

Category : Hospital

Issue Areas/Comments

Issues 11-20

ESRD Discharges

CMS is proposing to change a long-standing policy to provide additional payments to hospitals if the hospital's ESRD Medicare beneficiary discharges are 10 percent of more of its total discharges. CMS is proposing to revise 412.104(a) to make it clear that, in determining a hospital's eligibility for the additional Medicare payment, only discharges involving ESRD Medicare beneficiaries who have received a dialysis treatment during an inpatient stay are to be counted toward meeting the 10 percent threshold. Most hospitals that currently qualify for this special add-on payment are barely meeting the threshold. Implementing this proposed change will essentially make it impossible for the majority of hospitals that treat a high number of Medicare ESRD patients to qualify for the additional payment.

The additional payment to hospitals that treat a high percentage of ESRD patients is appropriate because ESRD patients are chronically sicker than average patients and require more intensive resources and care, even when they do not receive dialysis services during an inpatient stay. The special add-on payment was originally intended to compensate hospitals for providing this level of service to ESRD patients.

CMS does not provide an adequate explanation or rationale for changing a policy that has been in place for over twenty years. Fiscal Intermediaries are aware that some ESRD patients do not receive a dialysis treatment during an inpatient stay in some cases. They have inquired to the CMS regional office and have obtained written statements that a diaylsis treatment is not necessary to qualify the patient for this special payment.

We strongly ask that this policy not be implemented to prevent a serious detrimental financial impact on hospitals that treat this medically fragile population.

CMS-1428-P-194

Submitter : Mr. Dennis Crum **Date & Time:** 07/12/2004 04:07:56

Organization : Tift Regional Medical Center

Category : Hospital

Issue Areas/Comments

Issues 21-30

Hospital Reclassifications

Tift Regional Medical Center is a 191 Bed regional referral center serving the citizens of Tifton, Tift County and surrounding areas of South Central Georgia.

For the past several years, Tift Regional has applied for a wage index reclassification to Albany, GA, but has not met the 82% criteria to receive a reclassification. The hospital believes that the only reason it has not been able to obtain a reclassification is possibly erroneous data of another hospital which Tift Regional has not been able to get corrected.

Because of this unusual circumstance, Tift Regional asks that CMS exercise their discretionary authority and grant Tift Regional a reclassification for FFY 2005 to the Albany, GA MSA.

We appreciate the opportunity to submit this request. Should you have any questions please do not hesitate to contact Dennis Crum at 229-386-6146.

CMS-1428-P-195

Submitter : Mr. Donald Apple **Date & Time:** 07/12/2004 05:07:13

Organization : Saint John's Health System

Category : Hospital

Issue Areas/Comments

Issues 21-30

Hospital Reclassifications

On behalf of Saint John's Health System and Community Hospital Anderson both of Anderson, Madison County, Indiana ("Anderson Hospitals"), we are pleased to comment on the proposed rule, "Proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal year 2005 Rates" which appeared in the Federal Register, vol. 69, pages 28196 - 28817.

While the proposed rule eliminates, modifies or creates various criteria affecting Medicare hospital payment rates effective for federal fiscal year 2005 (beginning October 1, 2004), two changes will have a particularly devastating effect on the Anderson Hospitals and their ability to care for patients in the community.

Specifically, FFY 05 will be the first year that Area Wage Indexes ("AWIs") will be adjusted by using 2000 Census data to reconfigure Metropolitan Statistical Areas ("MSAs"). The Anderson Hospitals have been a part of the Indianapolis MSA for years and were and are an integral and indistinguishable part of the greater Indianapolis metropolitan area. The Centers for Medicare and Medicaid Services ("CMS") is proposing that the Anderson Hospitals, now located in a one county MSA, Anderson, Indiana, have a substantially reduced Medicare AWI by virtue of their location in the new MSA. Specifically, the AWI for Anderson, Indiana MSA will be 0.879 for FFY 2005 and it was 0.9916 for FFY 2004 when the Anderson Hospitals were a part of the Indianapolis MSA. This 11.36% reduction results in reduced Medicare payment of over $5,500,000.00 annually to the two hospitals.

The Anderson Hospitals still must pay wages at Indianapolis MSA levels and supplies and vendor costs remain the same. The only change is the arbitrary and unjustified reductions in Medicare payment.

The second modification of previous criteria as proposed by CMS would limit future countywide group reclassifications to those counties that are within a metropolitan division of a large urban area (a MSA with a core population of at least 2.5 million representing an employment center, plus adjacent counties associated therewith). This proposal eliminates any opportunity for the Anderson Hospitals to seek countywide group reclassification to the Indianapolis MSA. This is patently inequitable since the concept of geographic reclassification exists so hospitals may obtain higher Medicare payments if they can show reasonable proximity and comparable costs.

We urge you to consider the following alternatives to lessen the impact of the significant Medicare payment reductions to the Anderson Hospitals:

1. Notwithstanding the reconfiguration of MSAs following the 2000 Census, hospitals located in the Anderson, IN MSA should received Medicare payment as if located in the Indianapolis MSA given the homogeneous and interrelated nature of metropolitan Indianapolis as well as the uniform and consistent wage structure throughout the area.
2. Modify the criteria so that hospital groups located in a large urban Combined Statistical Area ("CSA") are afforded the opportunity to seek reclassification to another contiguous metropolitan division within the CSA. In this way, the Anderson Hospitals, and others similarly situated, would have the opportunity to prove that their costs of providing care to Medicare beneficiaries was comparable to hospitals in adjacent MSAs.
3. Consistent with maintaining the integrity of the geographic reclassification process in MSAs containing two or fewer hospitals paid under the Medicare Prospective Payment system, such hospitals should be eligible for individual reclassification to contiguous MSAs without being required to have an average hourly wage 108% higher than its home area. The 108% requirement in MSAs with one or two hospitals mathematically forecloses any opportunity for reclassification.

We hope and trust you will review our comments and consider the merits of modifying the proposed rule accordingly.

CMS-1428-P-196

Submitter : Dr. Mario Pacheco **Date & Time:** 07/12/2004 05:07:29

Organization : Northern New Mexico Family Practice Residency Prog

Category : Physician

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

I request that CMS to make very clear in regulation or intermediary instruction that if there are no payments made to the non-hospital site by the hospital, that is not an a priori reason to deny time spent by residents in that environment. If the hospital is paying the resident?s salary and benefits, travel costs, lodging, etc., there may in fact be no costs (hence payments) to the non-hospital site. This would frequently be the case in situations where the preceptor is volunteering his/her teaching or supervisory time.

Redistribution of Unused Residency Slots:

Demonstrated Likelihood Eligibility Criteria:

?I support CMS including in the final rule a definition that ?fill rate? is meant to be the number of residents training in a program or programs as of July 1st of each year

Criterion 3: Resident count exceeds Cap

?Item One: Cost report data: The use of the cost report is the most obvious way for CMS to get this information. However, it is not the sole indicator available. In many instances an FTE request greater than the cap is not entered into the cost report due to the fact that it is futile to do so as the reimbursement will not change. However, Intern and Resident Information Survey (IRIS) data, contract cover pages, resident schedules, etc. can all be used to demonstrate that the actual resident FTE that could be counted for IME and DME purposes is greater than the cap allows. I propose that CMS allow hospitals to use these alternative sources of information.

?Item Three: Copies of Recent Accreditation Letters: I think this requirement is useful for the purpose of showing a program is accredited and to what degree the program intends to expand the program.

Priority for Redistribution, Priorities within a category:

I applaud CMS in attempting to meet not just the letter of the law, but the spirit, in crafting its priority list to include priorities such as rural and underserved areas, minority institutions, etc.

?Family practice programs with only three or more months of rural training have production rates of over 50% practicing in rural settings. For our rural training tracks, although small in number, the rate of production of those practicing in rural communities rises to over 70%. For comparison, the other two primary care specialties, general internal medicine and pediatrics, the proportions were 8% and 7.4 % in rural practice respectively.

?I encourage CMS to address the question of an additional evaluation criterion granted based on where the graduates of the program go in to practice. Many worthwhile programs not located in rural or underserved designated areas produce a fair number of residents who locate their practices in such areas. As such, in keeping with the Congressional intent of this section of statute, it makes sense for CMS to award a priority point for those situations as well.

CMS-1428-P-197

Submitter : Ms. Esther Bailes **Date & Time:** 07/12/2004 07:07:02

Organization : Southern Regional Medical Center

Category : Hospital

Issue Areas/Comments

Issues 21-30

Hospitals-Within-Hospitals

My comments exceeded the 4000 character limit so I am attaching a word document for review.

CMS-1428-P-198

Submitter : Mr. Lacy Thomas **Date & Time:** 07/12/2004 07:07:11

Organization : University Medical Center of Southern Nevada

Category : Hospital

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

Dear Doctor McClellan:
Thank you for the opportunity to submit comments on the draft rule: ?Proposed Changes to the Hospital Inpatient Prospective Payment System for Fiscal Year 2005,? published in the Federal Register on May 18, 2004. University Medical Center of Southern Nevada is the primary training site of Graduate Medical Education for the State of Nevada. As you know, though UMCSN is located in the largest urban center, Las Vegas, the majority of the state is considered rural. As Nevada expands, the demand for quality healthcare increases, and UMCSN is committed to meeting these growing needs; in both the rural communities, as well as the urban center. Currently, the State of Nevada lacks an Emergency Medicine Training Program. Since it is well understood that physicians frequently remain where they train, or return to their home state, we anticipate a training program within the state should assist us, as we continually strive to improve the healthcare of Nevadans.
UMCSN is pleased that Congress addressed the issue of disparities in residency training opportunities in the MMA (Sec. 422), and we appreciate CMS? efforts to develop objective implementation criteria. We feel strongly that CMS should ensure that hospitals that receive redistributed positions use them only for the specialty programs that meet the evaluation criteria.
The Balanced Budget Act?s (BBA) imposition of aggregate and hospital-specific caps on GME programs in 1996 had a significant negative effect on increasing training programs and positions for medical students seeking board-certification in emergency medicine. Demand for emergency services continues to rise. The Emergency Department continues to manage an increasingly larger volume and higher acuity of patients, and the most qualified physicians are those that are residency-trained and board-certified. Fortunately, demand for emergency residencies is consistently high, and the national fill rate for emergency resident positions has been close to 100 percent over the past five years.
The legislative language in the MMA, as well as the draft regulations included in this rule, are priority weighted to foster reduction in geographical mal-distribution of physicians by providing more residency training opportunities in rural areas. Though we are considered a rural state, EM training occurs in high-volume Emergency Departments located primarily in urban settings. Therefore, the proposed evaluation criteria in the six-page form: ?Application for the Increase in a Hospital?s FTE Caps under Sec. 422 of the MMA? would diminish the priority of Emergency Medicine Training Programs without taking into account the state?s status as a rural state. UMCSN urges CMS to give priority weight to emergency residency programs that serve largely rural states. Because Emergency Medicine Physicians will serve as a first line of defense, we urge consideration be given to programs fulfilling ?Section C - Evaluation Criteria? that include bio-terrorism and disaster preparedness training and coordination with state EMS organizations and the Department of Homeland Security.
We appreciate your efforts, and ask that you give increased weight and consideration to those programs that are ?the first of their kind in the state?. Those training programs that are the first of their kind in the state, and likely the only in the state, will meet the greatest need, and carry the greatest burden of training physicians.
Additionally, we would like clarification on newly accredited programs that will start in 2006. Are these eligible to receive the full complement of accredited positions, or are only the first and second year eligible, (e.g. 12 of 18 accredited slots) under these regulations?
UMCSN appreciates the opportunity to offer these comments, and looks forward to the opportunities in expanding its training of physicians.
Sincerely,
Lacy Thomas, CEO
University Medical Center of Southern Nevada

Submitter : Dr. Andrew Oliveira **Date & Time:** 07/12/2004 07:07:52

Organization : Valley Family Medicine

Category : Physician

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

Written Agreements:

1 I agree there is no need for CMS to require a written agreement, and we appreciate the attempt to lighten the regulatory burden for hospitals complying with the regulations surrounding graduate medical education. However, for the purposes of family medicine education, written agreements are already required by the Residency Review Committee (RRC) for Family Practice and are part of the accreditation process.

2 CMS's proposal to replace the written agreement with a payment requirement is not a better solution. To expect an institution to pay within 30 days after the training has occurred adds a tremendous burden to the hospital. It makes more sense to require that payment, if any is incurred, be made within the cost reporting period, without any further restrictions.

3 We request that CMS to make very clear in regulation or intermediary instruction that if there are no payments made to the non-hospital site by the hospital, that is not an a priori reason to deny time spent by residents in that environment. If the hospital is paying the residents salary and benefits, travel costs, lodging, etc., there may in fact be no costs (hence payments) to the non-hospital site. This would frequently be the case in situations where the preceptor is volunteering his/her teaching or supervisory time.

CMS-1428-P-200

Submitter : **Date & Time:** 07/12/2004 07:07:13

Organization :

Category : Hospital

Issue Areas/Comments

Issues 1-10

Revised MSAs

see attachment

Issues 11-20

ESRD Discharges

see attachment

Hospital Quality Data

see attachment

Post Acute Care Transfers

see attachment

Issues 21-30

Hospitals-Within-Hospitals

see attachment

Issues 31-40

Operating Payment Rates

see attachment

CMS-1428-P-200-Attach-1.doc

CMS-1428-P-200-Attach-1.doc

CMS-1428-P-200-Attach-1.doc

CMS-1428-P-200-Attach-1.doc

CMS-1428-P-200-Attach-1.doc

CMS-1428-P-200-Attach-1.doc

CMS-1428-P-201

Submitter : **Date & Time:** 07/12/2004 07:07:51

Organization :

Category : Hospital

Issue Areas/Comments

Issues 1-10

Revised MSAs

see attachment

Issues 11-20

ESRD Discharges

see attachment

Hospital Quality Data

see attachment

Post Acute Care Transfers

see attachment

Issues 21-30

Hospitals-Within-Hospitals

see attachment

Issues 31-40

Operating Payment Rates

see attachment

CMS-1428-P-201-Attach-1.doc

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CMS-1428-P-201-Attach-1.doc

CMS-1428-P-201-Attach-1.doc

CMS-1428-P-201-Attach-1.doc

CMS-1428-P-202

Submitter : Ms. Esther Bailes **Date & Time:** 07/12/2004 08:07:21

Organization : Southern Regional Medical Center

Category : Hospital

Issue Areas/Comments

Issues 21-30

Hospitals-Within-Hospitals

Please see my attached file with my comments.

CMS-1428-P-202-Attach-1.doc

CMS-1428-P-203

Submitter : Mr. Mark Taylor **Date & Time:** 07/12/2004 08:07:20

Organization : Spectrum Health

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

Occupational Mix

CMS is proposing to base the FY05 wage index on a blend of 10% of the wage data adjusted for occupational mix and 90% of the data unadjusted for the occupational mix with the CMS not currently proposing a phase-in of the occupational mix adjustment beyond 2005. We would request that since the timeframe was so short and that the instructions for completing the survey were not clear, that CMS base the wage index on a blend of 5% of the wage data adjusted for occupational mix and 95% of the data unadjusted for occupational mix
to furter minimize the impact. Furthermore, we would request that no ocuupational mix adjustment be applied in future years.

Issues 21-30

Graduate Medical Education

CMS is proposing that if a hospital can document that a particular resident matches simultaneously for a first year of training in a clinical base year in one medical specialty, and for additional years of training in a different specialty program, the resident's initial residency period would be based on a period of board eligibility associated with the specialty in which the resident matches for the subsequent years of training and not on the period of board eligibility associated with the clinical base year program, for GME payment purposes.
We strongly support this proposal that CMS use the second year of training to determine the proper residency period, as it will prevent potentially negative impacts of using the first year to determine initial residency period.

CMS is proposing to eliminate the the requirement of a written agreement to demonstrate that the hospital incurs all, or substantially all, of the costs for the training program at the non hospital site. We support that proposal. We also request that the CMS eliminate the requirement that payment for training costs in any one month must be made in the by the end of the following month. This would create a significant paperwork burden on hospitals, as contracts would need to be rewritten to incorporate this new requirement. We request that the CMS should eliminate the requirement for payment within 30 days as a condition for counting the resident as the contract should provide ample evidence of the intent of the relationship.

For purposes of counting unused resident slots, we request that the CMS provide hospitals with the option of including appealed resident counts (if successful) in the determination of unused resident slots. Furthermore, we request that CMS recognize that affiliation agreements exist whereby joint programs between providers for resident services are set up through a separate organization. The providers fund this organization which in turn pays the costs of the rotations to non provider settings. Even thought the providers are not directly paying the costs of the rotations to the non provder site, they are indirectly paying via a funding mechanism, and these rotations should be included for purposes of the count.

CMS-1428-P-204

Submitter : **Date & Time:** 07/12/2004 08:07:06

Organization :

Category : Hospital

Issue Areas/Comments

Issues 1-10

Revised MSAs

see attachment

Issues 11-20

ESRD Discharges

see attachment

Hospital Quality Data

see attachment

Post Acute Care Transfers

see attachment

Issues 21-30

Hospitals-Within-Hospitals

see attachment

Issues 31-40

Operating Payment Rates

see attachment

CMS-1428-P-204-Attach-1.doc

CMS-1428-P-204-Attach-1.doc

CMS-1428-P-204-Attach-1.doc

CMS-1428-P-204-Attach-1.doc

CMS-1428-P-204-Attach-1.doc

CMS-1428-P-204-Attach-1.doc

CMS-1428-P-205

Submitter : **Date & Time:** 07/12/2004 08:07:22

Organization :

Category : Hospital

Issue Areas/Comments

Issues 1-10

Revised MSAs

see attachment

Issues 11-20

ESRD Discharges

see attachment

Hospital Quality Data

see attachment

Post Acute Care Transfers

see attachment

Issues 21-30

Hospitals-Within-Hospitals

see attachment

Issues 31-40

Operating Payment Rates

see attachment

CMS-1428-P-205-Attach-1.doc

CMS-1428-P-205-Attach-1.doc

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CMS-1428-P-205-Attach-1.doc

CMS-1428-P-205-Attach-1.doc

CMS-1428-P-205-Attach-1.doc

CMS-1428-P-206

Submitter : Mr. Mike DeVaughn **Date & Time:** 07/12/2004 08:07:40

Organization : WakeMed Health and Hospitals

Category : Hospital

Issue Areas/Comments

Issues 1-10

Hospital Redesignations

See Attachments

CMS-1428-P-206-Attach-1.doc

CMS-1428-P-206-Attach-2.pdf

CMS-1428-P-207

Submitter : Mr. J Peter Selman **Date & Time:** 07/12/2004 08:07:14

Organization : Appling Healthcare System

Category : Individual

Issue Areas/Comments

Issues 1-10

Revised MSAs

As the administrator of a small, rural hospital in southeast Georgia I know firsthand that the proposed payment decrease of 1% (rural payment calculations by a negative 0.514 will be devastating to our ability to survive. We are the largest employer in the City of Baxley (350 employees) but have had a negative operating margin for the past six years in a row. I support a wage index cap at 2.5% which would give us a modest 1.1% increase. Georgia's PPS rural and most MSA payments increases are some of the lowest in the nation.

Issues 31-40

Critical Access Hospitals

Appling Hospital is a 39-bed hospital in southeast Georgia. We are an excellent candidate for the critical access hospital program. However, our Board of Directors decided against CAH when the bed limit was 15 beds with 10 swing beds. We then proceeded to convert 15 of our 39 beds for geriatric behavioral health purposes. This has been a tremendous success for our community. Subsequently, Medicare changed the CAH bed limit to 25 beds and allowed up to 10 beds for a psych unit. I respectfully request that our hospital be grandfathered in the CAH program. We desperately need to be a part of the CAH program but we would like an exception to be made that would allow up to keep our 15 bed psych unit. Thank you for your consideration.

CMS-1428-P-208

Submitter : Mr. Christopher Carney **Date & Time:** 07/12/2004 08:07:09

Organization : Bon Secours Health System

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan,

On behalf of the Bon Secours Health System, I thank you for the opportunity to submit the following comments on the notice of proposed rulemaking on the Fiscal Year 2005 Hospital Inpatient Prospective Payment System.

PROPOSED CHANGES IN THE AREA WAGE INDEX
We urge CMS to provide at least a three-year hold harmless protection policy for any hospital that is adversely impacted by more that 10 percent in their area wage index as a result of the adoption of the proposed new labor market definititions.

OUTLIER PAYMENT ADJUSTMENT FACTOR
We urge CMS to revise its assumptions concerning the rate of increase in charges by using a projection rather than historical data as the historicla period utilized precedes the October 1, 2003 policy changes.

EXPANSION OF POSTACUTE TRANSFER PAYMENT POLICY
We are concerned about the apparent arbitary manner in which the alternative criteria for proposed new DRG 541 and DRG 542 was developed and request that CMS provide analytical support and rational for the new criteria.

HOSPITAL WITHIN A HOSPITAL
We are strongly opposed to the proposed universal requirement that would impose a 25 percent cap on admissions referred by the host hospital to a long term care hospital within a hospital. If such an approach is adopted to address abuses by a few hospital, the restrictins will severely curtail the availability of needed care for Medicare beneficiaries - forcing hospitals, patients and their families to seek out alternative and less optimal service options.

We strongly urge CMS to re-evaluate its policy options in relation to its concerns. If CMS is concerned about the criteria's ability to protect the Medicare program from certain abuses, it would be better for CMS to target its policy changes to address just those situations, rather than using a broad policy approach that adversely impacts all hospital with co located hospital within a hospital.

In closing, thank you again for the opportunity to comment on the proposed hospital inpatient PPS rule. We hope you find these comments helpful.

Sincerely,

Christopher Carney
President and CEO
Bon Secours Health System

CMS-1428-P-209

Submitter : Dr. Elizabeth Burns **Date & Time:** 07/12/2004 08:07:12

Organization : University of North Dakota SOMHS, DFM

Category : Academic

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

I represent the three Family Medicine Residencies in North Dakota. All the Centers are operated by the university and we have affiliation agreements with the local hospitals. Denials of GME payments after auditing due to interpretation of the volunteer faculty rule is putting stress on the finances of the residencies and almost resulted in the closure of our Bismarck program this year. I would like you to consider the following comments:

Written Agreements:

We agree there is no need for CMS to require a written agreement, and we appreciate the attempt to lighten the regulatory burden for hospitals complying with the regulations surrounding graduate medical education. However, for the purposes of family medicine education, written agreements are already required by the Residency Review Committee (RRC) for Family Practice and are part of the accreditation process.

CMS?s proposal to replace the written agreement with a payment requirement is not a better solution. To expect an institution to pay within 30 days after the training has occurred adds a tremendous burden to the hospital. It makes more sense to require that payment, if any is incurred, be made within the cost reporting period, without any further restrictions.

We request that CMS to make very clear in regulation or intermediary instruction that if there are no payments made to the non-hospital site by the hospital, that is not an a priori reason to deny time spent by residents in that environment. If the hospital is paying the resident?s salary and benefits, travel costs, lodging, etc., there may in fact be no costs (hence payments) to the non-hospital site. This would frequently be the case in situations where the preceptor is volunteering his/her teaching or supervisory time.

Implementation of Moratorium:

We are extremely pleased that the agency interpreted the statute to include both audits undertaken during this calendar year, and agreements for this calendar year. However, we are still concerned that CMS is abrogating its own regulatory policy by denials of payment for time spent in nonhospital sites where the supervisory physician is volunteering his/her services. Again, we urge CMS to discontinue its audit denials on this issue in the future.

CMS-1428-P-210

Submitter : Ms. Donna Fox **Date & Time:** 07/12/2004 08:07:20

Organization : Cambridge Health Alliance and Mt. Auburn Hospita

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

We are writing to offer comments on the proposed rule for the FY 2005 Inpatient Prospective Payment System (IPPS). In concert with the Massachusetts Hospital Association, we request revisions to the proposed rule in order to more accurately define wage areas in the Greater Boston region and to provide relief to hospitals, like ours, that have been negatively impacted by the proposed wage index changes.

Specifically, the exclusion of our two health systems from the new Boston-Quincy Core Based Statistical Area (CBSA) unduly interferes with natural geographic labor patterns and the practical workings of the area health care labor market and, as a consequence, inequitably places our institutions at a financial and competitive disadvantage in the marketplace.

Our two health systems, Cambridge Health Alliance and Mount Auburn Hospital based in Cambridge, Massachusetts, are geographically the most proximate to the Boston area. Our health care locations are within two to three miles of all the major Boston hospitals ? which define the competitive wages in our area. Some of our outpatient health care locations are just over one mile away from Boston hospitals. The proximity and ease of travel between our facilities and the major Boston hospitals drive the local wage indices and labor market, and are not arbitrarily bound by the new county-based lines drawn in the proposed 2005 regulations. This new county boundary, as a practical matter, does not serve as a rational border on the labor market. We rely on the same labor pool as those hospitals located in the new Boston-Quincy grouping.

In addition, both of our health care systems are clinically affiliated with Boston-based academic medical centers and health systems. In many instances, our clinicians jointly practice in both our health care systems and affiliates? locations in Boston. Given these close clinical affiliations, the arbitrary boundary excluding Cambridge and other close-in health care institutions from the Boston CBSA is particularly troublesome and incompatible with clinical practice patterns. Furthermore, our locations are more economically and socially connected to the Boston area than to the balance of the new Middlesex County designation to which we have been moved. Several of the hospitals in our new county designation extend to a 30 - 35 miles radius in distance from our facilities, requiring substantial travel time and a variation in labor market.

This will have an adverse impact on our ability to recruit and retain employees, as closely located facilities will have an advantage in the Medicare area wage index. As proposed, neighboring hospitals within a short, several mile proximity of our facilities will have a greater than 4.2% advantage in the area wage index ? a meaningful differential that would in fact erode our recruitment and retention of employees in this tight market. Left uncorrected, this will ultimately have negative ramifications on our financial performance and our ability to serve the Medicare population. By moving us out of our natural labor market designation, one of the two Cambridge-based health systems has the highest average hourly wages in the new region as we were among the top percentile in the Boston region.

CMS-1428-P-211

Submitter : Mr. Jeffrey Moore **Date & Time:** 07/12/2004 09:07:03

Organization : South Central Regional Medical Center

Category : Hospital

Issue Areas/Comments

Issues 1-10

Hospital Redesignations

In its proposed rule entitled, ?Medicare Programs; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates; Proposed Rule,? published in the May 18, 2004 Federal Register, the Centers for Medicare and Medicaid Services (?CMS?) solicited public comment on various proposals which would affect the wage index reclassification process for various categories of hospitals. This comment is submitted on behalf of South Central Regional Medical Center (?South Central?), CMS Provider No. 25-0058. The purpose of this comment is to request relief for hospitals, including South Central, who qualify for reclassification to a Metropolitan Statistical Area (?MSA?) in which all hospitals have reclassified to another MSA.

1. South Central suffers because it reclassified to an ?empty MSA? in which all hospitals have reclassified to another MSA.

South Central is a 285-bed Medicare-designated sole community hospital and rural referral center located in Laurel, Jones County, Mississippi. South Central?s nearest competitors offering comparable services are located approximately 30 miles from South Central in Hattiesburg, Mississippi. South Central provides vital health care services that residents of Jones County and the surrounding areas otherwise would receive from hospitals in larger medical communities many miles distant. These services include emergency services, a women?s center, rehabilitation services, a wellness center, surgical services, diagnostic and imaging services, cardiac services, outpatient services, a nursing home, home health services and hospice services.

Until fiscal year 1995, South Central was periodically reclassified to the Jackson, Mississippi MSA and received a substantial benefit from reclassification. Reclassification allowed South Central to compete, not only with nearby urban hospitals, but also with nearby rural hospitals that reclassified to the Jackson MSA and the Gulfport-Biloxi MSA.

In fiscal year 1995, the Hattiesburg, Mississippi MSA was formed, comprised of Forrest and Lamar counties. The Hattiesburg MSA borders Jones County, where South Central is located. In fiscal years 2002-2004, all of the hospitals located within the Hattiesburg MSA reclassified for wage index purposes to the next closest MSA, the Gulfport-Biloxi MSA (formerly the Biloxi-Gulfport-Pascagoula MSA). This reclassification resulted in significant increased Medicare payments to these hospitals. Suddenly, through no action of its own and no shift in the labor market, South Central?s ability to compete with other hospitals in the area was drastically reduced. South Central now may apply for reclassification to the Hattiesburg MSA but, unlike each of its competitors, receives no benefit from such reclassification.

Since fiscal year 1995, the MGCRB has reclassified most Mississippi rural referral centers, including South Central?s competitors, to MSAs with a higher wage index. South Central?s competitors include rural referral centers in Meridian, Mississippi (58 miles distant) and in Hattiesburg, Mississippi (23 miles distant). These hospitals each reclassified to the Jackson MSA and the Gulfport-Biloxi MSA. As a result of its reclassification to the Hattiesburg, Mississippi MSA and its inability to reclassify to any other urban area, South Central receives a lower wage index than any other rural referral center in Mississippi meeting the reclassification criteria.

This situation places South Central in the position of reclassifying to the Hattiesburg MSA, which receives the rural floor wage index (0.7665 for fiscal year 2005), while its nearest competitors qualify for reclassification to the Gulfport-Biloxi MSA or the Jackson MSA, each of which receive a much higher reclassified wage index (in fiscal year 2005, 0.8783 and 0.8305, respectively). Based on proposed fiscal year 2005 PPS rates, South Central will receive an estimated $268.41 less per Medicare discharge in fiscal year 2

Submitter : Mr. Craig Melin **Date & Time:** 07/12/2004 09:07:01

Organization : Cooley Dickinson Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

There is no questions that the population is aging and that our patients will need both the OR's and the patient care space to care for them. Unexpected and dramatic drops in revenue from Medicare threaten our ability to provide care in appropriate facilities. The short term impact of inadequate facilities will be in care. The longer term impact could well be a shift of patients from our organization to the teaching hospital, at higher cost (and higher AWI) that is 12 miles away. Already, eastern Massachusets has lost its community hospitals. This AWI change threatens the community hospitals in Western Massachusets, a deterioration that will actually bring higher costs to CMS, much as the lack of community hospitals in Boston means a higher average cost for CMS in Eastern Mass.

The second impact of a low AWI is comparative. At the same time that Cooley Dickinson and all other community hospitals in Western Mass have a yet lower AWI at 1.0188, Baystate Medical Center, the teaching hospital in our midst is classified as located in Hartford, with an AWI of 1.0981. The entire region has a lack of nurses and other clinical/technical staff. We draw from the same pool of employees. Yet the AWI discrepancy, treating the largest hospital, with the most staff, as if it were located in Hartford, creates an imbalance that is a hardship for all of the community hospitals. Essentially, the teaching hospital has an 8% advantage in funding to recruit from the same pool of staff. The lack of sufficient staff for the area, coupled with an economic advantage for the "Hartford" hospital in our midst, means a built in drain of staff from the community hospitals to the teaching hospital.

For both sets of reasons, the unintended impact sudden and repetitive cutbacks have on our viability, and the market pressures that incent staff to go to the Springfield, MA hospital "located" in Hartford for purposes of AWI, we respectfully request that the final AWI allocations be reconsidered. Two guidelines stand-out - First: changes, especially negative changes, should be made gradually, not all at once (nor, as is the case and worse, twice). Second: the AWI should not create market inequities that compromise the ability of hospitals to succeed (in this case, community hospitals).

A clear remedy is spelled our in the President's Pay Agent's Annual Report on Locality-Based Comparability Payments for the General Schedule, published on December 4, 2003 by the Office of Personnel Management. Specifically on page 20, there is a recommendation that for the purposes of paying federal government employees, the Springfield Area be treated as if it were part of Hartford. The federal government should be consistent. Already, you've moved our largest hospital to Hartford. The logic was that Baystate Medical Center was recruiting from the same labor pool as the Hartford Hospitals. Cooley Dickinson and the other hospitals in our community draw from the same pool as Baystate. Both the remarkable drops in AWI and the inequity of recruitment could be corrected if the provisions which the federal government applies to its own employees were applied to the employees of hospitals in the Springfield area.

If I can provide you with any additional information regarding our comments, please do not hesitate to contact me at (413)582-2212.

Sincerely,

Craig N. Melin

Issues 1-10

Wage Index

Craig N. Melin, President/CEO
Cooley Dickinson Hospital
60 Locust Street
Northampton, MA 01060

July 12, 2004

The Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

RE: CMS-1428-P; Medicare Program, Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates

Dear Dr. McClellan:

On behalf of Cooley Dickinson Hospital in Northampton, MA, for which I am CEO, I am writing to express my great concern for the series of Area Wage Index drops in payment level in Western Massachusetts. For fiscal '04, with virtually no warning, this change in AWI from 1.128 to 1.0543, dropped our revenue by over $1,000,000. Now we find yet another drop in AWI for '05. We are further informed that the AWI quoted in the currently available Federal Register overstates our AWI for '05, so we have another short notice drop in revenue. As the wage index drops to 1.0188 Cooley Dickinson will lose an additional $500,000 per year, for a total loss per year of over $1.5 million.

We fully support the letter sent to you by Mr. Kirkpatrick of the Mass Hospital Association. However, I wanted to make clear the impact of sudden changes and the impact of what look like "numbers" in Washington, and how they translate into people and care when they reach Medicare providers and our patients.

Last year, when CMS dropped from the Massachusetts rural floor, those hospitals which became critical access, CMS broke with past practice and dropped the transition in payment methodology that would have smoothed the revenue impact for the hospitals in Western Massachusetts that were then confronted with a sudden drop off in revenue. This was done in the final printing of the guidelines, with no prior warnings, leading to a drastic drop-off in payment for us.

We therefore anticipated that CMS might recognize the unintended disruption to our care and would perhaps provide some mitigation in the upcoming '05 year. Instead, the AWI is dropping again, from 1.0543 to 1.0188 and even that drop-off is understated in the Federal Register. We are fortunate that the Massachusetts Hospital Association and our Congressman warned us of your printing error this year.

Two things happen as a result of these cutbacks - a scramble to contain costs further than we thought possible, immediately, and a market recruitment problem, based on comparison to nearby hospitals that receive a different payment structure.

Regarding the sudden cutback, Cooley Dickinson Hospital is one of the remaining hospitals in Massachusetts. In the late 80's we nearly closed, we were down to three days cash and had 7 years of successively larger losses. We've been fortunate, and we've managed well. We've pulled ourselves to better than break even on an annual basis for a dozen years. But those years of losses devasted our facilities and equipment. So any surpluses have been put back into facilities and equipment.

We have a major capital project in the final planning stages, as our OR's are too small for current procedures, and too few, and our inpatient beds are far too cramped - they are grandfathered to allow for their current configuration, but we wouldn't be allowed to build space this cramped under today's guidelines. In addition, we have too few beds to accommodate our patients.

So we've been moving forward on a major capital project to replace the OR's and build more bed space. Doing this requires some accumulation of capital, and it also requires borrowing. Lenders don't lend to organizations whose finances don't support being able to pay them back. The difference is the most surplus we've been able to squeeze out, except for the unexpected one-two punch from the Medicare Area Wage Index, and the underpayments from the Medicaid (which pays CDH at just over 60% of cost).

SEE CONTINUATION UNDER GENERAL COMMENTS

CMS-1428-P-212-Attach-1.doc

CMS-1428-P-212-Attach-1.doc

Submitter : Patricia Andersen **Date & Time:** 07/12/2004 09:07:29

Organization : Oklahoma Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

Issues 1-10

Hospital Redesignations

Hospital Reclassifications

Special Circumstances of Hospitals in All-Urban States
CMS is requesting comments on the need for a special adjustment for all-urban states. The law specifies that the wage index for an urban area cannot be less than the wage index applicable to rural hospitals in the state. This is referred to as the ?rural floor?. A few states have no rural areas and it has been suggested that hospitals in these states are disadvantaged by the absence of some minimum wage index such as a rural floor. CMS suggests that it might be possible to impute a wage index floor for these states.

We question whether CMS has the authority to administratively create a minimum wage index for all-urban states. The rural floor was established through legislation and it would seem that any alternative that served the same purpose would also require legislation. In addition, CMS notes that this change would need to be budget neutral, reducing payments for all other areas. The only way that budget neutrality could be avoided is through legislation.

Wage Index Floor
The OHA believes that the concept of a floor for all-urban states is a clear example of a more general problem. An imputed floor for hospitals in all-urban states would protect those hospitals from unreasonable decreases in their wage index. However, the hospitals in the rural areas of all states have a similar problem in that they also have no protection from unreasonably low wage indexes. More generally, many urban and rural hospitals across the nation can point to specific circumstances that cause them to have an inequitable wage index that does not accurately reflect the labor market in which they must compete. We believe that a general solution is preferable to a piece meal fix that only applies in a few specific cases.

CMS should seek a legislative solution that does not fix the problem at the expense of other hospitals. Legislation has been proposed in the past that would establish a national wage index floor that would apply to all hospitals. The OHA continues to support the concept of a national wage index floor or some other means of providing an equitable minimum wage index for all hospitals. We urge CMS to seek a legislative solution that would accomplish this goal.

LTC-DRGs

Proposed Re-weighting of the LTCH DRGs
The proposed rule would re-weight and reclassify the LTCH DRGs in manner that would inappropriately decrease aggregate payments to LTCHs by $55 million. In the proposed rule, CMS notes that the change in relative weights is due to an increase in the average LTC-DRG relative weight as a result of an increase in cases being assigned to LTC-DRGs with higher relative weights. It would appear that an aggregate decrease in LTCH payments of $55 million based upon changes in the LTC-DRG relative weights violates the basic principle of maintaining budget neutrality. We encourage CMS to either adjust the weights to ensure that the total payments to LTCHs is budget neutral, or to make a corresponding increase to the LTCH standardized amount to account for the anticipated $55 million payment reduction.

Revised MSAs

Revisions to MSAs

CMS is not required by law to update wage area definitions, but has proposed to adapt the new Office of Management and Budget (OMB) definitions based on the 2000 U.S Census data. OMB guidelines state that the definitions are established solely for statistical purposes and ?are not intended to serve as a general-purpose geographic framework for non-statistical activities?. If the definitions are used for non-statistical purposes, OMB indicates that it is the sponsoring agency?s responsibility to ensure that the definitions are appropriate for such use. The guidelines

specify that the agency may modify the OMB definitions as appropriate for the purposes of the program.

The revised wage area definitions have a substantial impact on some hospitals. CMS has recognized the negative payment implications for hospitals that are currently located in an urban area but would become rural under the new definitions. Therefore, CMS proposes to allow these hospitals to maintain their assignment to the urban area for a three year transition period. OHA supports this proposal. However, the OHA requests that CMS specify that the urban assignment will apply not only for wage index purposes, but will also apply for other inpatient payment methodologies. For example, disproportionate share payments for these hospitals should not be subject to the 12% limit that is applied to rural hospitals.

The revised definitions could also have a substantial negative impact for some hospitals that are currently rural but would be redefined as urban. Hospitals with special rural status, such as Rural Referral Centers (RRC), Sole Community Hospitals (SCH), Medicare Dependent Hospitals, and Critical Access Hospital (CAH) should not lose that status because of a change in geographic definition. The OHA urges CMS to provide a ?grandfather? provision to protect the hospitals in this situation.

An additional problem for many hospitals that are currently rural but would be redefined as urban will surface in years subsequent to FFY 2005. Many of these hospitals that have reclassifications for FFY 2005 may not be able to meet the criteria for reclassification in the future. As urban hospitals, they will have to meet a 15 mile distance test rather than the 35 mile test that is currently applied to them as a rural hospital. In addition, the average hourly wage criteria will be more stringent. Reclassification requests for FFY 2006 will be due this September so CMS must address this issue in the final rule. We urge CMS to provide protection for rural hospitals that are redefined as urban by allowing them to continue to apply for reclassification using the rural criteria.

Wage Index

Wage Index

Hospitals with Reclassification Alternatives
The proposed rule includes several changes to wage index reclassifications. These include the affect of new wage area definitions, Section 1886 (d)(8)(B) redesignations (referred to as Lugar redesignations), and the proposed wage index adjustment based on commuting patterns of hospital employees. As a result, a hospital may have been granted a reclassification for FFY 2005 by the Medicare Geographic Classification Review Board (MGCRB) and also be eligible for a reclassification based on one of the new alternatives. CMS instructs hospitals in this situation to compare the wage index under the potential reclassifications or adjustments and submit a request to withdraw its MGCRB reclassification request if an alternative is more beneficial. Withdrawals were required within 45 days of the publication of the proposed rule.

The OHA believes this requirement for withdrawal of an existing reclassification is unnecessary and unfair. It requires that the hospital give up the certain benefit of the existing reclassification for the uncertain benefit of a proposal. It is possible that CMS could modify the new reclassification rules or that data corrections could change the adjustment such that the hospital no longer benefits by the alternative that was selected.

We join the AHA in requesting that CMS grant all hospitals the most advantageous wage index value possible for FFY 2005. Reclassifying hospitals should be allowed 30 days after publication of the FFY 2005 inpatient PPS final rule to withdraw their reclassification request or to reverse a withdrawal that they made based on the proposed rule.

Hospitals with Lugar and Out-migration Adjustments
CMS automatically reassigns any hospital located in a county that meets specified commuting criteria for a Section 1886(d)(8)(B) Lugar redesignation. In addition, the MMA requires that CMS develop an alternative adjustment to the wage index based on commuting patterns of hospital employees known as the out-migration adjustment. The out-migration adjustment is available to all hospitals in a county that meets the specified criteria. If a hospital in a county meeting the out-migration criteria does not have an existing reclassification, they will automatically receive the adjustment. If a hospital has an existing reclassification, they were instructed to withdraw that reclassification in order to receive the adjustment instead. It is unclear how this instruction applies in the case of a hospital that is eligible for both the Lugar assignment and out-migration adjustment, and benefits by receiving the out-migration adjustment. These hospitals were automatically assigned to the Lugar reclassification area and do not have a reclassification request to withdraw.
Given the lack of clear instructions, these hospitals should be provided an opportunity to determine whether they want to accept the Lugar reassignment or the out-migration adjustment when the final rule is published.

Issues 11-20

Post Acute Care Transfers

Post-Acute Transfers

In the 2004 inpatient PPS rule, the Centers for Medicare and Medicaid Services (CMS) developed specific criteria to determine which Diagnostic Related Groups (DRGs) should be covered by the post-acute transfer payment policy. Base on these criteria, CMS expanded the policy to cover 29 DRGs in FFY 2004. In the 2005 proposed rule CMS found that no additional DRGs met these criteria. However, CMS now proposes alternative criteria which would increase the number of DRGs to 31. The OHA strongly opposes this proposal.

The CMS proposal extending the post-acute care transfer policy to two additional DRGs is arbitrary and should not be implemented. CMS has determined that two new DRGs (DRG 541: Tracheostomy with Major Operating Room Procedure and DRG 542: Tracheostomy without Major Operating Room Procedure) should be covered by the policy because they are replacing a single DRG that is currently on the list (DRG 483: Tracheostomy). Neither of the two new DRGs meets the criteria to be included in the transfer policy. Therefore, CMS proposes to establish alternative criteria that are designed to cover these DRGs. In addition, CMS proposes to add DRG 430: Psychoses to the list of post-acute transfer DRGs. DRG 430 has been in existence sense the initiation of the post-acute transfer policy and has never been considered to be an appropriate DRG for coverage under the policy. Now, due to CMS? proposed alternative criteria, it would be added to the list.

The OHA objects to the implementation of alternative criteria for which there is no sound policy rationale and urge that it be withdrawn in the final rule.

Standardized Amounts

Cost Outliers

The OHA joins the American Hospital Association in opposing the proposed increase in the outlier threshold. CMS proposes setting the FY 2005 threshold at $35,085, a substantial increase of over the FY 2004 threshold of $31,000. This rise will make it more difficult for hospitals to qualify for outlier payments and will put them at greater risk when treating high-cost cases. Shifting this increased financial risk to hospitals will increase the cost shifting to non-Medicare patients of America?s hospitals.

CMS? estimate of the FY 2005 outlier threshold does not take into account its June 9, 2003 final rule that significantly changed outlier payment policy. The rule implements the use of more up-to-date data when determining a hospital?s cost-to-charge ratio (CCR) ? specifically, a hospital?s most recent final or tentatively settled cost report. It eliminates use of the statewide average CCR when the hospital?s CCR falls below established thresholds. It also instructs fiscal intermediaries, in certain situations, to retrospectively reconcile outlier payments when a hospital?s cost report is settled.

CMS itself estimates that actual outlier payments for FY 2004 will be 4.4 percent of actual total inpatient payments, which is 0.7 percentage points less than the 5.1 percent withheld from hospitals to fund outlier payments. The AHA has estimated that the FY 2004 threshold should have been set at $26,565, rather than $31,000, to result in outlier payments of 5.1 percent.

Instead of being increased, the outlier threshold should be lowered to reflect the modifications in outlier payment policy. It is absolutely necessary to ensure hospitals receive the full 5.1 percent of payments that will be withheld from base inpatient payment in FFY 2005, and ensure that hospitals have access to these special payments to cover extremely high-cost patients.

The OHA urges CMS to lower the outlier threshold.

Issues 21-30

Graduate Medical Education

Graduate Medical Education

Residents in Non-Hospital Settings ? Requirement for Written Agreements for Residency Training in Non-hospital settings (pg 28315):

Under the current policy, in order for a hospital to count residents training in non-hospital settings, there must be a written agreement stating that the hospital will incur all, or substantially all, of the costs for the training program at the non-hospital site. CMS states that numerous hospitals have failed to comply with this requirement. CMS believes that a written agreement is not the most efficient aid to fiscal intermediaries in determining if hospitals are actually incurring all of the costs as required. Therefore, CMS proposes to replace the written agreement requirement with a requirement that the hospital pay for the non-hospital training on a concurrent basis.

If the written agreement is not necessary or useful, CMS should eliminate the requirement. However, CMS should not impose a burdensome new requirement for concurrent monthly payments. CMS states that, in addition to checking for a written agreement, the fiscal intermediaries are currently required to determine that hospitals are incurring the appropriate costs. CMS should allow the intermediaries to continue to make these determinations following their current practices. The proposed concurrent payment requirement would impose a substantial burden on hospitals, particularly those with cash flow problems due to financial difficulties. In addition, tracking and confirming the monthly payments it would impose a new and significant task on fiscal intermediaries.

Direct Medical Education Initial Residency Period
The Conference Report that accompanied the Medicare Modernization Act of 2003 (MMA) required that ?the initial residency period for any residency for which the ACGME [Accreditation Council on Graduate Medical Education] requires a preliminary or general clinical year of training is to be determined in the resident?s second year of training.?

CMS notes that ?in many cases? a medical student who wants to train as a specialist is matched to both the clinical base year program and the specialty training program at the same time. CMS is proposing that if a hospital can document that a particular resident matches simultaneously for a first year of training in a clinical base year in one medical specialty and for additional years of training in a different specialty program, the resident?s initial residency period would be based on the period of board eligibility associated with the specialty program in which the resident matches for the subsequent years of training and not on the period of board eligibility associated with the clinical base year program, for purposes of DME payment.

The CMS proposal only partially satisfies the Conference Report instructions. While many specialty program residents may be simultaneously matched, others are not. The Conference Report does not differentiate between the two situations. Instead it covers any specialty program that requires a general year of clinical training.

CMS should revise the policy for all such programs, not just those with a simultaneous match.

Hospital Reclassifications

Hospital Reclassifications

Special Circumstances of Hospitals in All-Urban States
CMS is requesting comments on the need for a special adjustment for all-urban states. The law specifies that the wage index for an urban area cannot be less than the wage index applicable to rural hospitals in the state. This is referred to as the ?rural floor?. A few states have no rural areas and it has been suggested that hospitals in these states are disadvantaged by the absence of some minimum wage index such as a rural floor. CMS suggests that it might be possible to impute a wage index floor for these states.

We question whether CMS has the authority to administratively create a minimum wage index for all-urban states. The rural floor was established through legislation and it would seem that any alternative that served the same purpose would also require legislation. In addition, CMS notes that this change would need to be budget neutral, reducing payments for all other areas. The only way that budget neutrality could be avoided is through legislation.

Wage Index Floor
The OHA believes that the concept of a floor for all-urban states is a clear example of a more general problem. An imputed floor for hospitals in all-urban states would protect those hospitals from unreasonable decreases in their wage index. However, the hospitals in the rural areas of all states have a similar problem in that they also have no protection from unreasonably low wage indexes. More generally, many urban and rural hospitals across the nation can point to specific circumstances that cause them to have an inequitable wage index that does not accurately reflect the labor market in which they must compete. We believe that a general solution is preferable to a piece meal fix that only applies in a few specific cases.

CMS should seek a legislative solution that does not fix the problem at the expense of other hospitals. Legislation has been proposed in the past

that would establish a national wage index floor that would apply to all hospitals. The OHA continues to support the concept of a national wage index floor or some other means of providing an equitable minimum wage index for all hospitals. We urge CMS to seek a legislative solution that would accomplish this goal.

Low-Volume Hospital Adjustment

Low-Volume Adjustment

The Medicare Modernization Act (MMA) requires that ?the Secretary shall provide for an additional payment amount to each low-volume hospital?. The MMA defines a low-volume hospital as having less than 800 discharges. CMS proposes to provide a payment adjustment only for hospitals with 500 or fewer discharges. CMS states that the MMA also requires that CMS determine the amount of the adjustment based on empirical evidence of the relationship between incremental costs and discharges. CMS states that they found no relationship for discharges above 500. CMS states that the MMA language allows them to set the increase at zero if there is no evidence of higher incremental costs.

The MMA requires that CMS provide ?an additional payment amount?. An adjustment of zero does not satisfy this Congressional intent.

CMS should satisfy the statutory requirement and provide an adjustment for hospitals with less than 800 discharges as specified in the MMA.

Issues 31-40

Critical Access Hospitals

Critical Access Hospitals

The OHA continues to oppose the change of policy that patients must be ?physically present in a critical access hospital? when a laboratory specimen is collected in order for the hospital to continue to receive cost-based reimbursement. Currently, Medicare regulations state that payment to a CAH for outpatient clinical diagnostic laboratory tests will be made on a reasonable cost basis if the individuals for whom the tests are performed are outpatients of the CAH at the time the specimen is collected. Tests performed on all others are paid based on the laboratory fee schedule.

This proposed revision is not a clarification of current policy, but rather an implicit change that is contrary to the spirit around the creation of the CAH program. In 1997, Congress created the CAH program and granted cost-based reimbursement for Medicare inpatient and outpatient services to ensure that isolated rural communities have access to critical health care services. Because there are frequently few or no reasonable alternatives to care, CAHs often are the sole source of essential health care services for their communities. Thus, CAHs often provide laboratory services to Medicare beneficiaries in other rural settings, such as rural health clinics (RHCs), skilled nursing facilities (SNFs), nursing homes and patients? homes. This is especially important when the off-site services are provider-based and owned by the CAH.

Compromising the financial stability of CAHs by paying for laboratory testing on a fee schedule is not sound policy. The additional Medicare spending necessary to ensure all CAH clinical laboratory services continue to receive cost reimbursement is minimal, and yet the dollars are incredibly important to CAHs that continue to struggle to survive.

Finally, the change in policy would require Medicare beneficiaries to physically travel to a CAH to have laboratory specimens drawn in order the CAH to be paid as Congress intended. This provides an additional burden on the frail elderly, and the additional time and expense incurred by the patient is unnecessary if the CAH is willing and able to draw a specimen at the point of patient care and transport it back to the CAH for analysis. The elimination of cost-based reimbursement may make it prohibitive for CAHs to continue offering this service, which in turn could limit beneficiary access to a necessary service.

If CMS is concerned that CAHs will become huge reference lab sites for large PPS hospitals, another approach to assuring that lab specimens collected from patients that are not on-site at the CAH should be developed rather than risking the financial health of the CAH and putting an undue burden on Medicare beneficiaries living in the community served by the CAH which currently is in conflict with Congressional intent.

CMS-1428-P-214

Submitter : Michael Capuano **Date & Time:** 07/12/2004 08:07:17

Organization : Michael Capuano

Category : Congressional

Issue Areas/Comments

Issues 1-10

Revised MSAs

July 12, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1428-P
P. O. Box 8010,
Baltimore, MD 21244-1850

Re: CMS-1428-P; Medicare Program, Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates

Dear Dr. McClellan:

As the Member of Congress from the 8th Congressional District of Massachusetts, I have the honor of representing some of the nation?s finest hospitals. I appreciate the opportunity to comment on the proposed rule for the FY 2005 Inpatient Prospective Payment System (IPPS), which corrects long-standing inequities by increasing the Areas Wage Index (AWI) reimbursement for Boston?s teaching hospitals. However, it is also clear that defining labor markets is not always a precise science. Any changes to the IPPS should provide those hospitals that are negatively impacted with some form of relief.

I would like to propose the following revisions to the proposed rule:

1. There should be a new window of opportunity for reclassification for 2005.
2. When significant changes are made in the wage index there should be a transitional ?hold-harmless? provision that cushions any significant and sudden reduction in a hospital?s reimbursement to allow adequate time for adjustment.
3. Relief for hospitals that are impacted negatively by the changes should not come at the direct expense of the hospitals that benefit from the changes.

New window of opportunity for reclassification for 2005

Under the proposed criteria for geographical reclassification, hospitals in the Essex CBSA and the Cambridge-Newton-Framingham CBSA would likely have qualified for reclassification to the Boston-Quincy CBSA had they known of the change in areas in time to apply. Some facilities in the Cambridge-Newton-Framingham CBSA are less than two miles from the hospitals in the city of Boston. However, because CMS?s deadline for filing for reclassification has passed, hospitals that may qualify for reclassification under the proposed criteria will not be able to do so for FFY 2005. I urge CMS to open a new window of opportunity for reclassification for 2005 for these hospitals.

Transitional hold-harmless:

When significant changes are made in the wage index there should be a transitional ?hold-harmless? provision that cushions any significant and sudden reduction in a hospital reimbursement to allow adequate time for adjustment.

CMS has already proposed a three-year hold harmless for former urban hospitals changed to ?rural,? citing a disproportionate impact on these hospitals. CMS reports in the Federal Register that the impact of the proposed adoption of new MSAs on urban hospitals in New England is disproportionately high at -0.4%, the highest among urban hospitals nationally.

Hospitals had no advance warning that these drastic changes would be proposed, and because the proposed rule does not provide negatively impacted hospitals with any new opportunity for reclassification for 2005, they should be held harmless for at least one year. A hold harmless provision would serve two purposes. First, it would protect negatively impacted hospitals them from a sudden, unexpected drop in payments in 2005. Second, it would allow them to explore and apply for reclassification for relief for 2006.

Specifically, I believe there should be a ?hold harmless? provision for hospitals located in counties that are adversely affected by the discontinued use of New England County Metropolitan Areas (NECMAs).

Ensure relief for those negatively impacted does not come at the direct expense of those that benefit

Hospitals that will benefit from the proposed rule should not be negatively impacted by any relief for those hospitals that were adversely impacted by the rule. I suggest that CMS calculate two wage indices, the first using only data for those hospitals that were previously in a NE

CMS-1428-P-215

Submitter : Dr. Gary Stein **Date & Time:** 07/12/2004 09:07:35

Organization : American Society of Health-System Pharmacists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1428-P-215-Attach-1.doc

Submitter : Mr. Cal Calhoun **Date & Time:** 07/12/2004 09:07:21

Organization : Georgia Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

Revised MSAs

See Attached Document

Wage Data

Wage Index

See Attached Document

CMS-1428-P-216-Attach-1.doc

CMS-1428-P-216-Attach-1.doc

CMS-1428-P-216-Attach-1.doc

Submitter : Miss. Kimberly Loden **Date & Time:** 07/12/2004 09:07:21

Organization : South Central Regional Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

This comment is a continuation of the comments on Hospital Redesignations submitted by Jeffrey Moore and myself on behalf of South Central Regional Medical Center. In subsection III.N.3. of the preamble, CMS proposes to use this authority to assist urban rural referral centers that fail to meet the 84% urban threshold for reclassification but would have been able to meet the 82% threshold. In subsection III.N.4., CMS proposes to use this discretion to aid sole community hospitals in certain low population density states that were not assisted by reclassification under Section 508 of the Medicare Prescription Drug, Improvement and Modernization Act (the ?MMA?). In subsection III.N.5., CMS requests comments concerning use of its discretion to allow reclassifications for dominant hospitals and hospitals in single-hospital MSAs. In subsection III.N.6., CMS requests comments on the position of hospitals in all-urban states relative to hospitals that receive the ?rural floor? in other states, and on whether it would be advisable to adopt an imputed floor measure or some alternative measure to address the concerns of hospitals in these all-urban states.
South Central supports CMS?s decision to use its discretion to assist hospitals that are unintentionally disadvantaged by the Medicare geographic reclassification rules. South Central believes that it, too, falls into a category of hospitals unintentionally disadvantaged by these rules. For the reasons stated in Section 1 above, rural hospitals reclassifying into ?empty? MSAs, due to the fact that their competitors have reclassified out of that MSA to an MSA with a higher wage index, are also disadvantaged by the reclassification process. South Central requests that CMS use its discretion pursuant to 42 U.S.C. ? 1395ww(d)(5)(I)(i) to assist South Central.
4. Suggested Remedies.
There are several possible ways to correct these inequities suffered by South Central and other rural hospitals that may reclassify only to an empty MSA. The wage index rules could be revised to provide that when all hospitals within an MSA (the ?home MSA?) qualify to receive payment rates of another MSA (the ?reclassified MSA?), the home MSA will be assigned the same wage index as the reclassified MSA. This would allow rural hospitals reclassifying to the home MSA to receive the wage index assigned to hospitals located with the home MSA after they reclassify to the reclassified MSA. Alternatively, the geographic reclassification rules could be revised to state that if all urban hospitals within the home MSA are reclassified to a reclassified MSA, rural hospitals otherwise seeking reclassification to the home MSA will be exempt from proximity criteria and will be reclassified to the reclassified MSA. Finally, a grandfather clause could be added to the rules for rural hospitals that are detrimentally affected by the formation of a new MSA, which would allow a rural hospital to continue to reclassify to the previous MSA to which it reclassified prior to the formation of the new MSA.
5. Conclusion.
For the reasons set forth above, South Central requests relief pursuant to 42 U.S.C. ? 1395ww(d)(5)(I)(i) to aid South Central and other similarly situated hospitals in their reclassification efforts.

Issues 1-10

Hospital Redesignations

This comment is a continuation of the comment filed by Jeff Moore for this topic. Based on proposed fiscal year 2005 PPS rates, South Central will receive an estimated $268.41 less per Medicare discharge in fiscal year 2004 than it would have received had it reclassified to the Jackson MSA, and an estimated $468.88 less per Medicare discharge than it would have received had it reclassified to the Gulfport-Biloxi MSA. South Central?s payment from Medicare on a per discharge basis is lower than that of any of its competitor hospitals in Hattiesburg, Meridian, Jackson and the Mississippi Gulf Coast and than any other reclassification-qualifying rural referral center in Mississippi.
In fiscal year 2004, South Central is the only rural referral center in Mississippi that qualifies for reclassification, but does not receive a benefit from such reclassification. South Central competes with reclassified hospitals for labor from the same labor pool, buys supplies and equipment from the same suppliers and has costs comparable to the competing hospitals. As a rural referral center, South Central must comply (as must other referral centers) with federal statutes, such as the Emergency Medical Treatment and Active Labor Act, that restrict activities of rural referral centers and impose upon South Central expensive administrative and clinical burdens. Yet South Central receives lower Medicare payments per discharge than any of its competitors.
2. The reduction in Medicare payment to South Central may cause serious detrimental effects to Jones County and the surrounding areas.

According to the U. S. Census Bureau, in 2000, 14.2% of the 64,536 residents of Jones County (over 9,000 people) were over the age of 65. Obviously, South Central?s ability to provide services to Medicare recipients is vital to the residents of Jones County. However, the drastic reduction in Medicare payment that South Central experiences as a result of the formation of the Hattiesburg MSA threatens South Central?s ability to provide services to these individuals.

Additionally, like many hospitals, South Central?s ability to remain viable as a provider of health care services in central Mississippi is largely dependent upon Medicare revenues. Therefore, the reduction in Medicare payment to South Central that results from its inability to gain a benefit from reclassification to an urban area affects not only the health care services that it provides to Medicare beneficiaries, but its overall ability to provide quality health care services at prices comparable to its competitors. South Central?s inability to compete with nearby hospitals for labor threatens its very existence.

In addition to providing health care services, South Central participates actively in many community activities, including ALIVE Jones County, the diabetes education and support group, Health Break and activities sponsored by the Women?s Life Center. The reduction in funds that South Central receives threatens its ability to participate in such outside activities. Thus, Jones County is threatened in its ability to obtain not only health care services, but many community outreach services as well.

3. The May 18, 2004 proposed rule provides relief for four categories of hospitals that would otherwise be disadvantaged by the Medicare geographic reclassification rules.

In Section III.N. of the preamble to the May 18, 2004 proposed rule, entitled ?Medicare Geographic Classification Review Board (MGCRB) Reclassifications,? CMS proposes to use its discretion under 42 U.S.C. ? 1395ww(d)(5)(I)(i) to make exceptions to the Medicare geographic reclassification rules for four different categories of hospitals which would otherwise be disadvantaged by these rules.

CMS-1428-P-218

Submitter : Patricia Andersen **Date & Time:** 07/12/2004 09:07:45

Organization : Oklahoma Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comment letters

CMS-1428-P-218-Attach-1.doc

CMS-1428-P-218-Attach-2.doc

CMS-1428-P-219

Submitter : Ms. Donna Fox **Date & Time:** 07/12/2004 09:07:48

Organization : Cambridge Health Alliance

Category : Hospital

Issue Areas/Comments

Issues 1-10

Hospital Redesignations

Special Case for Highly Proximate Geographies to Major Metropolitan Areas

While we will be collaborating with our hospital colleagues in Middlesex County to apply for county-wide reclassification, we believe that our two health systems uniquely merit reclassification to the Boston-Quincy CBSA as individual hospital systems.

As noted above, we request that CMS administratively initiate the necessary changes to include us in the Boston-Quincy CBSA during the final rulemaking process for fiscal year 2005. Wage areas must recognize that the proposed labor market borders are somewhat arbitrary and that reclassifications must be allowed to avoid inequities among hospitals competing in the same labor markets, but are designated in different wage areas.

Our exclusion from the Boston-Quincy CBSA does not accurately reflect wage levels or the reality of the labor market. We believe that the Medicare rule should be adjusted to better reflect the relative wage level of the Greater Boston area and account for the significant problem created at the newly drawn borders of the CBSAs, both detrimental to the dynamics of the labor market and anti-competitive for health systems, like ours, at the borders.

Reclassification of Our Health Systems in 2005

In addition, we align with the request by the Massachusetts Hospital Association and others to re-open the 2005 reclassification time period so that we are not adversely impacted in the coming fiscal year.

According to initial analysis, Massachusetts hospitals in the Cambridge-Newton-Framingham CBSA and the Essex CBSA would have qualified for ?county-wide? reclassification to the Boston-Quincy CBSA under the proposed criteria for geographical reclassification had we known of the change in areas in time to apply. Because the extensive changes in the wage areas applicable to Massachusetts hospitals we not made publicly available until after CMS?s filing deadline for reclassification, we urge CMS to re-open the period for applications for reclassification in fiscal year 2005 for hospitals that meet current reclassification criteria.

Transitional Hold-Harmless Provisions

In tandem with the requests above and in concert with the Massachusetts Hospital Association, we request the promulgation of a ?hold harmless? provision for hospitals located in counties that are adversely affected by the discontinued use of New England County Metropolitan Areas (NECMAs). This type of hold harmless initiative is crucial to mitigate the adverse financial impacts as reported by CMS in the Federal Register as ?disproportionately high at -0.4%?, which is the highest among urban hospitals nationally. At a minimum, a hold harmless provision for at least one year is critically needed to give us a temporary reprieve to explore reclassification opportunities. This seems consistent with other CMS proposed hold harmless provisions, such as the proposed three-year hold harmless for urban hospitals redefined as rural.

In this regard, we support the proposal outlined by the Massachusetts Hospital Association suggesting that CMS calculate two wage indices, one using only data for those hospitals that were previously in a NECMA and are now in a new CBSA showing an increase in wage index due to the area changes. For hospitals that were previously in NECMAs and that are impacted negatively by the new area designations, we join in requesting CMS to calculate a hold harmless wage index calculated by using data from all hospitals in counties formerly included in the NECMA but now in separate CBSAs.

We are available to provide any further information that may be required. Thank you for this opportunity to provide comments on the proposed Medicare Inpatient Prospective Payment System rule. We respectfully request your favorable consideration of these requests.

Wage Index

We request that the reclassification opportunities be broadened to recognize the realities of labor markets in which we deliver health care services. Specifically, we ask that CMS take steps to include our two health care systems and others closely proximate to the Boston area in the Boston grouping applicable for the federal fiscal year 2005. We request that CMS administratively make these corresponding adjustments in the final regulations, to the extent possible during the final rule-making process. Short of this, we support re-opening the window for reclassification for the coming 2005 fiscal year to allow hospitals, under existing CMS parameters, to apply for reclassification from areas with lower wage indexes to those with higher wage indexes ? as we were permitted no advance notice to do so this year. In tandem, we ask that transitional hold harmless provisions be extended for a period of at least one-year to allow hospitals both a necessary adjustment and re-application period.

CMS-1428-P-219-Attach-1.doc

CMS-1428-P-219-Attach-1.doc

CMS-1428-P-220

Submitter : Ms. Harriet Franklin **Date & Time:** 07/12/2004 09:07:05

Organization : Divine Providence Hospital & Williamsport Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter

CMS-1428-P-220-Attach-1.doc

CMS-1428-P-221

Submitter : Ms. Harriet Franklin **Date & Time:** 07/12/2004 09:07:05

Organization : Divine Providence & Williamsport Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached.

CMS-1428-P-221-Attach-1.doc

Submitter : Mrs. Derwin Manning **Date & Time:** 07/13/2004 12:07:18

Organization : PROMISED LAND FAMILY SERVICES,

Category : Home Health Facility

Issue Areas/Comments

Issues

BACKGROUND

We are having a large quanity of individual that need long term home health care receiving medicare being referred to our agency. Will there be any changes in the future funding for long term medicare patients. Please send a reply at your earliest convience.

dmanning910@yahoo.com

CMS-1428-P-222

Submitter : Dr. John McConaghy **Date & Time:** 07/13/2004 04:07:41

Organization : The Ohio State University Family Medicine Residenc

Category : Physician

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

Please see the attached comments

CMS-1428-P-222-Attach-1.doc

CMS-1428-P-223

Submitter : Dr. Robert Buchanan **Date & Time:** 07/12/2004 12:07:00

Organization : University of California, San Diego, School of Medicine

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Re: New Technology Applications-Kinetra.
I am Assistant Professor of Neurosurgery, Psychiatry, and Radiology. As a physician, any new procedure or device that has patient benefits not previously available, I feel that I must strongly support. The Kinetra device can be placed MUCH easier than the previous generators (Soletras). The ability to tunnel only one wire will drastically decrease patient morbidity, complications, and mortality through being less invasive. I have seen both the lung punctured and the skin inadvertently pierced during the tunneling procedure. These are the kinds of complications that will be decreased by ~50%, if only one traumatic tunneling and incision are required. The new Kinetra device has a longer battery life (longevity) and predictability, which helps the patient avoid coming to the operating room too soon, with all of its inherent risks. I personally do staged implants in my patients. I feel that it provides the safest and quickest way of treating DBS patients. Most of the patients requiring DBS have multiple medical problems and the first part of the DBS procedure is done at UCSD, with the patient awake and fully cooperative. After this first stage, we allow the patient recover for 1-2 weeks. I then bring the patient back for an implantation under general anesthesia. I feel that every patient needs to be assessed by their physician, as to the risk benefit ratio of a single or staged operation. Most DBS patients in my experience are best and most safely operated on in a staged fashion.
Please also approve both, the new technology ambulatory payment classification for the Kinetra system when considering it in the outpatient payment system, and the impatient add-on payment system as well.
Thank you; please feel free to contact me for any further help I could provide.
Robert J. Buchanan, M.D.
Assistant Professor

CMS-1428-P-224

Submitter : Mr. Robert Milewski **Date & Time:** 07/12/2004 12:07:00

Organization : Mount Clemens General Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter for comments

CMS-1428-P-225

Submitter : Mr. Robert Milewski **Date & Time:** 07/12/2004 12:07:00

Organization : Mount Clemens General Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file for comments

CMS-1428-P-226

Submitter : Mr. Anthony Cawiezell **Date & Time:** 07/12/2004 12:07:00

Organization : RSM McGladrey, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See the attached letter regarding CMS-1428-P FFY 2005 IP Proposed Rule

Submitter : Mr. Arthur Tedesco **Date & Time:** 07/12/2004 12:07:00

Organization : Danbury Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

July 12, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: CMS-1428-P; Medicare Program; Proposed Changes to Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates; Hospital Reclassifications

Dear Sir or Madam:

Danbury Hospital (070033) appreciates the opportunity to submit these comments regarding the Centers for Medicare and Medicaid Services (CMS) proposed rule: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates [CMS-1428-P]. If implemented, the changes proposed in the rule will result in a significant cut in funding to all Connecticut hospitals, threatening hospital financial viability and access to care for Medicare beneficiaries.

The significant unintended adverse consequence for Connecticut hospitals is due to the adoption and application of the new Core Based Statistical Areas (CBSAs) for purposes of hospital geographic classifications. The proposed rule would increase hospital inpatient rates by 3.3% for inflation while cutting funding for wages by 7% for most Connecticut hospitals. The net effect of the new wage indices is that: 2005 IPPS payments to Connecticut hospitals will be $46.6 million lower than they were in 2004 and outpatient payments will be $11.6 million lower than they were in 2004. The impact of the other rule elements, i.e. transfers, outliers, and IME, are estimated to cut funding to Connecticut by another $11 million. In sum, these changes would reduce current Medicare funding to Connecticut hospitals by about $70 million dollars.

The specific impact of the proposed rule on Danbury Hospital (070033) is a reduction of 7.8% in our current Wage Index, which represents an overall reduction of reimbursement of approximately $3.1 million. We have met the requirements over several periods and as a result were granted geographic reclassification by the Medicare Geographic Classification Review Board (MGCRB).

I urge you to act on the recommendations submitted as formal comments by the Connecticut Hospital Association that would address the unintended adverse consequences to Connecticut hospitals:

o Allow Connecticut hospitals that were unable to reclassify to elect to adopt the wage index of the next nearest hospital that was able to reclassify, similar to what is being proposed by CMS for hospitals in states with low population density.
o Given the unpredictability of wage indices and their seemingly counterintuitive effect in Connecticut, set as a floor for the next three years those values that were established as of April 2004.
o Include the hospitals of Litchfield County, i.e., The Charlotte Hungerford Hospital, New Milford Hospital, and Sharon Hospital, in Hartford County for wage index purposes, as they have been since 1979.
o Allow hospital groups in Combined Statistical Areas to be able to seek group reclassification, and/or allow hospital groups to be in either a Core-Based Statistical Areas or Consolidated Metropolitan Statistical Area to seek group reclassification.
o Hold harmless those five Connecticut hospitals that have routinely been granted a wage reclassification to prevent any reduction in their wage index for the next three years.
o Hold harmless the hospitals that were able to reclassify under section 508 of MMA for any reduction to their wage index for the next three years.
o Since the criteria to reclass evolve, allow those Connecticut hospitals that have already been reclassed grandfathered in the future.

Sincerely,
Arthur N. Tedesco
Senior Vice President and Treasurer

Submitter : Dr. Peter Pronovost **Date & Time:** 07/12/2004 12:07:00

Organization : Johns Hopkins University School of Medicine

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1428-P: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2005 Rates

Other DRG Issues

CMS has concluded that a new DRG for severe sepsis is not warranted at this time. This is a critical issue that affects quality of care and the ability of hospitals to improve mortality for this highly deadly disease.

We recommend CMS reconsider their decision and create a new DRG for severe sepsis with organ support.

Severe sepsis is a common disease that impacts significant morbidity, mortality and costs of care. More than 750,000 cases of severe sepsis occur in the US annually , which is more than the incidence of congestive heart failure (American Heart Association, 2000). Half of those severe sepsis cases require ICU care1. In the United States, the costs associated with severe sepsis exceed $16 billion2. The mortality associated with severe sepsis has ranged from 30% to 50% despite advances in critical care medicine .

Until recently, there was little evidence to guide therapy for these patients. However, recent studies have demonstrated that specific therapies are associated with improved clinical outcomes for patients with severe sepsis. Unfortunately, these therapies, like many effective therapies, are used infrequently. We are currently leading efforts in over 40 hospitals and in the Fall will add over 100 hospitals in the state of Michigan, to improve the quality of care in patients with severe sepsis. As part of these efforts, we will measure use of effective interventions (process measures). Unfortunately, we have little ability to measure outcomes such as mortality and length of stay. There are no effective mechanisms to identify patients with severe sepsis through discharge data, and it is not feasible for caregivers to track these patients outside the ICU. As a result, in evaluating the quality of care in patients with severe sepsis, we are limited to the use of process measures, rather than outcome measures. This is particularly concerning given that we are working with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to incorporate these sepsis measures into their national ICU core measure set.

If CMS were to create a DRG for severe sepsis, we would have an efficient mechanism to evaluate mortality, length of stay, and costs of care for patients with severe sepsis. In the absence of a DRG, our ability to evaluate the quality of care in severe sepsis patients is limited to process measures. Given the incidence of severe sepsis, its impact on morbidity, mortality and costs, and the national interest in improving the quality of care for patients with severe sepsis, the effort required to create a new DRG seems warranted.

CMS-1428-P-229

Submitter : Mr. David Ramsey **Date & Time:** 07/12/2004 12:07:00

Organization : Charleston Area Medical Center

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

CMS-1428-Long Term Care Hospital and Hospital within a Hospital Provisions--See attached Comment. Thanks

Submitter : Mr. John Heye **Date & Time:** 07/12/2004 12:07:00

Organization : Maine Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Attached please my comments on the CMS draft regulations regarding the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and FY05.

Submitter : Mr. Richard Smith **Date & Time:** 07/12/2004 12:07:00

Organization : JFK Medical Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1428-P-232

Submitter : Mr. John Heye **Date & Time:** 07/12/2004 12:07:00

Organization : Maine Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

July 9, 2004 Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1428-P, P.O. Box 8010 Baltimore, MD 21244-1850 RE: CMS-1428-P: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Dear Sir/Madam: On behalf of Maine Medical Center, I am pleased to comment on the proposed changes to the FY 2005 Inpatient Prospective Payment System (IPPS). Issue: Dominant Hospital Comment Basis:Federal Register May 18, 2004, page 28290, invites comments relative to concerns raised by hospitals. Definition: A hospital that pays a substantial proportion of all wages in its wage area designation. A dominant hospital has significant influence on its own area wages and as a result finds it difficult to meet certain wage threshold tests. [For example, if a hospital must meet a 108% wage test (i.e., its wages must be 108% of its area wages), it is difficult given its own wages are already driving the area average.] The Centers for Medicare and Medicaid Services (CMS) does currently provide an avenue for reclassification for certain .dominant hospitals. based on the following criteria: Criteria " Hospital must comprise 40% of its area wages;
" Hospital must meet the 108% test (without its own wages in average);
" Hospital must have been approved for reclassification for the years 1992 to 1997.
" Hospital must be within 15 miles of requested wage area. Benefit
" Hospital is eligible for reclassification. July 9, 2004 Page 2 Proposed Comment: Comment Reference CMS-1428-P (Hospital Reclassifications) The following summarizes our recommendations/comments relative to .Dominant Hospital Reclassification. issue. We believe and concur, as noted in the proposed rule, that certain dominant hospitals are disadvantaged with respect to wage reclassifications. As such, we would propose that CMS consider the following .Dominant Hospital. reclassification provisions: 1. A dominant hospital could continue to be defined as a hospital that comprises a minimum of 40% of the area wages, as current regulations stipulate. (At this level, the mathematics of any threshold test becomes unfair, and thus, alternatives to the general rule should be in place.) 2. A dominant hospital wage test threshold of 108% (without its own wages in the denominator) appears reasonable and could continue to be utilized. 3. In cases in which a dominant hospital exceeds the minimum of 40% of the area wages by 10% or more (so that the hospital comprises a minimum of 50% of area wages), we propose that the test threshold of 108% be applied to either a three year average or the most recent year to more accurately reflect market changes, and that the distance requirement be waived. 4. The specific criteria related to the requirement for having gained 1992 to 1997 geographic approvals is outdated and does not appear to have any factual relevance to the .Dominant Hospital. concept.Rather, CMS should consider replacement with another .dominant. related criteria -- such as hospital size (e.g., is the largest hospital or largest referral center in the State.) 5. Finally, given the fact that dominant hospitals likely compete for skilled workers in other CMS wage areas as well as its own area, the proximity rule should be eliminated (similar to the provisions afforded under special access rules for rural referral centers and sole community providers.)We would like to close by thanking Centers for Medicare and Medicaid Services for its consideration of our recommendations.Very truly yours, Maine Medical Cente

CMS-1428-P-233

Submitter : Mr. John Heye **Date & Time:** 07/12/2004 12:07:00

Organization : Maine Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

July 9, 2004 Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1428-P, P.O. Box 8010 Baltimore, MD 21244-1850 RE: CMS-1428-P: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Dear Sir/Madam: On behalf of Maine Medical Center, I am pleased to comment on the proposed changes to the FY 2005 Inpatient Prospective Payment System (IPPS). Issue: Dominant Hospital Comment Basis:Federal Register May 18, 2004, page 28290, invites comments relative to concerns raised by hospitals. Definition: A hospital that pays a substantial proportion of all wages in its wage area designation. A dominant hospital has significant influence on its own area wages and as a result finds it difficult to meet certain wage threshold tests. [For example, if a hospital must meet a 108% wage test (i.e., its wages must be 108% of its area wages), it is difficult given its own wages are already driving the area average.] The Centers for Medicare and Medicaid Services (CMS) does currently provide an avenue for reclassification for certain .dominant hospitals. based on the following criteria: Criteria " Hospital must comprise 40% of its area wages;
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CMS-1428-P-234

Submitter : Mr. John Heye **Date & Time:** 07/12/2004 12:07:00

Organization : Maine Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

July 9, 2004 Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1428-P, P.O. Box 8010 Baltimore, MD 21244-1850 RE: CMS-1428-P: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Dear Sir/Madam: On behalf of Maine Medical Center, I am pleased to comment on the proposed changes to the FY 2005 Inpatient Prospective Payment System (IPPS). Issue: Dominant Hospital Comment Basis:Federal Register May 18, 2004, page 28290, invites comments relative to concerns raised by hospitals. Definition: A hospital that pays a substantial proportion of all wages in its wage area designation. A dominant hospital has significant influence on its own area wages and as a result finds it difficult to meet certain wage threshold tests. [For example, if a hospital must meet a 108% wage test (i.e., its wages must be 108% of its area wages), it is difficult given its own wages are already driving the area average.] The Centers for Medicare and Medicaid Services (CMS) does currently provide an avenue for reclassification for certain .dominant hospitals. based on the following criteria: Criteria Hospital must comprise 40% of its area wages; Hospital must meet the 108% test (without its own wages in average); Hospital must have been approved for reclassification for the years 1992 to 1997.Hospital must be within 15 miles of requested wage area. Benefit Hospital is eligible for reclassification. July 9, 2004 Page 2 Proposed Comment: Comment Reference CMS-1428-P (Hospital Reclassifications) The following summarizes our recommendations/comments relative to .Dominant Hospital Reclassification. issue. We believe and concur, as noted in the proposed rule, that certain dominant hospitals are disadvantaged with respect to wage reclassifications. As such, we would propose that CMS consider the following .Dominant Hospital. reclassification provisions: 1. A dominant hospital could continue to be defined as a hospital that comprises a minimum of 40% of the area wages, as current regulations stipulate. (At this level, the mathematics of any threshold test becomes unfair, and thus, alternatives to the general rule should be in place.) 2. A dominant hospital wage test threshold of 108% (without its own wages in the denominator) appears reasonable and could continue to be utilized. 3. In cases in which a dominant hospital exceeds the minimum of 40% of the area wages by 10% or more (so that the hospital comprises a minimum of 50% of area wages), we propose that the test threshold of 108% be applied to either a three year average or the most recent year to more accurately reflect market changes, and that the distance requirement be waived. 4. The specific criteria related to the requirement for having gained 1992 to 1997 geographic approvals is outdated and does not appear to have any factual relevance to the .Dominant Hospital. concept.Rather, CMS should consider replacement with another .dominant. related criteria -- such as hospital size (e.g., is the largest hospital or largest referral center in the State.) 5. Finally, given the fact that dominant hospitals likely compete for skilled workers in other CMS wage areas as well as its own area, the proximity rule should be eliminated (similar to the provisions afforded under special access rules for rural referral centers and sole community providers.)We would like to close by thanking Centers for Medicare and Medicaid Services for its consideration of our recommendations.Very truly yours, Maine Medical Cente

CMS-1428-P-235

Submitter : Mr. Richard Smith **Date & Time:** 07/12/2004 12:07:00

Organization : Muhlenberg Regional Medical Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1428-P-236

Submitter : Ms. Kathleen Ciccone **Date & Time:** 07/12/2004 12:07:00

Organization : Healthcare Association of New York State

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments.
Ref: CMS-1428-P . Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2005 Rates; Proposed Rule (69 Federal Register 28196), May 18, 2004. .Reporting of Hospital Quality Data for Annual Hospital Payment Update

CMS-1428-P-237

Submitter : Mr. Richard Smith **Date & Time:** 07/12/2004 12:07:00

Organization : JFK Medical Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1428-P-238

Submitter : Mr. Richard Smith **Date & Time:** 07/12/2004 12:07:00

Organization : Muhlenberg Regional Medical Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1428-P-239

Submitter : Mrs. Heather Aaron **Date & Time:** 07/12/2004 12:07:00

Organization : Bayonne Medical Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file

CMS-1428-P-240

Submitter : Mr. Timothy Burgers **Date & Time:** 07/12/2004 12:07:00

Organization : Home & Health Care Association of Massachusetts, Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please see comments attached.

Submitter : Mrs. Crista Durand **Date & Time:** 07/12/2004 12:07:00

Organization : Day Kimball Hospital

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-1428-P-242

Submitter : Mr. Kenneth Becker **Date & Time:** 07/12/2004 12:07:00

Organization : Catholic Health East

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached File

CMS-1428-P-243

Submitter : Mr. Elliot Schwartz **Date & Time:** 07/12/2004 12:07:00

Organization : Jordan Hospital, Inc.

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

see attached file

Submitter : Ms. Donna Sanders **Date & Time:** 07/12/2004 12:07:00

Organization : Saint Francis Medical Center

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached file for comments.

CMS-1428-P-245

Submitter : Mrs. Dorothy DeCoster **Date & Time:** 07/12/2004 12:07:00

Organization : Bayshore Community Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1428-P-246

Submitter : Mr. John Beard **Date & Time:** 07/12/2004 12:07:00

Organization : Alacare Home Health Services, Inc.

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS-1428-P
Conditions of Participation: Discharge Planning . Sec. 482.43

As a Medicare participating Home Health Agency (01-7009, 01-7324 and 01-7326), Alacare Home Health Services, Inc. (Alacare) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services. (CMS) Notice of Proposed Rule Making (NPRM) on .Proposed Changes to the Hospital Inpatient Prospective Payment Systems. that was published in the Federal Register on May 18, 2004.

Alacare is specifically commenting on the section on Conditions of Participation, Discharge Planning to post-hospital home health services, which addresses Section 4321(a) of the Balanced Budget Act of 1997 (BBA .97).

Alacare is pleased that CMS proposes to include additional implementing requirements for Section 4321 in the hospital Conditions of Participation (COP). While Medicare Law since 1997 has required hospitals to provide a list of home health agencies to Medicare beneficiaries being discharged to post-hospital home care and must refrain from specifying or otherwise indicating a home health agency, the lack of clarifying regulations has contributed to uncertainty about the status and requirements of the law. The current enforcement process through the State survey agencies has not been wholly effective, in part because many home health consumers and agencies are not aware of this avenue of relief. The timing is fortuitous now that home health outcome measurements are being reported to the public through CMS.s Home Health Compare website. Along with others commenting, Alacare urges CMS to move expeditiously to finalize these clarifying COP regulations to make outcome reporting more significant by ensuring that consumers will be able to choose the home health agency from which they will receive services based on an agency.s Quality Indicator scores, the range and level of services, cultural and linguistically appropriate care, and personal preference.

Alacare wishes to raise the following issues and make several recommendations to address these concerns:

The Notice of Proposed Rulemaking would mandate provision of a list of home health agencies (HHA) and skilled nursing facilities (SNF) only to patients that the hospital discharge planner determines will require post-hospital Home Health Care or Skilled Nursing Facility (SNF) services. Along with other Home Health Agencies, Alacare often finds that discharge planners do not understand the scope of Medicare.s Home Health Care services and fail to always identify the Medicare patients for whom home care is or can be appropriate. To ensure that beneficiaries are not mistakenly denied post-hospital home care when such services may be appropriate, as part of the discharge planning process, CMS Regulations should mandate that all beneficiaries be provided with written information advising them that they may be entitled to Post-Discharge Home Health Care services and, if they qualify, they have the right to choose an agency from among the HHAs in the community.

The NPRM states that .the discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest&.and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare.. CMS elaborates on this at page 38334 of the May 18 Federal Register by adding .if the patient is referred to that entity.. This wording would indicate that beneficiaries are to be informed of the existence of a relationship only after they have been referred. Alacare believes this is too late in the process and the point of time of this notice is too vague. CMS should require discharge planners to provide information of this relationship when supplying the list of home health agencies so that beneficiaries can take this information into consideration in exercising their right to choose a home health agency based on outcomes and other factors.

John Beard
205-981-8581

Submitter : Mr. Robert Simpson **Date & Time:** 07/12/2004 12:07:00

Organization : Sisters of Providence Health System

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached File.

Submitter : Mr. Thomas Galluppi **Date & Time:** 07/12/2004 12:07:00

Organization : Illinois Home Care Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comment letter.

Submitter : Mr. Laurence Tanner **Date & Time:** 07/12/2004 12:07:00

Organization : New Britain General Hospital

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

July 12, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: CMS-1428-P; Medicare Program; Proposed Changes to Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates; Hospital Reclassifications

Dear Sir or Madam:

New Britain General Hospital appreciates the opportunity to submit these comments regarding the Centers for Medicare and Medicaid Services (CMS) proposed rule: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates [CMS-1428-P]. If implemented, the changes proposed in the rule will result in a significant cut in funding to all Connecticut hospitals, threatening hospital financial viability and access to care for Medicare beneficiaries.

The significant unintended adverse consequence for Connecticut hospitals is due to the adoption and application of the new Core Based Statistical Areas (CBSAs) for purposes of hospital geographic classifications. The proposed rule would increase hospital inpatient rates by 3.3% for inflation while cutting funding for wages by 7% for most Connecticut hospitals. The net effect of the new wage indices is that: 2005 IPPS payments to Connecticut hospitals will be $46.6 million lower than they were in 2004 and outpatient payments will be $11.6 million lower than they were in 2004. The impact of the other rule elements, i.e. transfers, outliers, and IME, are estimated to cut funding to Connecticut by another $11 million. In sum, these changes would reduce current Medicare funding to Connecticut hospitals by about $70 million dollars.

The specific impact of the proposed rule on New Britain General Hospital is a cut in current Medicare funding from $44,621,085 to $43,316,026, or a reduction of $1,305,059 (-2.925%). This dramatic reduction is driven by a proposed reduction in our wage index from 1.2183 to 1.1312 (-7.149%), changes in the DRG transfer rule, changes in DRG weight adjustments, and reductions in our IME payment. As an inner city hospital serving a disproportionate share of Medicaid and uninsured patients, New Britain General Hospital.s continued viability will be at risk as a result of the proposed regulations.

I urge you to act on the recommendations submitted as formal comments by the Connecticut Hospital Association that would address the unintended adverse consequences to Connecticut hospitals:

o Allow Connecticut hospitals that were unable to reclassify to elect to adopt the wage index of the next nearest hospital that was able to reclassify, similar to what is being proposed by CMS for hospitals in states with low population density.
o Given the unpredictability of wage indices and their seemingly counterintuitive effect in Connecticut, set as a floor for the next three years those values that were established as of April 2004.
o Include the hospitals of Litchfield County, i.e., The Charlotte Hungerford Hospital, New Milford Hospital, and Sharon Hospital, in Hartford County for wage index purposes, as they have been since 1979.
o Allow hospital groups in Combined Statistical Areas to be able to seek group reclassification, and/or allow hospital groups to be in either a Core-Based Statistical Areas or Consolidated Metropolitan Statistical Area to seek group reclassification.
o Hold harmless those five Connecticut hospitals that have routinely been granted a wage reclassification to prevent any reduction in their wage index for the next three years.
o Hold harmless the hospitals that were able to reclassify under section 508 of MMA for any reduction to their wage index for the next three years.

o Since the criteria to reclass evolve, allow those Connecticut hospitals that have already been reclassed grandfathered in the future.

Sincerely,

Laurence A. Tanner
President and CEO
New Britain General Hospital
100 Grand Street
New Britain, CT 06050

CMS-1428-P-250

Submitter : Ms. Roseann Franklin **Date & Time:** 07/12/2004 12:07:00

Organization : Bayshore Community Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please kindly accept attached document.

CMS-1428-P-251

Submitter : Mr. Murray Bevan **Date & Time:** 07/12/2004 12:07:00

Organization : COURTER, KOBERT & COHEN, P.C.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Comments of Warren Hospital and Hackettstown Community Hospital on CMS-1428-P - Revised MSAs and Hospital Reclassification

CMS-1428-P-252

Submitter : Mr. David Winslow **Date & Time:** 07/12/2004 12:07:00

Organization : Maine Hospital Association

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir/Madam

Please find the attached file: Maine Hospital Association's Comments on FY 2005 IPPS Proposed Rule.doc (MS Word) which contains our comments on CMS.1428.P: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates.

If you have any difficulty accessing this document please call me at (207) 622-4794 or Michael Ryan at (207) 838-0907.

Thank you.

Sincerely,

David Winslow

CMS-1428-P-253

Submitter : Mr. Kenneth Raske **Date & Time:** 07/12/2004 12:07:00

Organization : Greater New York Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1428-P-254

Submitter : Mr. John Beard **Date & Time:** 07/12/2004 12:07:00

Organization : Alacare Home Health Services, Inc.

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS-1428-P
Conditions of Participation: Discharge Planning . Section 482.43

Alacare has seen several .lists. that are confusing in that they list numerous HHAs, SNFs, durable medical equipment suppliers, assisted living facilities, hospices, and other providers in a single document. Since the listed entities are not properly identified as to the types of service they offer or the geographic areas, patients simply default to the hospital.s services that are listed in big bold print at the top of the page.
" CMS should remedy this by directing hospitals to supply separate lists for home health agencies and SNFs.
" CMS should also consider requiring that the lists include types of services the HHAs offer, e.g., physical therapy, occupational therapy, optional services such as telehealth, so beneficiaries can make better informed choices based on the scope and level of care they will require.

CMS should provide authorization that State Survey Agencies can find a violation of the hospital Conditions of Participation if the overall effect of a discharge/referral practice evidences a clear intent to subvert or violate the purpose of Section 4321 of BBA .97. Example: the type size and style should be uniform for each HHAs or SNF being listed and sufficienly large to be rad by Medicare patients whose vision is not often 20/20.

With regard to enforcement, CMS should address the issue of whether review of a patient.s hospital records by a HHA that the patient has not selected violates HIPAA privacy requirements. If yes, what remedy would be applied in addition to those stemming from a complaint filed with the State survey agency?

CMS proposes that hospitals would be able to compile the required list of home health agencies themselves or else generate it from CMS. Home Health Compare website. Sec. 482.43 (7) in the NPRM states that, .The hospital must not exclude qualified providers that are available to the patient.. Use of Home Health Compare, however, could lead to several problems that would limit beneficiaries. access to qualified home health agencies in their communities. According to the NPRM, .When the patient requires home health services, the CMS website list would be printed based on the geographic area in which the patient resides.. This raises the issue of how .geographic area. will be defined. Home Health Compare data can be sorted by state, county, and ZIP code. An HHA may serve the entire county where a beneficiary resides but not have provided services in the patient.s ZIP code in the previous year. If the list is generated entirely by ZIP code, the agency would not appear even though it serves the area where the patient lives and it has requested to be placed on the list. What.s more, all new home health agencies would be absent from any list generated by Home Health Compare, thereby depriving consumers of access to these providers. CMS should consider eliminating the sorting of HHAs by ZIP code and require hospitals to include all HHAs that request to be listed and serve the .County. where the patient resides.

If a hospital chooses to develop its own list of HHAs or SNFs, it would have flexibility in designing the format. The list should be formatted and used neither as a recommendation nor an endorsement by the hospital of the quality of care of a particular HHA or SNF. The list would be updated at least annually. Hospitals should be required to provide home health agencies with notice that the list is being updated; they must also be required to give HHAs a copy of the list once complied to ensure that they are listed and the information provided is accurate.

John G. Beard, MBA/JD, President
205-981-8581

CMS-1428-P-255

Submitter : Mr. John Beard **Date & Time:** 07/12/2004 12:07:00

Organization : Alacare Home Health Services, Inc.

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS-1428-P
Conditions of Participation: Discharge Planning . Section 482.43

Lastly, CMS states that the second part of 4321 mandating that CMS publish a report on the percentage of self-referral for each hospital will be addressed separately. Alacare urges CMS to move forward with all diligence since this reporting is essentially the only effective way to determine if patient freedom of choice is being protected by the listing regulations.

It does not require a large effort or even new data collection top implement this part of the BBA. CMS is already collecting the necessary data within the routine filings made by HHAs to receive Request for Anticipated Payments (RAPs) under the Prospective Payment System. If CMS and its contractors can identify whether HHAs have correctly coded M0175 of the OASIS to identify post-hospital discharges, then CMS can today produce a comprehensive report each quarter that shows for each HHA how many post-hospital admissions it received from each hospital and what percentage of the specific hospital.s post-discharge home care referral this constituted. This report can be produced right now and would serve as a bright light on instances where virtually all of a hospital.s post-hospital admissions were going to one or a few HHAs.

Alacare looks forward to working with CMS in the months ahead as the hospital Conditions of Participation are finalized to include the clarifying instructions on Section 4321 of BBA .97.

Sincerely yours,

John G. Beard, MBA/JD, President
Direct 205-981-8581

CMS-1428-P-256

Submitter : Mrs. Marilyn Lawrence **Date & Time:** 07/12/2004 12:07:00

Organization : Lee Memorial Health System

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

File Code: CMS-1428-P
Issue Identifier: Coronary Stent Procedures- Proposed Changes to DRG Classifications and Relative Weights

I am writing in support of restructuring the classification system of DRG.s 516, 526, 517, 527- Coronary Stent procedures with/ without AMI, bare metal or drug .eluting stents. I am currently employed by a not-for-profit organization located in Fort Myers FL. As a leading health care provider in southwest Florida, our organization strives to offer up-to-date diagnostic and interventional procedures with the specific intent of improving the quality of life of our patients. The financial impact of offering such services is understandably great.
As the ChargeMaster/APC Specialist for Invasive Cardiology, I see daily the financial impact on the organization relative to the use of stents for the treatment of coronary artery disease. One of my primary job duties is to examine each patient account for charge accuracy in patients who have undergone invasive cardiac procedures such as coronary stent placement as well as assignment of the appropriate DRG. This is critical when trying to balance the impact of resources consumed for such procedures with financial stability.
Approximately 32% of total procedures involve coronary artery stent placement. Of this 32%, 86% involve drug-eluting stent placement. The case mix breakdown of my last quarterly report was Medicare in-patients comprised 63% of our cases, Medicare out-patients 48%. What these figures do not reflect is the growing complexity of the procedures performed by the cardiologists. Specifically, the use of multiple stents per procedure either in the form of multiple stents in a single coronary artery, or stenting multiple coronary arteries. It is true that these complex procedures many times prevent the need for open-heart surgery and as a result, reduce the patient.s hospitalization and recovery times as well as cost to the organization. This however is a double-edged sword. Yes, the financial and resource impact of a decrease in open-heart surgery patients may be less on the organization but new technology does not come without a price.
You will notice I speak of the .financial impact. on our organization of these complex procedures but I do not provide you with a specific dollar impact. I do this for a reason. I realize that there are many variables that need be to taken into account such as hospital length of stay, existing co-morbidities, type of drug-eluting stent(s) used, whether the patient.s initial presentation was with or without acute myocardial infarction to name a few patient related issues. Other factors include initial purchase price and geographic location. The list would be too great to include.
In closing, I am asking for your consideration on the matter of appropriate reimbursement for these complex procedures especially those utilizing drug-eluting stents as you discuss the FY 2005 Inpatient Proposed Rule. I am in favor of retaining the distinction between non drug-eluting and drug-eluting stents with the addition of classifications for complex and non-complex procedures. The definition of .complex. procedures being multi-vessel or multi-stent procedures. As an organization, we firmly believe in providing the community and surrounding area with the most technically advanced and appropriate health care possible. Your support of a classification system for coronary artery stent(s) would serve to strengthen our ability to provide this health care and thusly improve the quality of life of our patients.

Thank You

Marilyn Lawrence MS, RT(R), RCIS
Chargemaster/APC Specialist- Invasive Cardiology
Financial Services
marilyn.lawrence@leememorial.org
(239) 432-4707

Submitter : Mr. Thomas Parker **Date & Time:** 07/12/2004 12:07:00

Organization : Legacy Health System

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See comments in attached letter.

CMS-1428-P-258

Submitter : Mr. Arthur Maples **Date & Time:** 07/12/2004 12:07:00

Organization : Baptist Memorial Restorative Care Hospital

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

CMS-1428-P
Comments attached as .pdf file.
Thank You.

CMS-1428-P-259

Submitter : Mr. Robert Trefry **Date & Time:** 07/12/2004 12:07:00

Organization : Bridgeport Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please See attached file/letter

Submitter : Ms. Carla Davila **Date & Time:** 07/12/2004 12:07:00

Organization : BAPTIST HEALTH SERVICE

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

PLEASE CONSIDER THE FOLLOWING COMMENTS REGARDING CMS-1428-P, PROPOSED INPATIENT PPS ESRD DISCHARGES.(SEE ATTACHED FILE)

CMS-1428-P-261

Submitter : Dr. Sharon Rounds **Date & Time:** 07/12/2004 12:07:00

Organization : American Thoracic Society

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file.

If you have questions or difficulty opening the file, please contact:

Mr. Gary Ewart
Director, Government Relations
American Thoracic Society
1150 18th Street, N.W., Suite 900
Washington, D.C. 20036
Ph 202 785-3377
Fx 202 452-1805
Email gewart@thoracic.org

CMS-1428-P-262

Submitter : Mr. Tom Fivek **Date & Time:** 07/12/2004 12:07:00

Organization : East Orange General Hospital

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Attached, please find East Orange General Hospital Comment Letter regarding the 2005 Proposed IP Rule-Wage Index Issue

CMS-1428-P-263

Submitter : Dr. Robert Zwolak **Date & Time:** 07/12/2004 12:07:00

Organization : Society for Vascular Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS-1428-P ISSUE: New Procedure 00.16 Pressurized treatment of venous bypass graft (conduit) with pharmaceutical substance.

Society for Vascular Surgery is the largest Vascular Surgery specialty society. Medicare beneficiaries comprise 60-70% of the typical vascular surgeon.s practice. We wish to commend and comment on new procedure code 00.16

Summary:
1) Gene therapy to prevent neointimal hyperplasia is an extremely promising new technology currently undergoing pivotal trials. The ability to block neointimal hyperplasia would reduce bypass graft failure, increase limb salvage, prevent major leg amputation, maintain Medicare beneficiary independence, and reduce the longterm care facility utilization costs associated with disabled amputees.

2) We are concerned that additional costs associated with this and other promising new technologies for lower extremity limb-salvage bypass surgery patients will be financially prohibitive for hospitals, due to fiscal constraints imposed by DRGs 478 and 479. SVS suggests consideration be given to reclassifying the subset of patients undergoing lower extremity bypass for limb-salvage to DRG 110/111 (major cardiovascular procedures), or that new DRGs be created to more properly reflect the extreme resource utilization of this subset.

Background: 25,000 Medicare beneficiaries undergo lower extremity bypass surgery each year, using autogenous vein as conduit, for treatment of advanced peripheral artery occlusive disease. These procedures are represented on the physician payment side primarily by CPT codes 35556, 35566, 35585, and 35587. Operations performed using autogenous vein conduit typically differ in clinical indication from those performed with conduit .other than vein. as the former tend to be performed for the indication of limb-salvage, while the latter are usually done to treat intermittent claudication. Patients requiring limb-salvage bypass surgery have advanced ischemia with gangrenous digits, ischemic rest pain, and/or nonhealing ischemic foot ulcers. Successful surgery results in limb preservation and prevention of major lower extremity amputation. In turn, prevention of major amputation preserves independent mobility, keeps patients in their home environment, and prevents the extreme resource utilization associated with remainder-of-life nursing home placement.

Vein is used as conduit for arterial bypass operations in limb-salvage situations because its longterm graft patency exceeds that of bypasses constructed with synthetic. Nevertheless, a small percentage of vein-conduit bypass grafts fail early due to a smooth muscle proliferative process, neointimal hyperplasia. Unbridled smooth muscle replication results in wall thickening and a reduction in lumen caliber in those individuals unlucky enough to suffer this fate. Left untreated the endpoint is bypass closure with recurrent critical limb ischemia.

The new gene therapy agent represented by procedure code 00.16 is currently undergoing a large prospective multicenter trial to test promising single-center results that demonstrated inhibition of neointimal hyperplasia and increased vein graft patency. Successful results could bring an end to bypass failure due to this hyperplastic process. While very promising, this gene therapy agent is likely to be expensive, and it requires additional operating room time and resources.

Patients requiring limb-salvage bypass procedures with vein conduit areolder, sicker, & stay in the hospital longer. Even without the promising new technology represented by 00.16 this subset lies at the upper limit of resource utilization range inDRG 478/479. SVS is concerned that the additional hospital expenses associated with 00.16 may result in costs that substantially exceed DRG payment. For patients undergoing lower extremity bypass graft placement for limb-salvage, we suggest reclassification to DRGs 110 & 111 (major cardiovascular procedures).

Submitter : Ms. Deborra Torres **Date & Time:** 07/12/2004 12:07:00

Organization : Bayshore Community Hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1428-P-265

Submitter : Mr. Richard Smith **Date & Time:** 07/12/2004 12:07:00

Organization : JFK Medical Center

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule

CMS-1428-P-266

Submitter : Dr. Todd Dorman **Date & Time:** 07/12/2004 12:07:00

Organization : American Society for Critical Care Anesthesiology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached MS Word document

Submitter : Mr. John Biancamano **Date & Time:** 07/12/2004 12:07:00

Organization : Hartford Hospital

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

July 12, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: CMS-1428-P; Medicare Program; Proposed Changes to Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates; Hospital Reclassifications

Dear Sir or Madam:

Hartford Hospital appreciates the opportunity to submit these comments regarding the Centers for Medicare and Medicaid Services (CMS) proposed rule: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates [CMS-1428-P]. If implemented, the changes proposed in the rule will result in a significant cut in funding to all Connecticut hospitals, threatening hospital financial viability and access to care for Medicare beneficiaries.

The significant unintended adverse consequence for Connecticut hospitals is due to the adoption and application of the new Core Based Statistical Areas (CBSAs) for purposes of hospital geographic classifications. The proposed rule would increase hospital inpatient rates by 3.3% for inflation while cutting funding for wages by 7% for most Connecticut hospitals. The net effect of the new wage indices is that: 2005 IPPS payments to Connecticut hospitals will be $46.6 million lower than they were in 2004 and outpatient payments will be $11.6 million lower than they were in 2004. The impact of the other rule elements, i.e. transfers, outliers, and IME, are estimated to cut funding to Connecticut by another $11 million. In sum, these changes would reduce current Medicare funding to Connecticut hospitals by about $70 million dollars.

The specific impact of the proposed rule on Hartford Hospital is estimated to be approximately a $7.6 million reduction in payments (or 5.34%) prior to a Market Basket adjustment for 2005 and a$3.0 million reduction in payments (or 2.13%) after consideration of a Market Basket adjustment for 2005.

I urge you to act on the recommendations submitted as formal comments by the Connecticut Hospital Association that would address the unintended adverse consequences to Connecticut hospitals:

o Allow Connecticut hospitals that were unable to reclassify to elect to adopt the wage index of the next nearest hospital that was able to reclassify, similar to what is being proposed by CMS for hospitals in states with low population density.
o Given the unpredictability of wage indices and their seemingly counterintuitive effect in Connecticut, set as a floor for the next three years those values that were established as of April 2004.
o Include the hospitals of Litchfield County, i.e., The Charlotte Hungerford Hospital, New Milford Hospital, and Sharon Hospital, in Hartford County for wage index purposes, as they have been since 1979.
o Allow hospital groups in Combined Statistical Areas to be able to seek group reclassification, and/or allow hospital groups to be in either a Core-Based Statistical Areas or Consolidated Metropolitan Statistical Area to seek group reclassification.
o Hold harmless those five Connecticut hospitals that have routinely been granted a wage reclassification to prevent any reduction in their wage index for the next three years.
o Hold harmless the hospitals that were able to reclassify under section 508 of MMA for any reduction to their wage index for the next three years.
o Since the criteria to reclass evolve, allow those Connecticut hospitals that have already been reclassed grandfathered in the future.

Sincerely,
John M. Biancamano, Vice President - Finance

CMS-1428-P-268

Submitter : Mr. Gerry Lowe **Date & Time:** 07/12/2004 12:07:00

Organization : Virtua Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services (CMS)
200 Independence Avenue, S.W.
Room 443-G
Washington, DC 20201

Ref.: CMS-1428-P

Dear Dr. McClellan,
Thank you for the opportunity to comment on the above referenced docket which pertains to the hospital inpatient prospective payment system and 2005 FRY rates.
The CMS proposal to utilize new Core Based Statistical Areas (CBSA) for purposes of calculating the Medicare wage index makes sense based on the results of the 2000 census. Specifically from this, the inclusion of the three New Jersey counties of Bergen, Hudson and Passaic within the New York City area will more accurately and equitably define those counties to the area with which they are economically integrated.
The CMS proposal to impute a rural floor wage index for both New Jersey and Rhode Island is also an appropriate action as hospitals in these states have not had the wage index protection afforded to hospitals in those states that are entirely urban. This proposal will provide equity for hospitals in those two states as well as ensure consistency for all hospitals with regards to protection.
In closing, thank you again for this opportunity to comment.

CMS-1428-P-269

Submitter : Mr. Thomas Ryan **Date & Time:** 07/12/2004 12:07:00

Organization : Alamance Regional Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

I would like the attached letter to serve as my comment on CMS-1428-P.
Thank you.

CMS-1428-P-270

Submitter : Mr. Daniel Myers **Date & Time:** 07/12/2004 12:07:00

Organization : Florida Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Re:Changes to the Hospital Inpatient PPS and FY 2005 Rates Docket Number: CMS .1428-P
New Technology Applications . CRT-D

I would like to comment on the section of the proposed rule dealing with CRT-D consideration as new technology. My current role at Florida Hospital is specifically related to charge accuracy and Medicare reimbursements. It has become clear to me that (1) CRT-D represents expanded clinical benefit for many patients, and it has also become clear that (2) current Medicare reimbursement for this technology is inadequate and might limit the ability for Medicare beneficiaries to receive this type of care.

Although, I have a finance background, I'm aware that this technology provides additional clinical benefits (primarily to the Medicare population). Improved quality of life and reduced mortality are the two most common long-term benefits of this product. I also believe that there is potential benefit from reduced hospital re-admissions and cost savings to both the hospital and Medicare program.

I.m also aware that the Medicare payment rate is below direct costs. We negotiate matrix prices with our defibrillator vendors, using volume and size to help us in the negotiations. Our current cost for a complete system is about $29,000. That does not include any of the costs related to implant of that device, care of the patient while in the hospital for implant, or any of the other resources utilized by the patient within the hospital for that stay. The DRG.s that our patients fall into are either 515, 535, or 536. For 2005, the proposed payments (excluding DSH & IME add-ons) for our facility for those 3 DRG.s are $26,814, $38,071, and $30,842. If our patients are DRG 535, we will get paid OK, but if our patients are DRG 515 or 536 we incur large net-losses on those cases. From January . June of 2004, we have had 61 Medicare DRG 535 cases, 106 DRG 536 cases, and about 25 CRT-D cases in 515.

I understand that the DRG system is based on providing a level of payment and then rewarding the hospitals that can effectively operate below the payment rates defined by Medicare. I also understand that the DRG system is based on an average system where some services will cost less than the payment, and some will cost in excess. However, with the CRT-D technology, the payments are not covering the costs for 2 of the DRG.s (515 and 536) that our patients fall into. I.m not sure that we can continue to operate our hospital with if this is a long-term payment disparity. I.m worried that we might not be able to provide the newest level of life-saving technology to our Medicare patients.

One last comment regarding the newness criteria. The final rule indicates that the two manufactures both received FDA approval for the CRT-D devices in May 2002. Using the 2-3 year newness criteria, the end date of the add-on payments should expire sometime between May 2004 and May 2005. I would recommend that the May 2005 date be used as the sunsetting period for newness for several reasons:
? I.m not convinced that the cost of these devices is fully included in the 2005 DRG rates. If our facility is similar to other facilities, we saw dramatic increased usage of this product during the 2nd half of the 2003 calendar year . although you indicate there are some cases reported in the Medpar 2003 data files, I.m concerned that the data files for July-Dec 2003 will show dramatic increase in usage and also billed charges (and costs).
? The nenewness criteria should be extended for the full 3-year period in order to provide adequate time for enough hospitals to begin using and billing correctly for this service for DRG payments to be set correctly
? Is it possible to end the newness criteria of these cases at March 31, 2005? I know there are supposed to be new ICD-9 codes implemented April 1, 2005. That seems like an appropriate time to consider sunsetting the nenewness criteria and payments for CRT-D new technogy.

CMS-1428-P-271

Submitter : Mr. Roger Sarao **Date & Time:** 07/12/2004 12:07:00

Organization : New Jersey Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS,

Attached are two sets of comments for CMS-1428-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates, as submitted by the New Jersey Hospital Association. One pertains only to the Long Term Care Hospital provisions, the other addresses the remaining provisions, including the many wage index related proposals. Please contact me with any questions. Thank you.

Sincerely,

Roger D. Sarao, CHFP, MPA
Assistant Vice President, Health Economics
New Jersey Hospital Association
760 Alexander Road, Princeton, NJ 08543
609-275-4026
609-452-9339 (fax)
rsarao@njha.com

CMS-1428-P-272

Submitter : Mr. Benjamin K. Chu **Date & Time:** 07/12/2004 12:07:00

Organization : New York City Health and Hospitals Corporation

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Attached please find the New York City Health and Hospitals Corporation's comments on Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2005 Rates, Docket ID CMS-1428-P

CMS-1428-P-273

Submitter : Mr. Maurice Hinchey **Date & Time:** 07/12/2004 12:07:00

Organization : U.S. House of Representatives

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file.

CMS-1428-P-274

Submitter : Mr. John Krichbaum **Date & Time:** 07/12/2004 12:07:00

Organization : American Burn Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

The American Burn Association is pleased to submit the attached comments (written copies have also been sent by FedEx) regarding CMS-1428-P.

Submitter : Mr. John Krichbaum **Date & Time:** 07/12/2004 12:07:00

Organization : American Burn Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

The American Burn Association is pleased to submit the attached comments regarding CMS-1428-P (written copies have also been sent by FedEx).

CMS-1428-P-276

Submitter : Mr. Michael Werner **Date & Time:** 07/12/2004 12:07:00

Organization : Biotechnology Industry Organization

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find BIO's comments to CMS' proposed changes to the hospital inpatient prospective payment system for FY 2005.

CMS-1428-P-277

Submitter : Mr. Edward Kennedy **Date & Time:** 07/12/2004 12:07:00

Organization : Senator Edward M. Kennedy

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

Comments on IPPS from Senator Edward M. Kennedy.

CMS-1428-P-278

Submitter : Ms. Celeste Moore **Date & Time:** 07/12/2004 12:07:00

Organization : The Charlotte Hungerford Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please accept the attached comments in relation to the proposed rule for changes to the inpatient prospective payment system (IPPS) for FY2005.

CMS-1428-P-279

Submitter : Mr. Michael Pelc **Date & Time:** 07/12/2004 12:07:00

Organization : Detroit Medical Center Hospitals

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

The Detroit Medical Center (DMC) hospitals . Children.s Hospital of Michigan, Detroit Receiving Hospital, Harper-Hutzel Hospital, Huron Valley-Sinai Hospital, Rehabilitation Institute of Michigan and Sinai-Grace Hospital are submitting this comment in connection with the notice of proposed rulemaking (the .NPRM.) addressing proposed changes to the inpatient prospective payment system for Federal Fiscal Year 2005. Specifically, this comment relates to the proposed increase in the outlier threshold to $35,085 from its current rate of $31,000. 69 Fed. Reg. 28196, 28376 (May 18, 2004). The Centers for Medicare and Medicaid Services (.CMS.) has based this proposed increase on charge data spanning from FY 2001 through FY 2003. Id. The DMC believes that the proposed increase is based on inaccurate assumptions relating to this data and urges CMS to revise its calculations accordingly.

In cases where the prospective payment for a given admission of a Medicare beneficiary is significantly less than the costs of the admission, outlier payments serve to soften the financial impact by paying providers a portion of their extraordinary expenses for the case. As such, these payments serve to reduce the disincentive hospitals would otherwise have towards treating severely ill patients. To calculate an outlier payment, a provider subtracts its Medicare payments received for an admission plus a fixed threshold amount from the total costs attributable to the admission. 42 C.F.R. ? 412.84(k). The Medicare program pays 80 percent of the difference. Id. Because of this formula, the threshold amount plays a critical role in determining a hospital.s financial exposure to high cost cases.

CMS has used the outlier threshold as its means towards controlling outlier spending. By statute, CMS must allocate a portion of inpatient payments to outlier payments. On a projected basis, this amount must be between 5 percent and 6 percent of total payments. 42 U.S.C. ? 1395ww(d)(5)(A)(iv). CMS has traditionally set the amount designated for outlier payments at 5.1 percent of total projected payments, and it estimates that, with a threshold amount of $35,085 for FY 2005, outlier payments will be equal to 5.1 percent of operating DRG payments for this upcoming fiscal year. 69 Fed. Reg. at 28376. CMS has not engaged in retroactive adjustments in cases where its estimates have been incorrect. Since the threshold amount proposed in the NPRM is grossly inflated, CMS must revise this figure in its final rulemaking. CMS itself acknowledges that it is using data relating to a period prior to a significant rulemaking revising the way that outlier calculations are performed. Id. (citing to 68 Fed. Reg. 34494). Thus, there is no basis for trending this data forward to the upcoming fiscal year. Indeed, CMS has proof that its calculations are clearly in error. For FY 2004, CMS similarly set the outlier threshold relying on data from the period prior to its regulatory revisions. According to the NPRM, outlier payments are now projected to be only 4.4 percent of total payments for FY 2004, which is approximately 0.7 percentage points lower than initial estimates. Since CMS can thus be virtually certain that its calculations will not result in outlier payments totaling 5.1 percent of total payments in FY 2005 as well, CMS must make a good faith attempt to better model payments to ensure that they are reasonably anticipated to total the targeted amount. At a minimum, CMS should use costs (as it has done traditionally) rather than charges to understand outlier trends.

The American Hospital Association estimates that the FY2004 threshold should have been set at 26,565 rather than 31,000 to result in outlier payments of 5.1 percent.

Thank you for your review of this submission. Please call me at (313) 578-2820 with any questions regarding these comments you may have.

Sincerely,

Michael A. Pelc
Vice President, Finance
T

CMS-1428-P-280

Submitter : Mr. Michael Pelc **Date & Time:** 07/12/2004 12:07:00

Organization : The Detroit Medical Center Hospitals

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter.

Submitter : Mr. Lee Layne **Date & Time:** 07/12/2004 12:07:00

Organization : Charleston Area Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Graduate Medical Education Commentse

CMS-1428-P-282

Submitter : Ms. Pat Booth **Date & Time:** 07/12/2004 12:07:00

Organization : American College of Chest Physicians

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document.

For questions please contact:

Pat Booth
Ph 301 718-0202
Fx 301 718-2976
pbooth@erols.com

CMS-1428-P-283

Submitter : Mr. Larry Sims **Date & Time:** 07/12/2004 12:07:00

Organization : Colquitt Regional Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

On behalf of the employees, medical staff and trustees of the Hospital Authority of Colquitt County I welcome the opportunity to comment on CMS-1428.P proposed rule (69 Federal Register 28196) establishing new policies and payment rates for hospital inpatient services for fiscal year 2005.

In reviewing the proposed rule I note one particular area of concern and that is about the redistribution of hospital payments due to the proposed revisions to metropolitan statistical areas (MSA.s) and the impact on rural hospitals in Georgia and our own rural facility.

The Medicare Modernization Act held a great deal of promise for rural hospitals, who have traditionally been subjected to lower reimbursement than urban facilities located in the same general geographic regions. In our case specifically we compete for nurses and other clinical staff with a number of hospitals within 25 to 50 miles from here. Some of those hospitals are in an urban MSA that has a wage index well in excess of 1.0. Rural Georgia.s wage index is well below. I was encouraged with the increase in disproportionate care percentage and the positive impact it would have on our rural facility as well as other rural hospitals in Georgia.

However, with the revised MSAs and the impact on our wage index I note that any positive gain from disproportionate share has been negated by a lowering of the rural Georgia wage index of 9.6%, from .8595 to .7774. As I understand it this proposal will cut 35 Georgia rural hospital.s Medicare payments by 1%. This is not acceptable.

I would propose a 3 year stop loss/hold harmless provision for all hospitals that experience a decline in their area wage index as a result of this sudden and unexpected change.

Again, thank you for allowing me to comment and I hope you will restore the promise issued at the time to .offer additional financial relief to rural hospitals..

Larry Sims, FHFMA
Vice President/CFO
Colquitt Regional Medical Center
3131 South Main Street
Moultrie, GA 31768

Phone 229-890-3531
Fax 229-890-3483

CMS-1428-P-284

Submitter : Mr. Michael Pelc **Date & Time:** 07/12/2004 12:07:00

Organization : Detroit Medical Center Hospitals

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached.

CMS-1428-P-285

Submitter : Mr. Michael Pelc **Date & Time:** 07/12/2004 12:07:00

Organization : Detroit Medical Center Hospitals

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached.

CMS-1428-P-286

Submitter : Mr. Michael Mabry **Date & Time:** 07/12/2004 12:07:00

Organization : Society of Interventional Radiology

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached the joint comments by ASITN, ASNR, and SIR regarding Medicare: Hospital inpatient prospective payment systems and 2005 FRY rates
(CMS-1428-P).

Submitter : Mr. Stuart Kurlander **Date & Time:** 07/12/2004 12:07:00

Organization : Latham & Watkins, LLP

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

Issue Identifier - Graduate Medical Education

CMS-1428-P-288

Submitter : Mr. John Krichbaum **Date & Time:** 07/12/2004 12:07:00

Organization : American Burn Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

The American Burn Association is pleased to sumit the attached comments on CMS-1428-P.

CMS-1428-P-289

Submitter : Ms. Maya Bermingham **Date & Time:** 07/12/2004 12:07:00

Organization : PhRMA

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Attached are PhRMA's Comments regarding the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates (CMS-1428-P)

CMS-1428-P-290

Submitter : Ms. Pat Booth RN **Date & Time:** 07/12/2004 12:07:00

Organization : NAMDRC

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached.For questions please contact:Pat Booth NAMDRC Ph 301 718-0202 Fx 301 718 2976 Email pbooth@erols.com

CMS-1428-P-291

Submitter : Mr. Kyle Kramer **Date & Time:** 07/12/2004 12:07:00

Organization : American College of Cardiovascular Administrators

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find comments on CMS-1428-P from the American College of Cardiovascular Administrators, a professional association for cardiovascular program administrators across the nation. Sincerely, R. Kyle Kramer President American College of Cardiovascular Administrators

CMS-1428-P-292

Submitter : Mr. John Krichbaum **Date & Time:** 07/12/2004 12:07:00

Organization : American Burn Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

The American Burn Association is pleased to submit the attached comments on CMS - 1428 - P.

CMS-1428-P-293

Submitter : Mr. Stephen Lynch **Date & Time:** 07/12/2004 12:07:00

Organization :

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

Commenting on CMS proposed rule re: CBSA for determining the Area Wage Index for Massachusetts hospitals in Suffolk, Norfolk, and Plymouth Counties. Additionally, original copy is being mailed.

STEPHEN F. LYNCH
9TH DISTRICT, MASSACHUSETTS

COMMITTEE ON FINANCIAL SERVICES
SUBCOMMITTEE ON CAPITAL MARKETS, INSURANCE AND GOVERNMENT SPONSORED ENTERPRISES
SUBCOMMITTEE ON HOUSING AND COMMUNITY OPPORTUNITY

COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON NATIONAL SECURITY, EMERGING THREATS AND INTERNATIONAL RELATIONS
SUBCOMMITTEE ON TECHNOLOGY, INFORMATION POLICY, INTERGOVERNMENTAL RELATIONS AND THE CENSUS

ASSISTANT DEMOCRATIC WHIP

Congress of the United States
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July 12, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Room 443-G
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

This letter is to express my strong support for the provision of the Centers for Medicare and Medicaid Services proposed rule, issued May 12, 2004, which creates a new Core Based Statistical Area (CBSA) for determining the Area Wage Index for Massachusetts hospitals in Suffolk, Norfolk, and Plymouth Counties.

For years, hospitals in the Boston area district that I represent have urged CMS to refine the Medicare labor cost calculation to more accurately reflect actual labor costs. During the last decade, CMS has used a vastly oversized area to define "Boston". The current Boston New England County Metropolitan Area (NECMA) ranges from three counties in southern New Hampshire to Worcester in the west to Fall River and New Bedford in the south. It includes 65 hospitals.

Hospitals in outlying areas have labor costs that are significantly lower than those in the City of Boston. When the wages hospitals must pay in Boston are averaged with those hospitals pay in outlying towns, the Area Wage Index is so diluted that Boston hospitals subsequently are grossly underpaid.

Experts have long acknowledged these flaws in Medicare's system for paying hospitals for their labor costs. For well over ten years, Boston Teaching Hospitals have sought relief from this reimbursement inequity.

In the proposed rule, CMS proposes revising its definition of the Boston labor market based on changes implemented by the Office of Management and Budget after the 2000 census to more accurately aggregate counties into distinct, geographically coherent areas based on patterns of employment and commuting. CMS would subdivide the Boston metropolitan area into multiple CBSA's, in order to more closely reflect wages actually paid in those areas. The Boston Teaching Hospitals would be included in a CBSA consisting of Suffolk, Norfolk, and Plymouth counties. As a result, the Boston AWI would increase from 1.1233 to 1.1649.

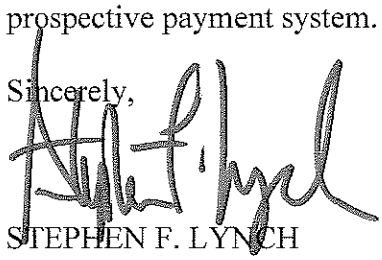
Hospitals in my district face the constant challenge of carrying out their missions of patient care, research, and physician training. That challenge is exacerbated by ever-increasing costs: new technology, drugs, bioterrorism preparedness, rising labor costs, uncompensated care and medical technology. The only long term solution to address these rising costs is equitable payment from all payers. The hospitals have worked very hard to redress payment inequities with all payers, most recently with private payers and the state Medicaid and uncompensated care formulas. Yet Medicare, the leading payer, has remained a gravely inequitable payer because Boston's Area Wage Index falls far short of actual labor costs.

The CMS proposed rule corrects this long standing inequity by increasing Boston hospitals' Area Wage Index reimbursement. Furthermore, updated OMB data drives this proposal, not any political or policy initiative. Finally, this change would restore Medicare's role as a prudent payer, more closely matching payment to actual costs incurred.

Additionally, while this new policy is implemented, CMS should work to ensure that there is a sufficient cushion for those hospitals that may see a reduction in Medicare payments as a result of this change. Specifically, I would ask that a transitional "hold-harmless" provision be adopted to allow for an adequate amount of time for adjustment by hospitals that are impacted negatively by the CBSA changes.

I strongly support this change and urge its inclusion in CMS's final rule on the inpatient prospective payment system.

Sincerely,



STEPHEN F. LYNCH
Member of Congress

CMS-1428-P-294

Submitter : Mr. Tim Johnson **Date & Time:** 07/12/2004 12:07:00

Organization : Greater New York Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Enclosed are comments on CMS-1428-P. Thank you. Tim Johnson Greater New York Hospital Association 212-506-5420 (phone) tjohnson@gnyha.org (e-mail)

GREATER NEW YORK HOSPITAL ASSOCIATION
GNYHA

Greater New York Hospital Association
555 West 57th Street, 15th Floor
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July 12, 2004

VIA ELECTRONIC MAIL AND SURFACE MAIL

Mark McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1428-P, P.O. Box 8010
Baltimore, MD 21244-1850

RE: **CMS 1428-P**; Comments on IPPS Proposed Rule, *Section O. Payment for Direct Graduate Medical Education (Existing Section 413.86)*

Dear Administrator McClellan:

Greater New York Hospital Association (GNYHA), which represents approximately 100 teaching hospitals in the metropolitan New York region, including hospitals in New York, New Jersey, Connecticut, and Rhode Island, is pleased to provide these comments on *Section O. Payment for Direct Graduate Medical Education (Existing Section 413.86)*, and accompanying proposed regulations, that were included in the Proposed Rule describing changes to the Hospital Inpatient Prospective Payments Systems (IPPS) and Fiscal Year 2005 Rates.

Specifically, this letter includes recommendation regarding the following GME provisions:

- Reductions of and Increases in Hospitals' FTE Resident Caps for GME Payment Purposes Under Section 422 of Public Law 108-173
    - General Comments on the Resident FTE Cap (pages 3 to 4)
    - Application to Hospitals That Participated in the New York Medicare GME Demonstration Project (pages 5 to 10)
    - Reduction of Hospitals' FTE Resident Caps Under the Provisions of Section 422 (pages 11 to 16)
    - Criteria for Determining Hospitals That Will Receive Increases In Their FTE Resident Caps (pages 17 to 22)
- Direct GME Initial Residency Period (pages 22 to 24)
- Requirements for Written Agreements for Residency Training in Nonhospital Settings (pages 24 to 25)

GNYHA comments on other sections of the proposed rule, including proposed changes to the Medicare wage index, are being sent under separate cover.

Outlier Payments

Before turning to the GME provisions, we wish to highlight one other feature of the IPPS proposed rule that is of great concern to GNYHA member hospitals, namely, outlier payments and the outlier threshold.

The proposed rule would increase the threshold by 13%, from $31,000 to $35,085, in FY 2005. This is a very significant increase, particularly given the proposed rule's observation that the outlier threshold in FY 2004 was apparently too high such that total outlier payments are now projected to fall below the statutorily defined range of between 5% and 6% of total IPPS payments. In particular, while the FY 2004 threshold was set so that outliers would comprise 5.1% of total DRG payments, CMS's current estimate is that they will approximate 4.4%. The very real result of under-spending on outliers is that hospitals that have provided critically important, complex, and unusually high cost care to Medicare beneficiaries have been deprived of needed payment relief from the outlier program. This negatively impacts Medicare beneficiaries by contributing to the financial de-stabilization of academic medical centers and other tertiary providers that provide complex and sophisticated care. In addition, since the outlier pool is funded by lowering the standardized amount, failure to spend the full amount underfunds the entire service sector.

The proposed rule notes that a new outlier payment policy mandating the use of updated cost to charge ratios (CCR) became effective in mid-2003, but that the outlier threshold was updated using the average annual rate of increase in charges per case from FY 2000 to FY 2001 and from FY 2001 to FY 2002, or prior to the very significant changes to outlier policy that were made as in 2003. GNYHA does not believe it is appropriate to use historical charge increase data to update the threshold because the essence of the 2003 outlier payment policy change was to update the CCR so that it now accurately estimates actual costs.[1] That is, the outlier payment policy changes made by CMS made charges largely irrelevant. GNYHA therefore recommend that CMS consider other approaches to set the threshold that would identify the rate of increase in *costs*, rather than *charges*. Above all, GNYHA urges CMS to strive to ensure that the 5.1% outlier set-aside is spent.

We also reiterate our recommendation that, given the difficulty of setting the correct cost outlier threshold in a prospective payment system, CMS turn its attention to reducing the need for outliers by implementing refined DRGs. Refined DRGs would much better match inlier payments with resource consumption. CMS has the authority to make this change administratively as well as to ensure that aggregate payments would not increase as a result of case mix increases.

Finally, we note that we continue to believe that it is inappropriate for CMS to include DSH payments in the outlier calculation. DSH is a critical support for hospital-based uncompensated care and should be preserved for that purpose. Thus, GNYHA recommends that CMS subtract DSH from inlier payments for the purpose of computing outlier payments.

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[1] As we noted in our outlier comment letter dated April 3, 2003, after extensive empirical analysis of proposed changes in the CCR we found no significant differences between tentative CCRs and CCRs that matched the period of time in which payments were actually made.

Section I. Reductions of and Increases in Hospitals' FTE Resident Caps for GME Payment Purposes Under Section 422 of Public Law 108-173 (Proposed Redesignated Section 413.79 (a Proposed Redesignation of Section 413.86(g))

(A) General Comments on the Resident FTE Cap

Before commenting on the specific components of the proposed rule related to implementation of Section 422 of the Medicare Modernization Act (MMA), GNYHA wishes to make these general comments regarding the resident caps.

GNYHA understood at the time the Balanced Budget Act (BBA) was passed that certain provisions that directly affected residency training and teaching hospitals were included in large part as cost saving measures. For example, the BBA included scheduled reductions in the multiplier used for Medicare indirect medical education (IME) reimbursement as a means of helping to balance the budget and extend the life of the Medicare trust fund. In the same way, we understood that Congress also included the resident cap provision principally as a means of helping to extend the life of the Medicare trust fund.

In addition, we understood that Congress included the resident cap provision in order to also address the conventional wisdom of the early to mid-1990's regarding an impending oversupply of physicians. This conventional wisdom was predicated in large part on reports that had been published in the early 1990s by the Federal Council on Graduate Medical Education (COGME), a body that advises the Congress and the U.S. Department of Health and Human Services on GME and the physician workforce.[2] Independent research conducted by health economists and policy experts generally supported these findings.

Thus, in deciding to include the resident cap provision within the BBA, Congress sought to accomplish two goals: 1) to extend the life of the Medicare trust fund and 2) to significantly limit the production of physicians and respond to the then conventional wisdom regarding a looming physician oversupply.

It is well known that following passage, the BBA quickly accomplished its principal goal, to balance the budget and extend the life of the Medicare trust fund. In the meantime, however, teaching hospitals were beginning to suffer from the significant loss of funding mandated under the BBA. GNYHA members are appreciative that in response to the balancing of the budget and the damage being done to teaching hospitals, Congress has seen fit to make adjustments to BBA provisions, including the schedule for the IME multiplier. Although the relief has been limited and short-term, GNYHA is appreciative of Congress's attention to this matter in an effort to ensure the viability of teaching hospitals.

In the same way, the resident cap provision contained in the BBA needs to be adjusted. The most recent GNYHA analysis, reflecting 2002 Medicare cost report data, shows that thirty-six New York teaching hospitals are above their BBA resident cap level. *In aggregate, these hospitals*

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[2] See, in particular, *Improving Access to Health Care Through Physician Workforce Reform: Directions for the 21st Century* (COGME Third Report, October 1992) and *Recommendations to Improve Access to Health Care Through Physician Workforce Reform* (COGME Fourth Report, January 1994).

trained 284 residents in 2002 above their resident cap level and had to forego Medicare GME reimbursement for these residents. The hospitals that are above their BBA resident cap level simply cannot receive this kind of financial hit year after year without suffering undue harm. An additional sixteen New York teaching hospitals were almost exactly at their resident cap level in 2002. These hospitals have been constrained from adding additional residents for a variety of reasons, but particularly because they know that training additional physicians add a significant cost that the hospitals themselves will have to bear without Medicare funding. (Of the eleven remaining teaching hospitals, which at least for 2002 were below their BBA resident cap level, the vast majority had recently withdrawn from the New York Medicare GME Demonstration Project that was focused on downsizing and had not yet returned to their BBA resident cap level.)

At its September 2003 meeting, the Federal Council on Graduate Medical Education (COGME) accepted a commissioned report indicating that the nation was facing a physician shortage and recommended that the nation increase the number of students graduating from U.S. medical schools by 15% over the next decade. In addition, the report calls for a similar expansion in the number of residency positions. In doing so, we understand that the report notes that the current cap on the number of residents and fellows eligible for Medicare reimbursement strongly discourages teaching hospitals from increasing the number of residents. The analysis, *Physician Workforce Policy Guidelines for the U.S., 2000 to 2020*, was prepared by the Center for Health Workforce Studies (CHWS), University at Albany, under contract to the U.S. Health Resources and Services Administration.

As presented at the Federal COGME meeting, the physician workforce analysis indicated that while the supply of physicians is expected to increase over the next two decades, demand for services is likely to grow even more rapidly. According to the analysis, the three major factors driving the increase in demand will be the projected U.S. population growth of 18% between 2000 and 2020, the aging of the population as the number of Americans over 65 increases from 35 million in 2000 to 54 million in 2020, and the changing age-specific per capita physician utilization rates, with those under age 45 using fewer services and those over age 45 using more services. The analysis notes that changing work patterns of physicians, such as decreases in working hours, could lead to greater shortfalls, while increases in productivity could moderate any shortfalls.

Other recent reports are also forecasting a shortage of physicians. As noted in another recent report, critical care physicians are just the latest to join the chorus of physicians and others concerned about an impending shortage. For this and other reasons, GNYHA strongly believes it is time for Congress to lift the resident caps and allow teaching hospitals to receive appropriate Medicare GME reimbursement for the public service they provide. GNYHA also believes that any provisions developed by Congress to provide resident cap relief should be at the Medicare GME reimbursement levels associated with the current GME payment policy.

(B) Application to Hospitals That Participated in the New York Medicare GME Demonstration Project

(1) General Comments

As you are aware, in 1996, GNYHA proposed an innovative demonstration project to CMS (then, the Health Care Financing Administration) whereby teaching hospitals in New York could elect to join the demonstration project in order to reduce resident positions in exchange for time-limited hold harmless payments. Forty-nine hospitals joined the demonstration and forty-two of those hospitals eventually withdrew, for a variety of reasons, while seven hospitals successfully completed the demonstration project. There was no due date for withdrawal from the demonstration and no penalty associated with withdrawal from the demonstration. Under the Terms and Conditions of the demonstration project, hospitals that withdrew from the program were not eligible for any hold harmless payments. That is, no Medicare funds beyond its usual reimbursement was received by a hospital that withdrew from the demonstration project.

Given the unique position of these hospitals that voluntarily elected to join the CMS-sponsored demonstration project, GNYHA is appreciative that Congress included within Section 422 of Public Law 108-173 the statement that the subparagraph shall *not* be construed to permit:

> the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6), under a demonstration project approved as of October 31, 2003, under the authority of section 402 of Public Law 90-248, or as affecting the ability of a hospital to establish new medical residency training programs under section 4(H).

CMS made note of this statement in the preamble to the proposed rule (pages 28306-07). GNYHA is appreciative in particular that CMS drew attention to the fact that this statement applies to hospitals that participated in the demonstration project "to the extent that a hospital's 'reductions in residency positions' were '*attributable*' to its participation in the demonstration project." GNYHA strongly believes that the emphasis on this point is appropriate and requests that CMS expand upon its current proposal to allow additional hospitals that do not meet the current proposed criteria to demonstrate that certain reductions were also "attributable" to its participation in the demonstration project and should therefore be exempt from reduction in the hospitals' FTE resident cap.

In particular, we note that the above statement from Section 422 prohibiting redistribution of reductions in residency positions does not specify a time frame in which those hospitals needed to refill those positions. Instead, the plain reading of the statutory language supports the view that if a hospital can demonstrate that any resident position was eliminated from its resident count as a result of participation in the voluntary reduction program, then CMS is absolutely prohibited from reducing the hospital's resident cap to account for that reduced resident position.

(2) Hospitals Participating in the Demonstration Project During the Most Recent Cost Report Year Ending On or Before September 30, 2002

GNYHA supports the CMS proposal that for a hospital that was participating in the demonstration project during the most recent cost report year ending on or before September 30,

2002, CMS would compare the higher of the hospital's base number of residents, and the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, to the hospital's otherwise applicable FTE resident cap. These hospitals either completed the demonstration project or were participating in the demonstration project during a period such that it would be completely unreasonable to expect that they would not be below their resident FTE cap. Given that all the hospital's "unused" resident positions in such a situation are attributable to participation in the demonstration project, GNYHA strongly supports the CMS proposal regarding application of Section 422 to these hospitals.

(3) Hospitals That Withdrew From the Demonstration Project Prior to the Most Recent Cost Report Year Ending On or Before September 30, 2002

(a) General Comment

GNYHA does not, however, support the accompanying proposal that a hospital that withdrew prior to the beginning of the most recent cost reporting period ending on or before September 30, 2002, should be automatically subject to the procedures applicable to all other hospitals for determining possible reductions to the FTE resident caps, for the following reasons.

Some hospitals that withdrew from the demonstration project prior to the most recent cost reporting period ending on or before September 30, 2002 withdrew after realizing that should they remain in the demonstration and maintain the resident reductions made as a result of participation in the demonstration project on a permanent basis, their educational and patient care missions would be compromised in the long run.

Because the Terms and Conditions "front-loaded" the hold harmless payments by means of a *declining* percentage of the hospital's usual Medicare GME reimbursement, all demonstration hospitals were incentivized to make as large a reduction as possible in the earlier years of the demonstration project. Many of these hospitals withdrew after making significant reductions within programs or closing multiple residency programs. Some hospitals that withdrew prior to the most recent cost reporting period ending on or before September 30, 2002 were able to rebuild their residency programs almost immediately and reached their applicable FTE resident cap level. Other hospitals have begun to rebuild their residency programs or are still in the preliminary or planning stages for rebuilding their residency programs. Again, we note that the part of Section 422 prohibiting redistribution of reductions in residency positions attributable to a voluntary demonstration project does not specify a time frame within which those hospitals need to refill those positions. The "bright line" distinction that CMS is proposing to draw suggests that there is some predetermined maximum amount of time that hospitals participating in the demonstration project had to increase their resident count to return to their FTE cap level. No time frame is identified in the statute, the Terms and Conditions of the demonstration, or any other law, regulation, or agreement relevant to this issue. Section 422 provides CMS with the authority to ensure that resident positions are not redistributed in some wholesale manner, yet that is precisely what is being contemplated in the proposed rule.

GNYHA believes it is not appropriate for CMS to automatically assume that every resident position reduced within a hospital that withdrew prior to the most recent cost reporting period ending on or before September 30, 2002 is subject to the procedures applicable to "all other hospitals," none of which made resident reductions attributable to a CMS-sponsored

demonstration project. Therefore, GNYHA recommends that in those cases where a hospital that withdrew from the demonstration project prior to the most recent cost reporting period ending on or before September 30, 2002 is found to be below its FTE resident cap in that cost reporting period, but can show that it is below that FTE resident cap in whole or in part as a result of reducing specific positions attributable to participation in the demonstration project, that these hospitals be granted the opportunity to show that "attribution," consistent with Section 422.

(b) Methodology for Determining Exemption of Reduced Resident Positions Attributable to the Demonstration Project

GNYHA appreciates the complexity involved in granting hospitals that participated in the New York Medicare GME Demonstration Project but withdrew prior to the most recent cost reporting period ending on or before September 30, 2002 the opportunity to demonstrate that particular reduced resident positions are "attributable" to the demonstration project and should be exempted from redistribution. GNYHA would therefore propose a multi-part criterion that hospitals would have to satisfy in order to demonstrate that particular positions should be exempted. The criteria focus on a two-part test for exemption from redistribution: *hospital eligibility* and *residency program eligibility*. A residency program's eligibility for consideration under the second-level criterion would be dependent on a hospital where training under that program occurred satisfied the first-level criterion.

GNYHA strongly believes that satisfaction of these two criteria provides sufficient proof that residency positions within specific residency programs were reduced as a result of participation in the New York Medicare GME Demonstration Project. GNYHA also believes that such a finding that reduced residency positions within these programs were reduced in order to satisfy the Terms and Conditions of the demonstration project automatically exempts these positions from redistribution under Section 422, consistent with the language of the MMA.

Finally, GNYHA recognizes that CMS may not be able to address all details of this recommended methodology in the final rule. As such, we would hope that time constraints would not preclude CMS from giving ample consideration to the reasonableness of this recommendation and its consistency with the relevant provisions within Section 422.

(i) First Level Criterion: Hospital Eligibility

GNYHA proposes the following criteria for CMS to use in making an initial determination whether a hospital would be eligible to claim that individual positions should be exempt:

- The hospital participated in demonstration project and withdrew prior to the most recent cost reporting period ending on or before September 30, 2002;
- The hospital's resident FTE count declined between the demonstration project base year and the point at which the hospital withdrew from the demonstration project; and
- The hospital's applicable FTE resident count in the hospital's reference resident level year is below FTE resident count during both the hospital's demonstration project base year and the hospital's most recent cost reporting period ending on or before December 31, 1996.

Should the hospital meet this threshold requirement, the hospital would be eligible to demonstrate that positions within particular residency programs should be exempted from redistribution. The following examples illustrate how the criterion should work.

First-Level Criterion Example #1
Suppose that Hospital A withdrew from the demonstration project in March 1999. Suppose further that Hospital A's FTE resident data shows the following:

Resident FTE Level	**# of FTEs**
BBA resident cap	200.0
Demonstration project base year amount	202.0
CR period ending on 12/31/99	185.0
CR period ending on 12/31/01	190.0

Based on this data, this demonstration hospital would meet the first level criterion.

First-Level Criterion Example #2
Suppose that Hospital A withdrew from the demonstration project in January 1999. Suppose further that Hospital A's FTE resident data shows the following:

Resident FTE Level	**# of FTEs**
BBA resident cap	200.0
Demonstration project base year amount	210.0
CR period ending on 12/31/99	190.0
CR period ending on 12/31/01	201.0

Based on this data, this demonstration hospital would not meet the first level criterion because the resident FTE level in the last cost reporting period ending on or before September 30, 2002 is greater than the BBA resident cap level.

(ii) Second Level Criterion: Residency Program Eligibility
GNYHA proposes the following criteria for CMS to use to make a determination regarding whether positions within particular residency programs would be eligible for exemption. Eligibility for consideration under this criterion would be dependent on satisfying the first-level criterion.

- The residency program was in operation during the base year for the demonstration project;
- The FTE resident count for that particular residency program declined between the demonstration project base year and the point at which the hospital withdrew from the demonstration project; and
- The FTE resident count for that particular residency program in the hospital's reference resident level year is below both a) the FTE resident count for that particular residency program during the base year for the demonstration project, and b) the FTE resident count for that particular residency program during the most recent cost reporting period ending on or before December 31, 1996.

Should the residency program meet this requirement, the hospital would be eligible to demonstrate that individual positions within that particular residency program should be exempted from redistribution. The following examples illustrate how the criterion should work.

Second-Level Criterion Example #1
Suppose that Hospital A withdrew from the demonstration project in March 1999 and satisfies the first-level criterion. Suppose further that Hospital A's FTE resident data for a particular residency program shows the following:

Residency Program FTE Level	**# of FTEs**
BBA resident cap year	77.0
Demonstration project base year amount	75.0
CR period ending on 12/31/99	51.0
CR period ending on 12/31/01	60.0

Based on this data, this residency program within this demonstration hospital would meet the second-level criterion and positions within this residency program would be eligible for exemption from redistribution.

Second-Level Criterion Example #2
Suppose that Hospital A withdrew from the demonstration project in March 1999 and satisfies the first-level criterion. Suppose further that Hospital A's FTE resident data for a particular residency program shows the following:

Residency Program FTE Level	**# of FTEs**
BBA resident cap year	77.0
Demonstration project base year amount	75.0
CR period ending on 12/31/99	51.0
CR period ending on 12/31/01	76.0

Based on this data, this residency program within this demonstration hospital would not meet the second-level criterion because the residency program FTE level in the last cost reporting period ending on or before September 30, 2002 is greater than the demonstration project base year level.

(iii) Potential Additional Criterion: Documentation to Support Exemption
As noted, GNYHA believes that satisfaction of these two criteria prove that these reduced resident positions are attributable to demonstration project and should be exempt from redistribution. That being said, GNYHA and the relevant hospitals would be pleased to work with CMS to develop basic documentation requirements to support the exemption should the agency believe such a requirement is needed. Examples of satisfactory documentation might include any of the following:

- Minutes of a meeting of the institutional GME Committee reflecting the decision to reduce the number of residents training in the program; or

- Minutes of a Board meeting reflecting the decision to reduce the number of residents training in the program; or
- Notification from the chief executive officer, chief financial officer, or other appropriate institutional representative regarding the decision to reduce the number of residents training in the program; or
- Notification to the appropriate accrediting organization regarding plans to close the residency program; or
- Notification to the appropriate accrediting organization regarding reductions in the residency program; or
- Notification to the sponsoring institution regarding the non-availability of the demonstration hospital as a future rotation site for the residency program.

(iv) Limitation on Number of Exemptions of Reduced Resident Positions Attributable to the Demonstration Project

GNYHA recognizes that hospitals that withdrew from the demonstration project prior to the most recent cost reporting period ending on or before September 30, 2002 might have, in certain instances, added resident positions in specialty departments other than where resident reductions attributable to the demonstration project were made. Therefore, in order to ensure the integrity of this proposed methodology and to ensure that the number of individual reduced residency position eligible for exemption does not exceed the appropriate number of positions, the number of exemptions should be "capped" at the difference between (a) the number of FTE residents in the hospital's reference resident level year, and (b) the *lower* of the hospital's demonstration project base year FTE resident count and the resident FTE count in the hospital's most recent cost reporting period ending on or before December 31, 1996.

The following example will serve to illustrate how the *exemption cap* would be determined for a particular hospital that meets the three-level criterion:

Table 1. Determining the Maximum Number of Hospital-specific Exemptions Attributable to the Demonstration

Hospital FTE Resident Level	**# of FTEs**
Demonstration project base year count	110.0
BBA resident cap number	105.0
Reference resident level year count	85.0
Maximum number of exemptions available	20.0

In the above example, the hospital is 25.0 FTEs below its demonstration project base year count in the reference resident level year. However, because the hospital's BBA resident cap is lower than the demonstration project base year count, that lower number (105.0 in the above example) and the count in the reference resident level year is used to determine the difference (20.0 in the above example) and that number is the maximum number of exemptions that would be available to the hospital.

(C) Reduction of Hospitals' FTE Resident Caps Under the Provisions of Section 422
Separate from the above comments regarding the New York Medicare GME Demonstration Project, GNYHA offers the following comments and recommendations regarding the reduction of hospitals' resident FTE caps under Section 422.

(1) Submitted vs. Audited FTE Resident Counts: Determinations of "Unused"
GNYHA concurs with the well-stated opinion expressed by the Association of American Medical Colleges in the organization's comment letter that in implementing Section 422, CMS should focus on the intent of the legislation as it related to a determination regarding whether a resident position is "unused." In particular, we urge the agency to direct the fiscal intermediaries to not use documentation and resident reporting issues that were defined specifically and narrowly for payment purposes to complicate such an important issue when there is reasonable evidence that a resident position is being "used."

In the Greater New York region, the large number of academic affiliations and resident rotations between hospitals are a great strength but also create a set of unique challenges. In some cases, an academic medical center might be rotating residents from one hundred programs to a large number of other hospitals and nonhospital settings in order to accomplish its goals of excellence in education. The complications in this academic market are reflected in the myriad difficulties that hospitals in this region have encountered completing the Intern and Resident Information System (IRIS) reports that are required to accompany the Medicare cost report. Although the accurate completion of these reports is a high priority among hospital finance and program staff, there have been and continue to be great challenges in ensuring that the various resident rotations translate into accurate reporting according to Medicare GME payment regulations.

The initial reporting to the Medicare program on the IRIS is subject to review and audit by the intermediary, and hospitals work hard at the front end (prior to submission) to avoid any resident rotation disallowances. These disallowances might occur as a result of assignment "overlap" (two or more hospitals reporting training the resident during the same time period) or upon audit when the fiscal intermediary concludes that the documentation supporting the resident or a particular assignment is insufficient according to a strict reading of the Medicare regulations. In such cases, the hospitals have attempted to clear up the overlaps and provide additional documentation, but have not always been successful in convincing the fiscal intermediary that the resident's training time is allowable.

Given the complexity in reporting and the process for settling on a hospital's resident FTE count, it is imperative that CMS recognize that a teaching hospital may be at or above its resident FTE cap, but the GME audit protocol used by the fiscal intermediary may determine gaps that would normally trigger a redistribution. In these cases, for all intents and purposes, the hospital had no unused positions in the reference resident level year. That is, the specific documentation and other requirements of an audit that are normally used for Medicare GME payment purposes in a particular year should not be used to disallow residents training in the hospital and trigger a lowering of the resident FTE cap. In such a case, the determination regarding if and how many "unused" resident positions are available for redistribution should be made on the basis of the hospital's best belief regarding its resident FTE count (generally, the submitted resident count).

There are examples of GME audits in the Greater New York region where the hospital has submitted a Medicare cost report and an accompanying IRIS diskette showing that it is at or above its resident FTE cap, but upon audit, the hospital is found to have a lower number of allowable residents *for payment purposes* in that specific year. It would be a misreading of the intent of the statute to view such a situation as evidence that the hospital had positions that were "unused." The hospital's best belief upon submission was that it would be found to be at or above its resident FTE cap.

By the same token, a hospital may believe that it is only one or two FTEs below its resident FTE cap, but an audit may determine a larger gap. Again, GNYHA believes that it would be a misreading of the statute to conclude that the hospital was not "using" the higher number of positions. If an audit had been performed contemporaneous with the training, the hospital would probably have recruited additional residents in immediate recognition of having room in its cap. The time lag for audit should not force poor decisions but should be considered in the context of hospitals' general desires to be as close to their cap number as possible. GNYHA therefore recommends that CMS direct its fiscal intermediaries that in the case of a discrepancy between the submitted resident FTE count and the audited resident FTE count such that the audited count would result in a more significant lowering of the hospital's resident FTE cap, that the determination be made on the basis of the submitted resident FTE count.

(2) Determination of the FTE Resident Cap Reduction and Hospital Opportunity for Appeal of Fiscal Intermediary Decisions

Section 422 states, "the aggregate number of increases in the otherwise applicable resident limits under this paragraph may not exceed the Secretary's estimate of the aggregate reduction in such limits." GNYHA agrees with CMS's reading of the statute that Congress granted the agency discretion in implementing Section 422, such that an exact one-for-one swap of downward and upward cap adjustment is neither required nor feasible, given the complexity involved in implementing Section 422 in a short timeframe. Rather, GNYHA agrees that CMS has been granted discretion to make a best estimate of the number of positions available by a particular date and proceed with the redistribution as of July 1, 2005. Although it is not ideal for program planning, GNYHA recognizes the agency's decision to use May 1, 2005 as the date for deciding the number of positions available for redistribution.

Having declared its intention to utilize this discretion, though, CMS should ensure that the discretion is used to ensure the overall integrity of the Medicare program and used to protect hospitals subject to Section 422 from inconsistent application of different rules within the Medicare program. GNYHA is concerned that CMS not misinterpret the provision within Section 422 that specifies, "there shall be no administrative or judicial review under section 1869, 1878, or otherwise, with respect to determinations made under the section." In including this provision within Section 422, GNYHA believes that Congress did not expect redistribution determinations made under Section 422 to be subject to *separate* appeals or judicial reviews, but to be subject to the same appeals process that are used for payment purposes. That is, Congress could not have meant to create different tracks for the resident FTE count determinations for a particular period (a "cap track" and a "payment track") since the only purpose of the auditor making a determination regarding a hospital's resident FTE cap is to fully inform payment decisions. GNYHA recommends that CMS allow the usual appeals and judicial reviews to which

hospitals are entitled to fully inform the process and ensure that determinations made under Section 422 are correct.

Specifically, any hospital at risk of having its FTE resident cap lowered must have ample opportunity to appeal an audit finding by the fiscal intermediary that it believes is incorrect. GNYHA urges CMS to not interpret the above statement within Section 422 to mean that a determination of the fiscal intermediary with regard to FTE resident cap reductions will be final, without any external appeal mechanism. Hospitals will still be entitled to the usual appeals process for Medicare payment purposes, and certainly for purposes of any reduction to their resident FTE cap if the hospital's BBA resident FTE cap amount is still under appeal. GNYHA notes that if a hospital believes it has not been able to account for all its residents in a particular year, the hospital still has the right to appeal a GME audit finding of the fiscal intermediary as it pertains to the particular cost reporting period for regular payment purposes.

It is imperative that determinations made for purposes of Section 422 be consistent with the mechanism for determinations made for payment purposes where hospitals believe that all residents have not been accounted for and seek the external appeal or judicial review mechanism. If appeals for payment purposes are made independent of resident count determinations used for purposes of Section 422, the Medicare program could be faced with the bizarre situation of a hospital's resident cap being permanently lowered by an amount that is later found to be based on an erroneous resident count determination, with the successful appeal or review not being applied to the much more important finding – the permanent setting of the hospital's resident FTE cap. Such a result serves no purpose other than to undermine the credibility of CMS, its fiscal intermediaries, and the process for making determinations under Section 422, and therefore, CMS should ensure that it does not occur.

3) Opportunity for Withdrawal of the Request to Use the Cost Report Year That Includes July 1, 2003 for Purposes of Section 422

CMS issued a One Time Notification (OTN) on April 30, 2004 that provided hospitals with the opportunity to make a "timely request" to have CMS use the Medicare cost report that includes July 1, 2003 for purposes of comparison to the hospital's relevant resident FTE cap amount. Absent this request, the hospital's most recent cost report ending on or before September 30, 2002 would be used for the comparison. The issues described in the OTN were also discussed in detail in the proposed rule. The request could be made if the hospital could demonstrate that it had an expansion in one of the years since its last settled cost report. The purpose of a hospital making the request would be to minimize the loss of residency positions under Section 422.

GNYHA has therefore been extremely dismayed to hear CMS staff describe the request as "binding" even if the hospital's loss would have been less absent the request. GNYHA's strong belief is that since the only purpose of the request is to come closer to or exceed its resident FTE cap, either through having a higher resident FTE count in comparison to its cap or demonstrating that it met the new program exception described below, then CMS should allow the hospital to withdraw the request or the agency should automatically withdraw it on behalf of the hospital if it turns out that non-submission would have benefited the hospital. As CMS has acknowledged repeatedly, the requirements for implementation of Section 422 include many difficult timing issues that must rely on collection of important resident data, audit of that information, and

decision-making associated with that data. It is absolutely not reasonable for CMS to make a request such as this "binding" in full knowledge that inherent in making such a request, there must be at least a small element of estimation, and an incorrect estimate might eventually work to a hospital's disadvantage when the data and documentation issues are reviewed more thoroughly.

GNYHA therefore recommends that if it is found that a hospital's loss of residency positions would be less if the hospital had not made the request in response to the OTN, then the request should be null and void. In such a case, GNYHA believes that CMS should allow the hospital to withdraw the request and the agency should use the hospital's most recent cost report ending on or before September 30, 2002 for the comparison.

(4) Application of the FTE Resident Cap Reduction to Hospitals Participating in a Medicare GME Affiliated Group Agreement as of July 1, 2003

GNYHA appreciates the challenges presented in implementing Section 422 while also giving consideration, as mandated in the MMA, to hospitals' participation in a Medicare GME affiliated group agreement "as of July 1, 2003." CMS is to be commended for its thoughtful approach to the application of the provision to hospitals that participated in such an agreement. That being said, GNYHA does have some concerns regarding this section of the proposed rule and offers these comments, principles, and recommendations as CMS moves to finalize the rule.

Principle1: Hospitals At or Above The Aggregate Cap Should Not Lose Any Positions

As noted in the preamble to the proposed rule, Congress explicitly gave special consideration to hospitals that had voluntarily elected to join an affiliated group for Medicare purposes. Given that the BBA authorized the affiliated group arrangement as a means of allowing hospitals to have hospital-specific resident FTE caps viewed as an aggregate resident FTE cap, CMS should ensure that an audit determination that finds the aggregate count higher than the aggregate cap should automatically and without question protect all hospitals within the group from any lowering of hospital-specific caps. Therefore, GNYHA recommends that if two or more hospitals that elected to form a Medicare GME affiliated group as of July 1, 2003 are determined to have an aggregate resident FTE count during the reference resident year level that is higher than the their aggregate resident FTE cap, then none of the hospitals within the affiliated group should be subject to a lowering of its hospital-specific resident FTE cap.

Principle 2: Hospitals Should Be Provided With The Opportunity To Amend Cap Adjustments

When hospitals elected to join or renew an affiliated group as of July 1, 2003, the due date for which was June 30, 2003, the relevant hospitals had no way of knowing that this election would have implications for potential reductions to their hospital-specific resident FTE caps. Given that the MMA was passed months after the due date for this election, it is important to recognize that Congress could not possibly have meant the voluntary election to provide undue harm to individual hospitals that had chosen to exercise their rights to form a Medicare GME affiliated group. Instead, the intent of the affiliated group provision within Section 422 is clearly designed to allow hospitals to utilize the voluntary election *in a positive manner* in recognition of their choice to aggregate their hospital-specific resident FTE caps.

GNYHA is appreciative that these hospitals were viewed with this positive consideration within the MMA since their election to aggregate resident FTE caps warrants this consideration. Aggregating hospital-specific resident FTE caps is a *de facto* election to use a portion or all of the "unused" positions. Given the positive nature of the special consideration, GNYHA is very concerned that CMS not use the election to cause undue harm upon particular hospitals that would experience less harm (or, no harm) absent the election. GNYHA urges CMS to ensure that the application of this special consideration does not have this inappropriate effect.

GNYHA recommends that hospitals that elected to form a Medicare GME affiliated group as of July 1, 2003 be given an opportunity after the final rule is published, for purposes of Section 422, to amend the cap adjustments that were in place as of June 30, 2004. This is particularly important since the end date for a potential amendment to the July 1, 2003 agreements occurred during the comment period for the 2005 inpatient PPS rule, while there was still much uncertainty regarding how the agreements would be accounted for in the redistribution process.

Principle 3: Allow Comparison to the Residency Program Year July 1, 2003 to June 30, 2004
GNYHA notes there is great concern in the teaching hospital community regarding the fact that the proposed rule mandates a process whereby adjustments to individual hospital caps that were made to reflect the period July 1, 2003 to June 30, 2004, must be compared to the hospital resident FTE counts corresponding to a different (in some cases, not even overlapping) period for purposes of Section 422. Although we recognize that CMS, in proposing this methodology, was attempting to reconcile several different aspects of Section 422, we strongly believe that teaching hospitals should be provided with the most straightforward option of all, and that CMS has the authority to provide this option. GNYHA therefore recommends that CMS allow the hospitals that signed a Medicare GME affiliated group agreement as of July 1, 2003 to elect to have their hospital-specific adjusted cap numbers compared to the hospital-specific resident FTE count for the period July 1, 2003 to June 30, 2004 for purposes of Section 422.

(5) Newly Approved Residency Program Exception
GNYHA believes the proposed "new program" exception as outlined in the proposed rule and the recently issued "One-Time Notification" is much too restrictive and makes no sense in the context of its supposed intent. Under the proposal, a hospital's resident count can only be increased if *no* residents from the newly approved program were training during the relevant cost reporting period. Such an overly restrictive reading of the statute flies in the face of the intent of the exception and is contrary to the implementation mechanisms for new programs exceptions that have been made since the passage of the BBA.

In the proposed rule, CMS is choosing to interpret the statutory language, "a medical residency training program ... which was not in operation," as mandating a requirement that not one resident had started training in the residency program. However, there are numerous new programs that were accredited prior to January 1, 2002 for which only a partial complement of residents is reflected on the relevant cost report. For example, if a new five-year residency program was accredited on January 1, 2001 and began training residents on July 1, 2001, and the hospital's relevant cost reporting year for implementing Section 422 was July 1, 2001 to June 30, 2002, that year would likely reflect only residents being trained in the first program year. If the hospital's FTE resident count is below its resident FTE cap for that year *to account for* the newly

approved program, it is at risk of having its cap reduced even though it has committed to training the residents in that program and was intending to use its "cap space" for that program.

GNYHA believes that such a result is contrary to the intent of Congress having including the exception within Section 422. Consequently, to ensure compliance with legislative intent, GNYHA recommends that "not in operation" should be interpreted as meaning "not fully in operation" and that the proposed rule should be modified accordingly to allow the residency program to maintain its commitments and grow to its full complement.

(6) Application to Hospital Proscribed From Merger by a Government Agency

In implementing Section 422, it is important that CMS give special consideration to any case that has been affected by the action of a competing government agency, particularly a State agency. In the case where that agency has effectively stopped the planned merger of the hospital in question with another hospital and the associated integration of residency programs and recruitment of residents into "unused" positions, GNYHA recommends that CMS either exempt those "unused" positions from redistribution or provide another special consideration to mitigate the effects of Section 422.

(7) Application to New Teaching Hospitals

Existing Medicare regulations define the criteria for the establishment of a resident FTE cap for any hospital that did not report residents in the most recent cost report ending on or before December 31, 1996. Following the establishment of the hospital's first residency training program, the hospital is allowed three years to establish a resident FTE cap. GNYHA recommends that CMS clarify in the final rule that a new teaching hospital that did not have a resident FTE cap established during the most recent cost reporting period ending on or before September 30, 2002 because that period of time overlapped with the hospital's three-year start up period for establishment of its resident FTE cap are exempted from redistribution of any resident positions.

(8) Application to Hospital Previously Classified As Rural But Proposed To Be Reclassified Into An Urban Area As of October 1, 2004

GNYHA notes that the FTE resident cap reduction under Section 422 does not apply to rural hospitals that have less than 250 beds and that CMS is proposing to apply this provision by exempting any hospital located outside a Metropolitan Statistical Area (MSA) that reported less than 250 beds in the most recent cost reporting period ending on or before September 30, 2002. A separate provision within the proposed rule would reclassify certain hospitals that had been in areas now classified as rural into an MSA as of October 1, 2004. GNYHA recommends that any hospital that was considered rural during the most recent cost reporting period ending on or before September 30, 2002 should be considered rural for purposes of Section 422 and if the hospital reported less than 250 beds, resident positions that are determined to be below the hospital's FTE resident cap should be exempt from redistribution.

(D) Criteria for Determining Hospitals That Will Receive Increases In Their FTE Resident Caps
GNYHA appreciates that CMS had a very difficult task in determining which teaching hospitals that wish to increase their FTE resident caps are "deserving" of such an increase. The combination of very specific statutory language (e.g., the hospital priority ordering) on the one hand and the discretion granted to the agency on the other hand, along with the short timeframe for implementation, clearly created significant challenges, and GNYHA applauds the thought and effort that went into developing the criteria, and CMS's attempt to develop an "objective process." That being said, GNYHA does have several concerns and recommendations regarding the agency's approach to redistributing residency positions.

(1) Comment Regarding Reimbursement For Redistributed Positions
(a) *Alternative Payment Formula*
Before commenting on the specific criteria that CMS has proposed for determining which institutions and residency positions will be approved for resident FTE cap increases, GNYHA wishes to note its strong objection to the formulas for determining Medicare direct GME and indirect medical education (IME) reimbursement for redistributed positions as defined in the MMA. Although we recognize that CMS does not have the authority to alter the formula defined in the statute, we wish it to be noted for the record that GNYHA strongly believes that the Medicare reimbursement formula for all residency positions should be consistent and Section 422 of the MMA should not have mandated a locality-adjusted national average per resident amount and a reduction in the IME formula multiplier.

The severe reduction in IME reimbursement for these redistributed positions is particularly egregious. It serves no purpose other than to further complicate the redistribution process, and set in statute an unsupported lower Medicare GME reimbursement formula, albeit for this limited pool of positions. GNYHA hopes that this outrageous disregard for the fragile financial condition of teaching hospitals that this formula represents is an anomaly and does not reflect the sentiment within the Congress regarding the importance of teaching hospitals in this country. These institutions continue to struggle financially while striving to provide top-notch patient care, educate tomorrow's physicians, and conduct important biomedical research. GNYHA also notes that the limited cap relief that Section 422 was supposed to represent for certain hospitals has been undermined by these MMA-mandated formulas.

(b) *Inclusion of Redistributed Position in the Three-Year Rolling Average Calculation and Prior Year IRB Cap*
GNYHA disagrees with CMS's proposal to include redistributed positions in the three-year rolling average calculation and the calculation of the prior year's intern and resident to bed (IRB) cap. CMS notes that Section 422 does not expressly exclude the resident counts associated with the redistributed cap slots from the IRB cap and the three-year rolling average. The agency then states that, "with no apparent reason to treat residents counted as a result of the FTE cap increases under section 1886(h)(7)(B) differently for purposes of the rolling average," those residents would be immediately subject to the rolling average. With all due respect to CMS, the reason "to treat the residents differently" and not subject them to the rolling average is because they are immediately being reimbursed differently as a result of the alternative payment formula mandated in Section 422. Also, the agency's desire to introduce "stability" and "predictability" is

uncalled for when the lower IME payment formula immediately destabilizes teaching hospital finances and the Medicare GME reimbursement system.

GNYHA believes that the absence of a directive within the statute to exclude redistributed FTE residents from the IRB cap and the rolling average calculation neither implies nor requires their inclusion. CMS has, in the past, created exceptions to including resident positions within the rolling average and the IRB cap when, in its view, there were compelling reasons to do so even in the absence of a statutory mandate. Congress clearly decided that residents that are redistributed to a hospital pursuant to Section 422 are to be treated differently than other residents already subject to the hospital's resident FTE cap.

GNYHA recommends that resident positions that are redistributed as a result of Section 422 should be counted outside the IRB cap and the three-year rolling average provisions.

(2) Positions Subject to the Alternative Payment Formula

In drafting Section 422, Congress decided to subject redistributed positions to an alternative payment formula, and GNYHA has noted its objection to the use of that alternative payment formula in the case of this limited number of positions. GNYHA also strongly believes that Congressional intent with regard to redistribution should not be misread by CMS in the case of a hospital that complies with mandated administrative requirements (both on the "decrease" side and the "increase" side) in order to protect as many of its residents as possible. That is, CMS should not artificially describe positions as "redistributed" and subject those positions to the alternative payment formula absent concrete evidence that a real redistribution has been experienced by the relevant hospital.

As mandated under the MMA, all hospital cap adjustments attributable to Section 422 will occur simultaneously as of July 1, 2005. That is, a hospital is subject to its BBA resident FTE cap up until June 30, 2004, and as of July 1, 2005, any adjustment to that cap as a result of application of Section 422 will be made. In the case of Hospital A, then, which currently has an BBA resident FTE cap of 100 FTEs, any adjustment to its cap that is going to occur will occur as of July 1, 2005. Specifically, on that date, Hospital A's cap will either remain the same, be lowered by a certain amount, or be increased by a certain amount as a result of Section 422.

In particular, we note that there is not a single point in time when Hospital A's BBA resident FTE cap will be lowered as a result of Section 422 and resident positions attributable to that lowering will reside in a "resident pool" awaiting distribution to hospitals seeking cap relief. GNYHA believes that this critically important point is necessary to understand in determining which positions are redistributed and subject to the alternative reimbursement formula included within Section 422. For a hospital, the only evidence of redistribution is the change in hospital cap level as of July 1, 2005. As such, the alternative payment formula should be limited to the aggregate number of positions accounted for by this difference.

To give an example, if Hospital A's BBA resident FTE cap is 100 FTEs on June 30, 2005, and Hospitals A's resident FTE cap is raised to 110 FTEs as of July 1, 2005, the number of positions that have been redistributed to Hospital A is 10 FTEs. By the same token, if Hospital B's resident FTE cap is 100 FTEs on June 30, 2005, and Hospitals B's resident FTE cap is lowered

to 95 FTEs as of July 1, 2005, the number of positions that have been redistributed from the hospital to another hospital is 5 FTEs, and in particular, all Hospital B's resident FTEs should be reimbursed under the usual payment rules.

To further clarify the case of Hospital B, the fact that there may have been an audit conducted by the fiscal intermediary that resulted in a particular determination and an application by the hospital to CMS for cap relief are separate administrative issues that do not alter the fact that the difference that occurs between June 30, 2005 and July 1, 2005 represents "redistribution." In particular, the fact that Hospital B's fiscal intermediary may have concluded that the hospital's cap should be lowered from 100 FTEs to 90 FTEs while at the same time, Hospital B has successfully applied to CMS for cap relief in the form of 5 FTEs does not warrant a reduction in the Medicare GME reimbursement formula associated with the 5 FTEs that represent the difference between the 90 FTEs and the 95 FTEs. In this example, Hospital B should receive its usual Medicare GME reimbursement for 95 FTEs as its cap has been lowered and it has not received *any* "redistributed" positions.

GNYHA requests that CMS use all means within its discretion to ensure that only the positions represented by the difference between the aggregate resident FTE cap amounts as of June 30, 2005 and July 1, 2005, are subject to the alternative Medicare GME reimbursement formula within Section 422. Since this difference in number of positions is the evidence of "redistribution," the figure should be the sole basis for use of that alternative payment formula.

3) Applicant Entity for Cap Adjustment

GNYHA agrees with the position of the Association of American Medical Colleges that hospitals should be viewed as the applicant entity for increases in their resident FTE cap without regard to the individual residency programs that the additional positions will be used for. In our view, it is unnecessary for CMS to require a hospital that can demonstrate that it has no difficulty attracting residents or, in particular, is above its resident FTE cap, to submit requests to CMS for additional residency positions at the program level. GNYHA would therefore recommend that CMS allow a hospital that is applying for an increase to its resident FTE cap not on the basis of its having a residency program that will be the only one in the hospital's state to apply for an increase in its resident FTE cap without having to specify the particular residency program for which the additional positions will be used. For hospitals that do wish to apply for additional positions on the basis of being the only residency program of its kind in its state, a separate application process should be developed by CMS.

On a policy level, GNYHA believes that the approach developed by CMS in the proposed rule grants the Medicare program too broad an authority, at the program level, in determining the worthiness of some specialty positions rather than others. This program-level detail is only needed in the case of a hospital applying on the basis of a program that would be the only one of its kind in the state. GNYHA believes that the accrediting bodies and the physician leadership organizations with which those accrediting bodies consult are in the best position to determine which residency training positions are worthy for "approval." GNYHA recognizes that the process CMS is proposing to establish would be for a one-time purpose, but we strongly believe that the process proposed by the agency extends its reach to an unacceptable area, whereby the

agency would essentially become a shadow "approval body," albeit strictly for Medicare reimbursement purposes.

GNYHA does not believe it is the responsibility of CMS to make program-specific decisions except where absolutely necessary. Rather, the agency's responsibility is to ensure that a resident is training in an "approved" program, and the resident's training time is therefore reimbursable under Medicare. We support the longstanding position of the Medicare program that it is not in the business of shaping the physician workforce beyond general policy goals and reimbursement for its fair share of the costs, but rather will support the costs of training a physician – any physician – as long as the physician is training in an "approved program."

(4) Use of Redistributed Positions

Regardless of what CMS ultimately decides to make the applicant entity for the redistributed positions, GNYHA is concerned that in granting the redistributed positions, CMS will make further requirements upon hospitals that have received increases in their resident FTE caps. In particular, if, as is currently proposed, a hospital is required to identify a particular program that the additional residency positions will be used for, we are concerned that the agency may attempt to create a separate set of requirements regarding those positions since they have been granted for use for a particular program.

GNYHA strongly believes that the fluidity of the academic and biomedical enterprise requires that teaching hospitals be given the maximum discretion in deciding the best use of additional residency positions. Therefore, GNYHA recommends that CMS make a clear statement in the final rule that subsequent to a hospital receiving an increase in its resident FTE cap, neither CMS nor the fiscal intermediary will impose special requirements regarding the use of those additional positions.

(5) Demonstrated Likelihood Criteria

(a) General Comment

GNYHA agrees with CMS in its decision to use the "demonstrated likelihood" that a hospital will use additional residency positions within three cost reporting periods after July 1, 2005 as a mandatory threshold requirement for receiving additional residency positions. GNYHA's membership consists of major academic medical centers and teaching hospitals that are in great demand among prospective residency trainees. We believe it serves no worthy programmatic or policy purpose for CMS to grant increases in resident FTE caps absent clear and convincing evidence that a hospital making the application is an institution with a proven track record of training residents in an environment in which physicians-in-training wish to be educated.

(b) *Preference To Hospitals Over Their Resident FTE Caps*

The education of future physicians is a key mission of academic medical centers and teaching hospitals. Consequently, a number of GNYHA member teaching hospitals have made the difficult decision to add and/or expanded residency programs while recognizing they would have to sacrifice associated Medicare GME funding because the additional resident count puts the hospital above its resident FTE cap. The decisions to increase resident counts in these situations is never made easily, as the decision has important financial implications for these institutions that must constantly worry about their financial health. Nonetheless, many institutions decided

to be true to their mission as centers of learning and attempt to offset this significant loss of funding through other means.

With regard to the specific criteria that CMS is proposing to use for a hospital to demonstrate the likelihood that it will fill positions within three cost reporting years, GNYHA notes that CMS seems to be judging the four criteria for demonstrating likelihood equally. We note that the single best piece of evidence that a hospital is likely to "fill" residency positions above its resident FTE cap is, of course, the fact that the hospital already is training a number of residents in excess of its cap.

A primary purpose (if not *the* primary purpose) of including Section 422 within the MMA as we understood it was to provide cap "relief" to hospitals that have resident counts in excess of their caps. Consequently, GNYHA believes that, at a minimum, CMS should significantly reflect this reality in its evaluation criteria by giving preference to institutions that were over their resident FTE caps in the most recent year prior to implementation of Section 422. GNYHA believes it is reasonable to give special weight to this criterion, for example, by assigning it between 25 and 50% of the weighting for evaluation. In addition, CMS should consider giving more weight to a hospital that is significantly over its resident cap (e.g., by 5% or more).

GNYHA recommends that for purposes of granting increases to hospitals' resident FTE caps, CMS give preference to hospitals that can document that during the hospital's most recent cost report year, the hospital was above its resident FTE cap for both direct GME and IME. CMS should weight a hospital that can document that it was at least 5% over its cap number by 50% and a hospital that is over its cap by less than 5% by a 25% weight.

(6) Priority Ordering

GNYHA is extremely appreciative that CMS included a sixth category, for hospitals that do not meet any of the statutorily defined priority criteria (e.g., hospitals located in large urban areas), within the priority ordering. Although, as noted in detail above, we have strong objections to the reimbursement formula that will be used for the redistributed positions, GNYHA does recognize that in certain cases, a hospital located in a large urban area may decide that it is in its best interest to apply for an adjustment to its resident FTE cap and we are grateful that CMS has allowed the hospital the opportunity to do so.

(7) Evaluation Criteria

GNYHA offers these comments and recommendations regarding three specific evaluation criteria.

- *Criterion One: Hospital has a Medicare inpatient utilization over 60 percent in two of its last three most recent settled cost reports.*

GNYHA believes that CMS should modify this criterion to include a Medicare share calculation based only on Medicare inpatients as a share of Medicare and privately insured patients. A criterion based on the percentage of all patients has the potential to penalize a hospital that provides more care to Medicaid or uninsured patients.

- *Criterion Two: Hospital will use the additional slots to start or add to an existing geriatrics program.*

GNYHA believes that CMS should not favor one specialty over another but should view all specialty programs equally and leave decisions regarding the use of additional residency positions to the hospital. GNYHA recognizes the rationale that went into the development of this criterion but we believe it should be removed from the list. The statement in the proposed rule, "geriatrics is the one specialty that is devoted primarily to the care of geriatrics patients," implies that CMS was required in its evaluation to favor *some* specialty and so settled on geriatrics. Contrary to the suggestion, Section 422 includes no explicit or implicit requirement to favor a particular specialty and so we see no need for such a criterion. This recommendation is consistent with GNYHA's above-mentioned belief that the role of the Medicare program in the context of support for teaching hospital costs is to ensure that residents are training in approved programs, but to not favor one specialty over another unless absolutely necessary.

- *Criterion Four: Hospital has continued the training of residents from a closed program or closed hospital after the temporary adjustment has expired.*

GNYHA believes that CMS should modify this criterion to recognize a hospital that qualified for a temporary adjustment because it was training displaced residents from either a closed program or a closed hospital *regardless* of whether the continued to train residents in that specialty. GNYHA believes that hospitals that have offered training to displaced residents have served a distinct public good and should be recognized for this practice even if the hospital decided it could not continue to support other trainees in that specialty absent Medicare GME funding.

Section II. Direct GME Initial Residency Period (Proposed New Section 413.79, a Proposed Redesignation of Section 413.86(g))

GNYHA is extremely appreciative that CMS chose to include a discussion of the "clinical base year" issue within the preamble to the proposed rule, and we provide these comments and make recommendations for clarification of the policy. GNYHA notes that the full and detailed discussion of the issue in the preamble, even absent accompanying proposed regulations, provides CMS with ample opportunity to clarify this rather confusing policy in the final rule. GNYHA is supportive of CMS issuing accompanying regulations (or including them separately within an interim final rule) should the agency wish to do so. That being said, GNYHA does not believe that any change to existing regulation is necessary as CMS has authority to clarify and reinterpret the statute based on the recent clear statement of Congressional intent.

GNYHA believes that a clarification is warranted because the CMS interpretation of the statute described in the proposed rule as "current" violates the statute, does not reflect Congressional intent, and results in inequitable payments to teaching hospitals for residents training in certain specialties. Prior to the pronouncement in the preamble of the so-called current policy, there had been no pronouncement regarding this policy in regulation, preamble discussion, or program memorandum as far as GNYHA has been able to determine. On that basis, GNYHA rejects the statement in the preamble that CMS has a "current" policy.

The most recent statement of Congressional intent with regard to this issue makes clear that the CMS interpretation described in the proposed rule is a misreading of the statute and, to the extent it has been applied incorrectly, the policy needs to be clarified. As stated by conference report language accompanying section 712 of the Medicare Modernization Act of 2003 (P.L. 108-173):

> The conferees also clarify that under section 1886(h)(5)(F), the initial residency period for any residency for which the ACGME requires a preliminary or general clinical year of training is to be determined in the resident's second year of training.

GNYHA urges that CMS reinterpret the statute to reflect the most recent statement of Congressional intent. This solution will ensure that any confusion regarding the policy will be removed and a consistent policy is applied across residency training programs. As the agency notes in the preamble, a large number of residents meet the general clinical year requirement by entering a preliminary year program for one year before moving in to more formal training in the specialty of choice. Residents are accepted for only one year into these preliminary year programs with the understanding that they will enter a specialty in which they wish to train in their second year. The second year specialty will be one into which they may have been accepted simultaneously with their acceptance into the preliminary year program, or to which they will apply during their first year of training.

The Medicare statute states that the IRP is "determined, with respect to a resident, as of the time the resident enters the residency training program." The statue also states that "the period of board eligibility" is the minimum number of years of formal training necessary to satisfy the requirements for initial Board eligibility in the particular specialty for which the resident is training. Under the interpretation of the statute described in the proposed rule as "current," hospitals providing training for residents who select a specialty that requires a general clinical year may not be able to count those residents as a 1.0 FTE for the full length of the specialty training. This is because using the IRP based on an overly literal reading of the statute and focusing on the program in the first year of training, regardless of the specialty for which the resident is actually training for in that first year within that program, may yield an incorrect labeling of the resident that does not reflect the resident's clear intent with regard to specialty training. The statute requires that the initial residency period be determined *as of* the resident entering the training program, but nowhere does the statute require the assignment of the IRP to a resident *during* the first year of the resident's training. If the statute did mandate such a requirement, then a resident training in a separately accredited transitional year program would not be eligible to have the initial residency period determined in the second year of training. CMS' longstanding policy allowing the initial residency period to be determined in the second year for residents training in transitional year programs is clear evidence that such a timeframe is permissible under the statute. CMS' reinterpretation should reflect the statute, as clarified by Congress in the MMA Conference Report language.

GNYHA also notes that there is no need to clarify this policy by determining whether a resident matched into two specialties simultaneously. Not every resident who is in a specialty that requires the clinical base year training matches simultaneously into both specialties, and there is no ACGME requirement that the resident do so. In addition, many residents are admitted to a residency program outside of any residency match, and there are some specialties that do not

even participate in a residency match. Such legitimate variations among the specialties and the means of entering residency training confirm that attempts to use "resident matching" for this purpose is simply not feasible. Having said that, should CMS determine that the agency absolutely requires concrete evidence of resident intention regarding specialty choice at the point that the resident began residency training, then we would encourage CMS to look more broadly than at match results and allow hospitals to produce documentation (e.g., a resident contract) to demonstrate that particular residents were training in one-year clinical base programs.

GNYHA recommends that in the final rule, CMS make a clear statement that for residents whose first year of training is completed in a program that provides a general clinical base year as required by the ACGME for certain specialties, an IRP should be assigned in the second year based on the specialty the resident enters in the second year of training.

Section III. Requirements for Written Agreements for Residency Training in Nonhospital Settings (Proposed Redesignated Section 413.78 (a Proposed Redesignation of Existing Section 413.86 (f))

(A) Proposal for Contemporaneous Payments

GNYHA is appreciative that CMS recognizes the myriad difficulties for hospitals in complying with the various requirements for a written agreement with nonhospital sites in order to claim the time residents spend training in the nonhospital setting. The requirement for a hospital to have incurred all or substantially all of the costs has presented numerous challenges when hospitals have attempted to satisfy the requirement for supervising physician activities to the satisfaction of CMS and the fiscal intermediary. CMS's attempt to streamline and simplify this requirement is appreciated by hospital staff. Unfortunately, the proposal that CMS has developed in response to industry concerns is not at all practical for hospitals and should be revised.

CMS's proposal to require that, "in order to count residents training in a nonhospital setting, a hospital must pay all or substantially all of the costs of the training in a nonhospital setting(s) by the end of the month following the month in which the training in the nonhospital site occurred," would essentially require hospitals to set up a separate tracking and payment system for this one type of contractual relationship. Hospitals have existing systems for reimbursing vendors and contractors for services provided, and the timeframes for this reimbursement are a function of many factors, including cash flow, the time of year, and other variables.

We also note that in most cases, reimbursement for a service cannot be forwarded without a proper invoice that reflects the services rendered. To ask hospitals to set up a separate system for this one type of contract would be extremely burdensome to administer. In the case of GNYHA member teaching hospitals that have current rotations to nonhospital settings, such a requirement would simply incentivize them to identify rotations within the hospital complex that might satisfy accreditation requirements in order to avoid dealing with this new level of complexity. Such a result would be contrary to the intent of the BBA, and would be an unfortunate result.

GNYHA does recognize that CMS would like to encourage a standard for current reimbursement in order for hospitals to claim the time residents spend training in nonhospital settings. GNYHA believes that a reasonable alternative would be for hospitals to demonstrate proof of payment

when the cost report is audited. Alternatively, CMS could require hospitals to make these payments within six months of the end of their cost reporting period. Either alternative achieves the same result as the current proposal — to ensure that hospitals make any required payments to nonhospital sites — but in a much less burdensome manner.

In summary, GNYHA recommends that CMS eliminate the requirement for a written agreement in order to claim the time residents spend in a nonhospital setting. GNYHA also recommends that CMS modify its proposal to require that in order to count residents training in a nonhospital setting, a hospital must pay all or substantially all of the costs of the training in the nonhospital setting(s) by the time the hospital's Medicare cost report that covers the period of time during which the training occurred is audited.

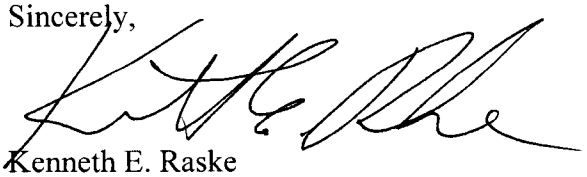
(B) Supervising Physicians Volunteering in Nonhospital Settings

GNYHA concurs with the position of the Association of American Medical Colleges and others that CMS should publish a clarification noting that it is absolutely permissible for supervising physicians in nonhospital settings to volunteer their time, i.e., provide services as a supervising physician without compensation. In such a situation, there would be no supervising physician costs for which the hospital must account in a determination of its responsibility in incurring "all or substantially all" of the cost of training in the nonhospital setting. GNYHA understands that there has been some confusion on the part of the fiscal intermediaries regarding the permissibility of such a situation, and it is CMS's responsibility to clearly address this issue and avoid further confusion.

Thank you for the opportunity to comment on these proposed regulations. Should you or your staff wish to discuss any aspect of the comments, please feel free to contact me at 212-246-7100, or Patricia Wang at wang@gnyha.org or 212-506-5407 regarding the outlier issue and Tim Johnson at tjohnson@gnyha.org or 212-506-5420 regarding the GME issues.

My best.

Sincerely,



Kenneth E. Raske
President

cc: Herb Kuhn, Director, Center for Medicare Management, CMS

CMS-1428-P-295

Submitter : Ms. Amy Melnick **Date & Time:** 07/12/2004 12:07:00

Organization : Heart Rhythm Society

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Attached are the comments from the Heart Rhythm Society. Thanks very much for providing this opportunity to comment.
Amy Melnick, Vice President, Health Poiicy
Heart Rhythm Society

CMS-1428-P-296

Submitter : Mr. Richard Rank **Date & Time:** 07/12/2004 12:07:00

Organization :

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments on New York Hospital Wage Index

CMS-1428-P-297

Submitter : Mr. Tony Orlando **Date & Time:** 07/12/2004 12:07:00

Organization : Englewood Hospital and Medical Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

REVISED WORD FILE ATTACHED - Comment submitted regarding file code CMS-1428-P, the Proposed Rule for the Inpatient Prospective Payment System, as published in the May 18, 2004 Federal Register. Our comment is specific to the "Revised MSA's". We are attaching two files; one, a WORD file, represents our narrative comments; a second file, in EXCEL, represents a Table attachment related to our narrative comments.

CMS-1428-P-298

Submitter : Mr. Elwin Bresette **Date & Time:** 07/12/2004 12:07:00

Organization : Lawrence & Memorial Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS-1428-P; Medicare Program; Proposed Changes to Hospital Inpatient Prospective Payment Systems and FY 2005 Rates; Hospital Reclassifications
Please refer to attached letter.
Thank you,
Elwin Bresette
Vice President and
Chief Financial Officer
Lawrence & Memorial Hospital

CMS-1428-P-299

Submitter : Mr. Donald Parseghian **Date & Time:** 07/12/2004 12:07:00

Organization : Jersey City Medical Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document.

Submitter : Mr. Donald Parseghian **Date & Time:** 07/12/2004 12:07:00

Organization : Meadowlands Hospital Medical Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document.

Submitter : Dr. Derek Angus **Date & Time:** 07/12/2004 12:07:00

Organization : University of Pittsburgh Medical Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

University of Pittsburgh

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July 12, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert Humphrey Building
Room 443-G
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS-1428-P

Dear Dr. McClellan:

I appreciate the opportunity to submit comments to be considered as CMS finalizes its rule regarding Medicare's Inpatient Prospective Payment System based upon proposals set forth in the Notice of Proposed Rulemaking (NPRM) published on May 18, 2004.

OTHER DRG ISSUES

In Section II, B, 16, c, page 28224, CMS states that it received a comment requesting that a new DRG be established for severe sepsis cases. Upon review of this program, it appears that CMS has concluded a new DRG for severe sepsis is not warranted at this time. I believe this is most unfortunate and would recommend that CMS should reconsider their position. My rationale follows:

Severe sepsis is now a well-recognized syndrome with consistent definitions.
An international consensus definition was established in 1992, clarifying that severe sepsis is a systemic inflammatory response to infection associated with acute organ dysfunction.[1] A second consensus conference in 2002 reinforced this definition and was endorsed by all major national and international critical care physician and nursing societies.[2]

More than thirty large, phase III, multi-center, international trials of molecules targeting the inflammatory cascade that underlies the pathophysiology of severe sepsis have been conducted over the last ten years, all using the same definition for severe sepsis. In addition, over the last few years, there have been 15 national epidemiologic studies of severe sepsis from the United States, Europe, and Australasia.

To provide a sense of how well-accepted and discussed severe sepsis has become, a study we published on the epidemiology of severe sepsis just three years ago has already been cited over 300 times in the literature.[3] In other words, two new articles cite our paper each week!

Severe sepsis is a very common, expensive, and deadly syndrome. More than 750,000 cases of severe sepsis occur in the US annually.[3] Half of those severe sepsis cases require care in an Intensive Care Unit (ICU), with hospital costs of $16 billion and a hospital mortality of around 30%.[3] Indeed, one in ten of all ICU admissions meet criteria for severe sepsis.

Severe sepsis is distinct from any other entity currently coded in the DRG system
Severe sepsis is quite different from common terms, such as septicemia or sepsis. The notion that the body's acute cellular and molecular response to infection can lead to deleterious organ dysfunction is a crucial underpinning of severe sepsis. On the other hand, a term such as septicemia conveys little more than the idea that a patient is infected with positive blood cultures. The focus of care for sepsis or septicemia is to provide appropriate anti-microbial therapy. In contrast, care for severe sepsis involves a complex, multi-pronged care paradigm that consists of initial resuscitation, antimicrobials, surgical management where appropriate, support for acute organ failure or dysfunction (such as mechanical ventilation or hemodialysis), and manipulation of the host cellular and molecular activation.

In my fifteen years of critical care practice and research, there have been thousands of papers focusing on severe sepsis and the associated acute organ dysfunction. Yet, there remains no DRG for this condition.

There are important new developments in care for severe sepsis
In recent years, a number of new therapies, including drugs such as activated protein C and corticosteroids, and protocolized approaches to care, such as protocols for physiologic goal-directed resuscitation, mechanical ventilation, and blood glucose control, have been demonstrated in leading journals to have large beneficial effects on mortality.[4-8]

Eleven of the world's leading critical care societies recently published a set of evidence-based guidelines for care of severe sepsis.[9] Organizations, such as the VHA hospital organization and JCAHO, are considering promoting compliance with some or all of these guidelines.

There is a need to ensure these advances in care are translated into practice.
The extent to which Medicare beneficiaries and other patients might receive these therapies depends on our efforts to ensure we overcome barriers to research translation. A first step is to accurately and easily identify patients with severe sepsis. In 2003, a new ICD-9 code was introduced for severe sepsis. However, use of that code has no financial consequence, and so it is unclear if hospital coders will use it.

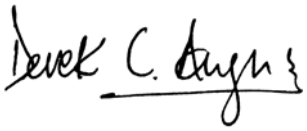
Implementing DRGs for severe sepsis will have two key advantages.
First, severe sepsis DRGs will facilitate tracking of patients with severe sepsis. Such tracking will, in turn, facilitate data collection and monitoring efforts required for across-hospital and within-hospital quality-improvement initiatives in the care of severe sepsis. Such initiatives are not only of generic value but are explicitly recommended under the 2003 Medicare Modernization Act.

Second, patients who develop severe sepsis are often very expensive. As such, they are usually outliers in their DRGs. The only inexpensive severe sepsis patients are those who die quickly. Given the volume of cases with severe sepsis, it seems prudent to group them separately, with a DRG reimbursement scheme that decreases the number of outliers.

Summary
Severe sepsis is a well-accepted entity that is quite distinct from any other condition currently coded in the DRG system. However, because there is no DRG for severe sepsis, these patients are widely distributed across all other DRGs. This pattern is inefficient, resulting in a large number of outliers, and makes tracking of severe sepsis extremely difficult. Yet, tracking of severe sepsis is essential if we are to engage programmatically in trying to promote better care of these patients. There has been an explosion of new evidence regarding the optimal way to care for severe sepsis, but it is unclear if this evidence has translated to the bedside. The first step towards better care is to identify the problem, and CMS is perfectly positioned to do so. I encourage CMS to implement new DRGs in the PPS that

encourage hospitals to accurately identify Medicare beneficiaries suffering from this expensive, serious, common, and life-threatening condition.

Yours sincerely,



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References

1. Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference. *Crit Care Med.* 1992;20:864-874.
2. Levy MM, Fink M, Marshall JC, et al. 2001 SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference. *Crit Care Med.* 2003;31:1250-1256.
3. Angus DC, Linde-Zwirble WT, Lidicker J, Clermont G, Carcillo J, Pinsky MR. Epidemiology of severe sepsis in the United States: Analysis of incidence, outcome, and associated costs of care. *Crit Care Med.* 2001;29:1303-1310.
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5. Annane D, Sebille V, Charpentier C, et al. Effect of treatment with low doses of hydrocortisone and fludrocortisone on mortality in patients with septic shock. *JAMA.* 2002;288:862-871.
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CMS-1428-P-302

Submitter : Ms. Heather olson **Date & Time:** 07/12/2004 12:07:00

Organization : Iowa Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please find the attached comment letters from the Iowa Hospital Association for the FY 2005 Inpatient PPS Proposed Rule.

July 12, 2004

The Honorable Dr. Mark McClellan
Administrator Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

Ref: CMS—1428-P Medicare Program; Changes to Inpatient Prospective Payment System and FY 2005 Rates; Proposed Rule (69 *Federal Register* 28195), May 18, 2004.

Critical Access Hospitals

Dear Dr. McClellan,

On behalf of Iowa's 58 critical access hospitals (CAHs), the Iowa Hospital Association (IHA) is pleased to take this opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the FY 2005 inpatient prospective payment system (PPS) published May 18, 2004 in the *Federal Register*. This notice proposes implementation of a number of positive provisions contained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), including some regulatory changes. IHA would like to take this opportunity to raise concern on several proposed policies and seek clarification on other items contained in the notice.

Payment Amounts

Prior to the enactment of the MMA, Medicare provided payment to CAHs for inpatient, outpatient and skilled nursing facility services on the basis of costs. Section 405(a) of the MMA provides for payment at 101% of the reasonable cost of the CAH in providing these services, effective for services furnished during cost reporting periods beginning on or after January 1, 2004. The rule proposes to revise regulations to incorporate the change in the payment percentage made by the MMA. IHA supports this provision and the corresponding regulatory changes. **However, the Association is concerned that the cost report revisions to implement this provision have only recently been issued and specific instructions to Medicare fiscal intermediaries directing them to revise interim rates to pay at 101% of costs are still forthcoming.** The lack of timeliness in addressing the operational aspect of this provision appears as contrary to congressional intent to provide CAHs with increased reimbursement on a more immediate basis and it appears CAHs will not receive this benefit until cost report settlement that occurs substantially after the services were provided**. IHA recommends CMS take immediate steps directing fiscal intermediaries to calculate interim rates for CAHs to reflect 101% of the cost of providing inpatient, outpatient, and swing bed services.**

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www.ihaonline.org

Condition of Application for Special Professional Service Payment Adjustment

The Social Security Act provides for two methods of payment for outpatient CAH services. A CAH will be paid under a reasonable cost method unless it elects payment under an optional method, also known as method II. Under this option, the CAH submits bills for both facility and professional services to the fiscal intermediary and Medicare makes payment for the facility services at the same level that would apply under the reasonable cost method (increasing to 101% for cost reporting periods beginning on or after January 1, 2004), but services of professionals to outpatients are paid at 115% of the amount that would have otherwise been paid under the physician fee schedule. Section 405 of MMA amended the Social Security Act by specifying that CMS may not require, as a condition for a CAH to make an election of the optional method of payment, that each physician or other practioner providing professional services in the CAH assign billing rights to the CAH with respect to the services.

CMS proposes to revise regulations to implement the changes made by section 405(d)(1) of the MMA by specifying that a CAH may elect to be paid for outpatient services in any cost reporting period beginning on or after July 1, 2004 under the method II option. The agency also proposes to clarify that such an election must be made at least 30 days before the start of the cost reporting period for which the election is made. Further, the provision would apply to all services furnished to outpatients during that cost reporting period by a physician or other practioner who has reassigned his or her rights to bill for those services to the CAH in accordance with Medicare reassignment regulations.

IHA supports this change to allow flexibility in the method II option. In fact, 31 Iowa hospitals with June 30 fiscal year ends elected this option and began billing under this provision as of July 1. However, IHA is concerned that a number of operational aspects of this option have yet to be clarified and in absence of more specific instructions, these facilities may run afoul of requirements to ensure proper payment of claims. Further, there remains a great deal of uncertainty about whether payments for both hospital and professional services will be processed correctly. Some of the outstanding billing questions regarding this method include the following:

1. Do the entire Medicare Part B physician billing and coding rules still apply? In other words, has the physician fee schedule along with the physician reimbursement methodology been loaded on to the fiscal intermediary claims processing system? For example, physician services are subject to correct coding initiative edits (CCI) that are different than the ones applied to the outpatient PPS but CAH outpatient services are not subject to these edits since they aren't paid on the basis of APCs. Further, will all the modifiers still be required and accepted? Physician services use modifiers such as -26 for radiology professional fees, -22 for unusual circumstances, -57 for a surgery consultant on the same day as the surgery, etc. Further there are other edits such as only one E&M code per day for physicians. All these items affect billing and reimbursement.

2. Is the physician billing number (not the UPIN) still required on the UB-92 and if so, where should it appear? This question relates back to one previously raised about the need to complete an 855R for emergency room physicians. Since the CAH is now doing the billing for the physician for CAH outpatient services, it shouldn't be necessary to complete an 855R for the facility to receive a billing number in order to bill those physicians' services to the Medicare carrier. Further, if more than one physician specialty is provided, how should or how will multiple practioners be reported?

3. How should CAHs bill for Locum tenums? Is it acceptable to bill for those services under the physician's UPIN for which they are substituting?

4. What local medical review policies/local coverage decisions will apply to the professional services billed on the CAH claim? How will medical review occur?

5. Do the same supervision requirements for PAs and NPs still apply which require a supervising physician?

6. Does the opportunity exist for interim payments for both hospital and physician services if the claims processing system fails to promptly and accurately pay claims under the method II election?

In addition to responding to the above questions, IHA recommends CMS keep CAHs **and** the fiscal intermediaries informed of physician billing changes. **It should be a routine matter for CMS to consider how CAHs will be impacted by all policies and instructions the agency issues and IHA encourages CMS to specifically address this fact in all its communications.**

Coverage of Costs for Certain Emergency Room On-Call Providers

Under existing regulations, Medicare payments to a CAH may include the costs of compensation and related costs of on-call emergency room physicians who are not present on the premises of a CAH, are not otherwise furnishing services, and are not on-call at any other provider or facility when determining the reasonable cost of outpatient CAH services. Section 405(b) of the MMA expands the reimbursement of on-call emergency room providers beyond physicians to include physician assistants, nurse practitioners, and clinical nurse specialists for the costs associated with covered Medicare services furnished on or after January 1, 2005.

CMS is proposing to revise current regulations to include the expanded list of emergency room on-call providers for whom reimbursement for reasonable compensation and related costs in a CAH would be available. In addition, the agency is making a conforming change to regulations governing the standard for emergency room personnel who are on call under the CAH conditions of participation to **include** clinical nurse specialists. IHA supports these changes because they will allow CAHs the additional flexibility of using non-physician practioners for emergency room coverage and to receive cost-based reimbursement for these expenses. IHA also supports the proposed conforming change to 42 CFR 485.618(d) governing the standard for emergency room personnel who are on call under the CAH conditions of participations. Further, IHA requests CMS include a comma to the proposed regulations after "clinical nurse specialist", to clarify that this is **not the only clinician required to be trained or to have experience in emergency care** but rather **all** the provider-types listed in this section must be qualified in this manner.

In the April 2004 version of the CAH interpretive guidelines many of proposed regulations pertaining to CAHs were incorporated, including this proposed rule. This version omitted clinical nurse specialist. While IHA **does not support** the issuance of interpretive guidelines inclusive of **proposed regulations** (see Interpretive Guidelines section), IHA is concerned this provision will be and has already been misinterpreted with the omission of the comma after "clinical nurse specialist" and requests CMS clarify this issue.

Authorization of Periodic Interim Payments

IHA supports the MMA provision that amends the Social Security statute by adding the ability for Medicare to provide for payments for inpatient services furnished by CAHs on a periodic interim payment (PIP) basis, effective for payments made on or after July l, 2004. In implementing this provision IHA understands CMS is using the existing regulations allowing for other providers to receive PIP and therefore, CAHs would operate under the same rules. IHA is concerned however that direction provided by the CMS regional office on the election of PIP would limit it to the beginning of the CAH cost reporting period, rather than to allow the flexibility of the CAH to chose PIP at any point during the year in which the facility determines the need exists to request stabilized payments from the Medicare program. In addition, the regional office has suggested PIP is only available to those CAHs that have at least one full twelve month cost report under cost-based reimbursement. Again, this direction causes concern because it does not appear to be consistent with congressional intent to extend PIP to CAHs to

allow them to establish flexibility in the timing of their payments. IHA recommends CMS provide direction to its regional offices, fiscal intermediaries, and CAHs that is consistent with the objective behind the MMA provision to allow for PIP to these facilities, and to minimize the administrative burden associated with this option.

Revision of Bed Limits

Prior to the enactment of the MMA, CAHs were restricted to 15 acute care beds and a total of 25 beds if the CAH had been granted swing-bed approval. The number of beds used at any time for acute care inpatient services could not exceed 15 beds. Section 405(e) of the MMA amended the Social Security Act to allow CAHs a maximum of 25 acute care beds for inpatient services, regardless of the swing-bed approval. This amendment is effective on January 1, 2004 and applies to CAHs designated before, on, or after this date. **IHA requests CMS clearly state in the final rule that the only change section 405(e) of the MMA made to the counting of CAH beds was to expand the CAH program to allow a maximum of 25 acute care beds for inpatient services. Any other interpretation of this provision would be contrary to congressional intent.**

Interpretive Guidelines

IHA would like to take this opportunity to raise the issue of CMS releasing revisions of Interpretive Guidelines inclusive of proposed rules, **prior to the release of final regulations.** As with the proposed rule to change reimbursement for certain emergency room on-call providers, IHA has learned the proposed rule to change the CAH bed limit was incorporated into the Interpretive Guidelines by CMS via a survey and certification letter issued in December 2003. However, this provision is just now going through the notice of proposed rule making (NPRM) process. **IHA requests CMS address this issue immediately and instruct surveyors to forgo enforcing any regulation that is currently under going the NPRM process.**

Further, these guidelines go far beyond congressional intent. Under the standard for the number of beds [42 CFR 485.620(a)], the agency's interpretation indicates that the CAH may not have more than 25 beds that could be used for inpatient care. The guidance goes on to state that any hospital-type bed located in area adjacent to any location where the bed could be used for inpatient care counts toward the 25 bed limit. The guidelines list the types of beds that do not count toward the 25 bed limit, including examination or procedure tables; stretchers; operating room tables located in the operating room, beds in surgical recovery that are used exclusively for surgical patients during recovery from anesthesia; beds in an obstetric delivery room that are used exclusively for observation of OB patients in active labor and delivery of newborn infants; newborn bassinets and isolettes used for well baby boarders; stretchers in the emergency department; and beds in Medicare certified distinct part rehabilitation or psychiatric units.

Particularly troubling, the guidance addresses observation patient services and states "beds, used by patients on observation status, that conform to the hospital-type beds previously discussed in this requirement, will be counted as part of the maximum bed count". This interpretative guidance to CMS surveyors is contrary to the legislative intent of the MMA to expand the CAH program. Although interpretive guidelines are not definitive for individual state behavior, they are frequently applied in a strict manner which would prevent most Iowa hospitals currently evaluating CAH status from moving forward, meaning greater financial hardships for those institutions that are struggling to survive under the Medicare prospective payment systems for inpatient and outpatient services. There is no compelling reason to treat observation beds differently than the other types of beds identified in the guidelines, particularly given the fact that observation patients are not considered inpatients of the hospital. IHA recommends CMS reissue this guidance upon release of the final regulation and to allow for the flexibility in the CAH program intended by Congress. Further, IHA recommends address of the guidance on observation services which prohibits observation patients from being commingled with inpatients. Forcing CAHs to maintain a separate, distinct unit for observation only patients, separate from inpatients, creates additional staffing requirements, and only adds to the cost of providing care and thus the expenditures of the Medicare program.

Again, IHA reiterates the only change the MMA made to the counting of CAH beds was to allow a CAH to have at any one time 25 acute care patients, rather than 15.

Authority to Establish Psychiatric and Rehabilitation Distinct Part Units
IHA is supportive of section 405(g)(1) of the MMA to modify the statutory requirements to allow CAHs to establish distinct part inpatient rehabilitation and psychiatric units of up to 10 beds each, exclusive of the 25 CAH bed count, effective for the cost reporting periods beginning on or after October 1, 2004. Although these units will be reimbursed under existing applicable payment methodologies for inpatient rehabilitation facilities and inpatient psychiatric facilities, and be required to meet the same conditions of participation, this provision should allow access to these types of services within rural communities.

IHA requests CMS provide clarification to the following outstanding questions:

- When can a hospital that is pursuing CAH status decertify beds in an existing DPU to meet the 10 bed criteria?
- IHA requests CMS clarify that a hospital can continue to operate an inpatient psychiatric or rehabilitation DPU during the conversion process to CAH.

Although CMS has issued instructions to implement this provision, those instructions stop short of addressing how a hospital that is in the process of becoming a CAH maintains existing DPUs.

Waiver Authority for Designation of CAH as a Necessary Provider
Section 405(h) of the MMA adds language to the Social Security Act that terminates a State's authority to waive the location requirement for a CAH by designating the CAH as a necessary provider, effective January 1, 2006. Currently, a CAH is required to be located more than a 35-mile drive (or in the case of mountainous terrain or secondary roads, a 15-mile drive) from a hospital or another CAH, unless the CAH is certified by the State as a necessary provider of health care services to residents in the area. Under this provision, after January 1, 2006, States will no longer be able to designate a CAH based upon a determination it is a necessary provider of health care. In addition, the MMA included a grandfathering provision for CAHs that are certified as necessary providers prior to January 1, 2006. Under this provision, any hospital that is designated as a necessary provider in its State's rural health plan prior to January 1, 2006, will be permitted to maintain its necessary provider designation. The proposed rule revises the existing regulations to incorporate the MMA amendments.

Given the fact that all Iowa CAHs were granted CAH status through the state's ability to designate the facility as a necessary provider, IHA is very supportive of the grandfather provision to allow these hospitals to maintain their status, and for this provision to continue until January 1, 2006. IHA also requests CMS clarify that hospitals that have been granted necessary provider designation by January 1, 200 may stay the course to complete the CAH certification process until it is licensed as such.

Payment for Clinical Diagnostic Laboratory Services
IHA continues to **strongly oppose** the CMS policy change from the FY 2004 inpatient PPS final rule and reiterated in the proposed FY 2005 rule which "clarifies" that payment to a CAH for clinical diagnostic laboratory tests for outpatients is made on a reasonable cost basis only if the individuals for whom the tests are performed are outpatients of the CAH and are physically present at the CAH at the time specimens are collected. Otherwise, payment for these tests is made on a fee schedule basis. Although CMS has stated its belief that extending reasonable cost payment in these instances is inconsistent with Medicare law and regulations and duplicates existing coverage and creates confusion for beneficiaries and others by blurring the distinction between CAHs and other types of providers, IHA believes the agency has repeatedly failed to understand the delivery of laboratory services in rural communities. The Association and challenges the assertion that the absence of this policy created increased cost to provide

care to Medicare patients without enhancing either the quality or the availability of that care. Although CMS has invited the public to submit further comments on actual, rather than merely potential or anticipated access problems and IHA is aware of CAHs that have ceased providing lab services to Medicare patients in nursing facilities, the fact remains that this is not occurring in a widespread manner because community hospitals have once again chosen to continue to subsidize the Medicare program by making these services available at far less than what it costs to provide them. In order to avert a crisis and to maintain access to services, Iowa CAHs are continuing to serve Medicare beneficiary needs for lab services, despite the lack of funding, and are using more profitable areas or reserves to cover these losses. However, this situation cannot continue indefinitely. As this becomes a more permanent interpretation and the losses on these services increase, CAHs will have to make difficult decisions to eliminate lab services in nursing facilities. **IHA implores CMS to reverse this policy interpretation and minimally, allow for cost-based reimbursement for lab services at provider-based clinics and rural health clinics associated with CAHs.**

Redefinition of Geographic Areas

Although the use of labor market areas is not an applicable concept for CAHs that are reimbursed at cost, IHA is concerned about a proposal by CMS to redefine the labor markets used to determine the wage index for the inpatient PPS. For the purpose of applying the Medicare wage index, CMS currently defines geographic areas using Metropolitan Statistical Areas (MSAs) based on 1990 census data. The Office of Management and Budget OMB) released new definitions last summer based on the 2000 census. The OMB definitions replace MSAs with Core-Based Statistical Areas (CBSAs). Although CMS is not required to update the definitions for wage index areas using the more recent census data, the agency has proposed in the FY 2005 rule to adapt the new OMB definitions beginning October 1.

The result of this proposal is the creation of 49 new MSAs as well as significant reconfiguration of existing MSAs throughout the country. Some hospitals with special rural status, such as sole community hospitals (SCHs), rural referral centers (RRCs), Medicare dependent hospitals (MDHs) or critical access hospitals (CAHs) would be relocated from rural to urban under the new geographic definitions. This proposed change affects 10 Iowa CAHs. However, CMS does not address this issue in the proposed rule so the impact of existing CAHs moving into an urban area is unknown at this time. **IHA requests clarification on the application of this new census data to the CAH program and clarify that existing CAHs as well as other specially designated rural providers that were located in rural areas at the time of their designation remain eligible for CAH payment.**

It should be noted that one Iowa CAH that is located in an existing MSA successfully applied for, and received redesignation as rural based on the Goldsmith Modification contained in 42 CFR 412.103(a)(1). IHA's research of the Office of Rural Health Policy's material to determine the Goldsmith Modification areas has revealed that the agency continues to use the list of metropolitan areas that was issued in 1999 while they study the 2000 census information. Each of the Iowa CAHs that will be located in a CBSA based on the OMB's 2000 census data as applied by CMS for Medicare payment purposes will continue to meet the Goldsmith modification and should retain CAH status. This information supports IHA's request to clarify that these facilities maintain their special Medicare CAH designation. When addressing the applicability of the metropolitan areas for CAHs, CMS must also provide clarification on several related issues. One, if a CAH located in an urban area is grandfathered to maintain its rural status or receives special treatment under 412.103, CMS must provide direction on whether these facilities are deemed rural for all purposes of the Medicare program such as the CRNA pass-through. Further, what wage index will apply to CAHs that choose to operate distinct part psychiatric or rehabilitation units? It is unclear whether the facility will receive the urban wage index from the area in which the CAH is located, or if the redesignation as rural for CAH purposes will require the rural Iowa wage index to be applied in these payment systems.

Again, IHA reiterates its request to make it a routine matter to consider how CAHs will be impacted by CMS policies and instructions even though there may not be an apparent connection to this group of hospitals.

Conditions for Participation-Discharge Planning

The MMA requires CMS to make publicly available to hospitals discharge planners, the public, and Medicare beneficiaries information on skilled nursing facilities (SNFs) that are participating in the Medicare program. The agency states it has fulfilled this requirement and is now proposing to require hospitals to make this list available to Medicare beneficiaries who upon discharge will be admitted to a SNF. Hospitals will be required to keep documentation of the list provided to the beneficiary in the medical record.

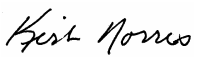
CMS is also re-proposing a rule issued December 19, 1997 requiring hospitals to make available to Medicare beneficiaries that are discharged to home health, and to keep documentation of in the medical record, a list of Medicare certified home health agencies (HHA) that have requested to be placed on the list and that serve the geographic area in which the patient resides.

IHA seeks clarification on the applicability of this provision to CAHs.

The proposed rule revises 42 CFR 482.483 which provides the condition of participation for discharge planning for acute care hospitals but does not make a corresponding change to the conditions of participation for CAHs. IHA requests CMS provide direction in the final rule on whether CAHs are obligated to abide by this provision regarding the delivery of information about post-acute care services to patients upon discharge.

Thank you for your review and consideration of these comments. If you have any questions please contact Heather Olson or Tracy Warner at the Iowa Hospital Association at 515/288-1955.

Sincerely,



J. Kirk Norris
President

Cc: Iowa congressional delegation
IHA Board of Trustees
Iowa hospitals
CMS Kansas City regional office

July 12, 2004

The Honorable Dr. Mark McClellan
Administrator Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

Ref: CMS—1428-P Medicare Program; Changes to Inpatient Prospective Payment System and FY 2005 Rates; Proposed Rule (69 *Federal Register* 28195), May 18, 2004.

Dear Dr. McClellan,

On behalf of Iowa's 116 hospitals, the Iowa Hospital Association (IHA) is pleased to take this opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the FY 2005 inpatient prospective payment system (PPS) published May 18, 2004 in the *Federal Register*.

IHA strongly supports the implementation of many of the provisions included in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, such as a full market basket update for participating in CMS' quality initiative, equalizing the standardized payment amount, and lowering the threshold by which the standardized amount is adjusted by the wage index. Many of the MMA provisions have been a long-time cornerstone of IHA's advocacy agenda in seeking to bring equity from the Medicare program to Iowa hospitals and the communities they serve. These payment enhancements are desperately needed by Iowa hospitals as total Medicare margins have declined to **-6.8 percent**, the lowest percentage since the Balanced Budget Act of 1997. Yet despite the inadequate reimbursement, Iowa hospitals continue to demonstrate value through the provision of efficient and quality healthcare services, as demonstrated by CMS rankings of Iowa at number sixth in the nation. IHA would also like to take this opportunity to express great concern and caution over a number of proposals in this voluminous rule. For instance, the numerous proposals to change the wage index and the negative impact these policies will create due to a budget neutral reimbursement system. Specifically, IHA opposes the increase in the outlier threshold, the expansion of the transfer provision, and the proposed protections for certain hospitals dues to wage index changes. The effect of such proposals will significantly diminish the movement towards payment equity for Iowa hospitals as a result of the MMA. The Medicare inpatient payment system is already one of the most convoluted reimbursement systems in the program. The provisions in this rule, if finalized, will maintain the system on a continual course of perpetuating disparity without regard to quality, and will create an even more difficult reimbursement methodology that makes it nearly impossible for hospitals to plan financially and strategically given the complex changes from year to year.

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Given the significant number of complex changes contained in this notice of proposed rulemaking, IHA urges CMS to closely examine the on-going effectiveness of the inpatient reimbursement system. For over 20 years now, the system has been pieced together through a series of legislative and regulatory changes and the result is a cobbled structure that has a significant number of exceptions to address special circumstances which does little to promote the efficient delivery of high quality care. The Iowa hospital community believes that the Medicare program should seek out and reward providers who have a record of providing high quality health care services in a fiscally efficient manner. Medicare should become a purchaser of value. For the Medicare program to become a purchaser of value, it must focus on improving the health outcomes for program beneficiaries and more effectively manage the disperse resources that Congress provides.

The following are IHA's detailed comments regarding CMS' proposed changes to the inpatient payment system. An additional comment letter on issues relating to critical access hospitals (CAHs) is being submitted under separate cover.

Cost Outliers

IHA strongly opposes increasing the current cost outlier fixed loss threshold.

In 2003 CMS instituted a number of substantial regulatory changes to the cost outlier calculation that instructed fiscal intermediaries to use the most recent available cost report data in determining a hospital's cost-to-charge ratio, implemented a ceiling and removed a floor to determine reasonableness of charge increases, and instructed fiscal intermediaries to reconcile outlier payments retrospectively in certain circumstances. The impetus behind these regulatory changes was due to small portion of alleged hospitals over-inflating charges to qualify for increased outlier payments. Implementing these changes has decreased overall outlier spending as detailed below. Further, the data CMS is using to construct the proposed outlier threshold for FY 2005 does not account for these modifications.

Secondly, under section 1886(d)(5)(A)(iv) of the Act, outlier payments for any one year must be projected to be not less than 5 percent and not more than 6 percent of total operating Diagnostic Related Group (DRG) payments. Historically, CMS has set aside 5.1 percent of total DRG payments to pay for medically complex and resource intense patients. In 2003, the Secretary estimated its total outlier payments would exceed the statutory threshold at 6.5 percent, yet its most current estimate for that time period is 5.7 percent. After instituting the regulatory changes in 2003, CMS not only **lowered** the outlier threshold by 8 percent in 2004, it is also projecting total outlier payments will be only 4.4 percent of total inpatient payments, or 0.7 percent **below** the 5.1 percent withheld from hospitals to fund outlier payments.

Third, CMS is proposing a **13.2% increase** in the cost outlier threshold for 2005. This increase is a much greater rate of increase than the rate of increase in hospital charges which typically range between three and five percent annually.

Given the recent regulatory changes, the lack of data recognizing these changes, projections indicating CMS will not meet the 5.1 percent threshold, and the rate of the outlier threshold percentage increase compared to the rate of hospital charge increases, CMS should maintain the cost outlier threshold at **status quo** for 2005 hospital inpatient payments, or **lower** the threshold to ensure hospitals receive the total 5.1 percent set aside to care for medically complex and resource intense patients.

FY 2005 Wage Index Data

In FY 2004, CMS implemented a change to the timetable of the wage index data review process with the intent on having more accurate data in the February release of the public use file (PUF) which is published in the inpatient proposed rule in May. Based on IHA's analysis of the May PUF versus this proposed rule, nearly 13 percent of hospitals reimbursed under the inpatient PPS made changes after the release of the February PUF. IHA submits this percentage remains high and creates increased challenges that prohibit hospitals from effectively budgeting for Medicare reimbursement and making strategic planning decisions. This percentage of errors also contributes to difficulties in determining reclassification decisions as discussed in further detail below.

IHA urges CMS to utilize more recent wage data to account for the variations in hospital salaries and benefits in a more timely fashion. The data used to calculate the wage index is **four years old** which is not sufficient to capture trends of health care professional shortages in specific labor markets and the corresponding salary increases as demand for certain health care professionals rise. Further, CMS is proposing to make an adjustment to the wage index based on occupational staffing patterns from a much more recent time period. **It is inconsistent to make adjustments to the standardized amount based on wage data that is four years old, and at the same time adjust the wage index for occupational mix with much more recent data.** IHA requests CMS give consideration to reviewing the current process and time table and take steps to use more recent data that reflects labor market trends in a timely fashion.

Occupational Mix Adjustment to Proposed FY 2005 Wage Index

IHA urges CMS to re-issue clear data collection instructions, re-collect the data, and to use only audited data in applying any adjustments to the wage index.

The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 required CMS to collect occupational mix data to be used in adjusting wage indices beginning October 1, 2004. IHA supports the intent of this legislative mandate based on the premise that it would dull the impact of staffing decisions by increasing the wage index for lower wage areas and decreasing wage indices for higher wage areas. However, IHA does not support the methodology CMS has chosen to implement this law, as it is clear it does not accomplish what the law intended.

In its June 2001 report to Congress, the Medicare Payment Advisory Commission (MedPAC) states "The expected effects of occupational mix adjustment—raising the wage index at the low end and reducing it at the high end." The report goes on to say "occupational mix differences are strongly positively related to the level of the wage index—these differences exaggerate the wage index smoothly at both ends, with the extent of exaggeration rising disproportionately the further the wage level departs from the national average."

Using the information and data available from CMS regarding this adjustment, IHA believes the occupational mix will not achieve the impact intended by Congress in implementing the adjustment as evidenced with many low wage index areas poised to experience even further wage index declines as a result of the occupational mix. One only needs to take a look at a few states with low rural wage indices to attest to this: Iowa, Montana, Nebraska, New Mexico, South Dakota, are among the rural areas that will be negatively impacted by this adjustment. Further it appears from an analysis of the submitted data that six of the fifteen largest metropolitan areas have a lower than average occupational mix which would result in increased Medicare payment while hospitals in the rural areas of 19 states will experience reduced Medicare payment.

The explanation for the inverse outcome of the occupational mix adjustment appears to be due to the data collected by CMS and the assumptions the agency is utilizing in the process. For example, it is unclear why CMS chose to collect data on some direct patient care areas yet exclude others such as laboratory and radiology personnel. Further, the use of BLS data to determine national average hourly wages to be used in the adjustment calculation has the potential to seriously impact the calculated values because it only represents a sampling of hospitals nationwide. Finally, due to the lack of precise instructions from CMS and an audit process, hospitals were forced to make independent evaluations of where to report data. IHA has significant concerns about the misapplication of wages in a category that may be inaccurate and that varies from hospital to hospital thus raising questions about the validity of the data collected and the reliability of the occupational mix adjustment developed based on this information.

IHA also sites specific concerns surrounding the process CMS instituted in collecting the occupational mix data, including vague and untimely instructions that lend themselves to further subjectivity within the wage index development; the lack of recognition of certain hospital occupational categories, e.g. radiology; the short time frame by which hospitals were to respond to the survey; and only 90 percent of all hospitals reimbursed under the PPS methodology responded to the survey. Each one of these issues intensifies concerns regarding the integrity of the data CMS collected and intends to use to adjust reimbursement. **IHA opposes adjusting hospital reimbursement, even by only 10 percent, based on flawed and incomplete data**.

Specifically, IHA recommends the following:

- CMS immediately begin re-collecting occupational mix data.
- Prior to re-collecting this data, CMS must issue complete, concise, and clear instructions allowing hospitals to complete the data submission leaving no room for interpretation or subjectivity.
- CMS include all occupational categories into the data collection tool.
- CMS only use audited data when its intended use will affect reimbursement in a federal healthcare program.

<u>Revised MSAs</u>

CMS is proposing to adopt the Office of Management and Budget (OMB) updates to Metropolitan Statistical Areas (MSAs) and rural areas based on 2000 census data. This proposal begs the question of whether the OMB's definition of MSAs and rural areas for defining the hospital labor market is the best methodology in determining hospital reimbursement policy. In its report to the Heads of Executive Departments and Establishments, the OMB cautioned that the new definitions "should not be used to develop and implement Federal, state, and local nonstatistical programs and policies without full consideration of the effects of using these definitions for such purposes. These areas are not intended to serve as a general purpose geographic framework for nonstatistical activities, and they may or may not be suitable for use in program funding formulas." While IHA does not have an alternative recommendation at this time regarding the appropriate definition of a hospital labor market, the Association echoes the OMB caution and acknowledges that other agencies, such as the Office for Rural Health Policy, have chosen not to recognize the 2000 census data.

Since the inception of the PPS, Medicare has relied on census data for determining urban and rural areas to drive reimbursement based on the flawed premise that it costs less to deliver healthcare in rural areas than urban areas. With the MMA and temporary legislation preceding the MMA to equalize the standardized payment amount for both rural/other urban, and large urban areas, this disparity has lessened but continues to this day. The practice of paying rural/other urban areas less than large urban areas has enabled the larger urban areas to pay employees more, which inflates the average hourly wage, and results

in higher wage indices for these areas and hence the self perpetuating nature of the wage index. As a result, health professionals from rural areas continue to out-migrate to these higher paying wage areas. In addition, Iowa hospitals must compete with facilities in adjacent states that have a much higher wage index.

As CMS proposes to redefine hospital labor markets based on this new data, there exists an even greater concern on behalf of Iowa hospitals regarding the current system's inherent flaws, its complexity and fragmentation which serves to promote payment inequity within the Medicare program. This proposed rule stands to make the current reimbursement system worse. The mere fact that CMS is recognizing that some hospitals are disadvantaged and is therefore proposing specific reclassifications that are not required under current law is an acknowledgement that the system is broken. At the same time CMS is choosing to propose new definitions of MSAs and rural areas, it is also required by law to make an occupational mix adjustment to the wage index. Given all the changes CMS is proposing to implement, and the existing complexity and inequity within the Medicare program, IHA would like to reiterate its recommendation that the Medicare program begin to look at a system that rewards hospitals based on efficiency and quality by becoming a purchaser of value.

Revised Labor Market Areas and Transition Period

By adopting the OMB's core-based statistical areas (CBSA) to redefine existing MSAs and rural area boundaries, many hospitals that are currently designated as urban will become rural and would be at a financial disadvantage as a result of using the rural wage index. CMS asks whether or not a 3-year hold harmless provision should be adopted for these hospitals. IHA opposes use of hold harmless provisions absent modeling the impact of the hold-harmless proposal on budget neutrality. IHA supports payment equity within the Medicare program, and proposals such as this disadvantage Iowa hospitals that are already underpaid by this system. **In making a determination regarding this policy, IHA asks CMS to weigh the impact this proposal will have if implemented on all hospitals and to publish analysis of the results.** In the proposed rule, it appears that CMS only published the standardized payment amounts that **do not** reflect a 3-year hold harmless provision, making it impossible for hospitals to determine the impact and to make comment on such a policy.

Hospital Reclassifications

The proposed rule identified seven areas of either new or existing reclassification criteria for hospitals to receive a higher wage index through geographic reclassification, some of which are required by law, while others are not. In the absence of an equitable reimbursement system CMS is proposing to recognize certain disadvantaged hospitals through new sets of criteria not otherwise legislatively required, including the reclassification criteria for sole community hospitals (SCHs) in low density states, and allowing dominant hospitals special reclassification criteria. These proposals serve to further increase the number of hospitals reclassified. While a limited number of Iowa hospitals benefit from reclassification, IHA suggests its not good policy to address special circumstances with all these adjustments. Further, IHA questions CMS on whether the agency has given full consideration and thought to the underlying problems within the reimbursement system, why they exist, and the equitability of proposing reclassification criteria that benefits a select group of hospitals. At a time when CMS is proposing not only to apply an occupational mix adjustment, new MSAs and rural definitional boundaries, it is also proposing to add additional layers of complexity to the payment system through the expansion of reclassification criteria, thus again begging the question about the appropriate definition of hospital labor markets. IHA requests CMS give thoughtful consideration to the consequences such proposals will have in years to come in terms of Medicare payment equity and policy setting standards.

With the proposal of the new MSAs and rural areas in conjunction with new geographical reclassification criteria, it was particularly difficult for hospitals qualifying for more than one set of reclassification

criteria to make an educated decision to either keep or withdraw existing reclassification status, and to apply for one of CMS' proposed criteria. This decision-making requires thoughtful consideration of all the variables; however, there were numerous errors in the wage index tables and missing data for specific areas, making it even more difficult to determine the best reimbursement strategy. Secondly, the date by which hospitals were to withdraw existing reclassifications was July 2, **ten days before the close of the comment period and before the wage index values are final**. IHA recommends to CMS that it change its existing process requiring hospital to withdraw reclassification criteria and to re-apply for a different reclassification within 45 days of the issuance of the proposed rule; to automatically grant that hospital the higher of the two re-classifications. This would eliminate an unnecessary use of federal funds as well as remove administrative burden for both CMS and the hospitals.

IHA would also like to raise concern regarding the discretion exercised by CMS to implement the special one-time geographic reclassifications under section 508 of the MMA. The Association's understanding of congressional intent in including this provision in the MMA was to allow an opportunity for hospitals not otherwise eligible for reclassification to be considered for this status. However, the criteria established by CMS failed to remove the already existing barriers for these facilities in meeting the thresholds for wage levels to be successfully reclassified. Although several Iowa hospitals were reclassified under section 508, the lack of funds available prevented others from benefiting from this provision. Yet, CMS is proposing to allow certain sole community hospitals (SCHs) that were precluded from reclassifying under 508 to request reclassification at this time because of the agency's concern that these hospitals could now be placed at serious disadvantage in comparison to other SCHs in their states and regions. **IHA objects to this proposal because SCHs in Iowa, as well as other Iowa hospitals who met the criteria of section 508, will not have this opportunity which places them at a disadvantage in this region, particularly given the fact that hospitals in neighboring states will be reclassified.**

Special Circumstances of Hospitals in All-Urban States
IHA opposes imputing a rural floor for states that do not have rural hospitals.

The proposed rule asks for input on the need for a special adjustment for all-urban states. The law specifies that the wage index for an urban area cannot be less than the wage index applicable to rural hospitals for both inpatient and outpatient PPS, otherwise referred to as the rural floor. The current methodology used in defining hospital labor markets results in a few states not having hospitals in rural areas and thus a rural floor does not exist. CMS states it may be possible to impute a wage index floor for these states.

IHA opposes this proposal based on the premise that CMS has chosen to use census data in defining hospital labor markets and as a result of this decision there are a few states without hospitals in rural areas. There is no new money to implement such a proposal so all other hospitals would be negatively impacted by adopting such a proposal. Hospitals in rural areas of all states have a similar problem in that they also have no protection from unreasonably low wage indices. Many urban and rural hospitals across the nation can point to specific circumstances that cause them to have an inequitable wage index that does not accurately reflect the labor market in which they compete. IHA opposes this proposal consistent with comments stated earlier regarding the complexity of the current inpatient PPS, the payment inequities, and the need for the Medicare program to become a value purchaser.

Low-Volume Hospital Adjustment
The MMA requires that the Secretary shall provide for an additional payment amount to each low-volume hospital. The MMA defines a low-volume hospital as having less that 800 discharges. CMS is proposing

to provide a payment adjustment only for hospitals with 500 or less discharges. CMS states that the MMA also requires that CMS determine the amount of the adjustment based on empirical evidence of the relationship for discharges above 500. CMS states that the MMA language allows them to set the increase at zero if there is no evidence of higher incremental costs.

The MMA requires that CMS provide an *additional payment amount.* An adjustment of zero does not satisfy this legislative requirement. CMS should satisfy this statutory requirement and provide an adjustment for hospitals with less than 800 discharges as specified in the MMA.

Rural Community Hospital Demonstration Program

Section 410A of the MMA provides for a special demonstration project by requiring the Secretary to establish a demonstration to test the feasibility and advisability of the establishment of rural community hospitals for Medicare payment purposes for covered inpatient hospital services to Medicare beneficiaries. The statute states the program shall be conducted in rural areas selected by the Secretary in states with low population densities, as determined by the Secretary. In using its discretion, the Secretary in the proposed rule limits the application of this demonstration project to ten states, excluding Iowa. This proposal is another example of an MMA provision that could benefit Iowa hospitals, yet the Administrative decision on where to arbitrarily limit such benefits denies opportunities for hospitals that may have benefited from such provisions.

Post-acute Care Transfer Payment Policy

IHA opposes any expansion of the post-acute care transfer policy to additional DRGs.

Last year CMS made extensive changes to the criteria a DRG must meet to be added to the post-acute care transfer policy resulting in a net **increase of 19 DRGs** from the original 10. Now, only a year later CMS is proposing to adopt an additional set of *alternative* criteria that would be applied to a DRG if it failed to qualify for the transfer provision under the FY 2004 criteria.

The criteria the agency is proposing appears to capture one of the current DRGs that given other changes, would no longer qualify for the post-acute care transfer policy. This rule proposes to split this DRG into two distinct DRGs, 542 and 543 based on whether or not the case had a major operating room procedure, neither of which meet the existing criteria. Because these DRGs pertain to the same cases as were assigned to DRG 483, CMS is proposing to change this post-acute care transfer criteria solely to capture these two DRGs; however the proposed criteria also would apply to DRG 430 for psychoses.

IHA opposes this proposal on three grounds. First, the Medicare PPS is established based on the average length of stay (LOS) for specific diagnostic categories. Second, each year CMS recalibrates the average LOS for each DRG and hospital payment is based on that average. The recalibration should already account for cases that are transferred prior to the average LOS and thus hospitals caring for patients falling into these diagnostic categories whose stays are longer experience the financial burden. Also, splitting DRG 483 into two more specific DRGs will better account for variation in LOS and cost per case, and thus the transfer policy for these DRGs is not appropriate or necessary. Lastly, IHA strongly opposes attempts by CMS to arbitrarily change the post-acute care transfer criteria year by year to ensure certain DRGs are included in the transfer policy. IHA maintains the position that the post-acute transfer policy penalizes hospitals unnecessarily for taking care of patients at the right time and place and is not necessary in a reimbursement system that is based on averages.

Graduate Medical Education (GMA)—Requirement for Written Agreements for Residency Training in Non-Hospital Settings

IHA supports eliminating the requirement for a written agreement between the hospital and non-hospital site as a precondition for a hospital to count residents training in non-hospital settings for GME and IME payments. IHA opposes a requirement that the hospital pay for the non-hospital training concurrently with the training that occurs during the cost reporting period.

Under current policy, in order for a hospital to count residents training in non-hospital settings, there must be a written agreement stating that the hospital will incur all, or substantially all, of the costs for the training program at the non-hospital site. Citing many hospitals have failed to comply with this requirement and upon retrospective review, CMS states the agency believes that a written agreement is not the most efficient aid to fiscal intermediaries in determining if hospitals are actually incurring all of the costs as required. Therefore, CMS proposes to replace the written agreement requirement with a requirement that the hospital pay for the non-hospital training on a concurrent basis.
If the written agreement is not necessary or useful, CMS should eliminate the requirement. However, CMS should **not** impose a burdensome new requirement for concurrent monthly payments. CMS states that, in addition to checking for a written agreement, the fiscal intermediaries are currently required to determine that hospitals are incurring the appropriate costs. CMS should allow the intermediaries to continue to make these determinations following their current practices. The proposed concurrent payment would impose an unsubstantiated financial burden on hospitals and reaches far beyond congressional intent.

Initial Residency Period-Simultaneous Match Issue

The IHA urges CMS to ensure that the initial residency period (IRP) for specialty physicians who complete a preliminary year in general clinical training is assigned based on the specialty the resident enters in their second year of training.

CMS states the agency is considering a policy change, yet stops short of an actual proposed change, in how the agency would weight the direct GME resident count for residents that pursue specialties requiring an initial year of broad-based training. Currently a number of programs, such as anesthesiology and radiology, require a year of generalized clinical training in internal medicine as a prerequisite to subsequent training in their chosen specialty. This requirement can be met by either spending the first year in internal medicine, pediatrics, or surgery, or participating in a one-year, freestanding transitional year program. CMS policy, however, bases direct GME payments on the resident's first year of training, without factoring in the specialty in which the resident ultimately seeks board certification. For example, an anesthesiologist who does a base year of generalized clinical training would be labeled with a three-year training period – which is the time required to be board eligible in internal medicine – rather than the four years it takes to be board eligible in anesthesiology. The result is that the resident is eligible for only partial direct GME reimbursement in the fourth year.

Current CMS policy violates the statute, does not reflect congressional intent, and results in inequitable payments to teaching hospitals for residents training in certain specialties. The MMA conference report language clearly states, "the initial residency period for any residency for which the Accreditation Council on Graduate Medical Education (ACGME) requires a preliminary or general clinical year of training is to be determined in the resident's second year of training."

CMS discusses the possibility of reweighing these residents to allow hospitals their full direct GME payments. Given that it has been CMS' longstanding policy to allow an appropriate calculation of the full residency period for those residents training in "transitional year" programs, IHA also feels strongly that

this interpretation should be extended to those spending their first year in internal medicine, pediatrics or surgery. **The IHA believes that this issue needs to be addressed and corrected in the final regulation.**

Conditions for Participation—Discharge Planning

The MMA requires CMS to make publicly available to hospital discharge planners, the public, and Medicare beneficiaries information on skilled nursing facilities (SNFs) that are participating in the Medicare program. The agency states it has fulfilled this requirement by publishing this list on its Web site, and is now proposing to require hospitals to make this list available to Medicare beneficiaries who upon discharge, will be admitted to a SNF. Hospitals are to keep documentation of the list provided to the beneficiary in the medical record.

CMS is also re-proposing a rule included in the December 19, 1997 *Federal Register* requiring hospitals to make available to Medicare beneficiaries, who upon discharge will be receiving home health services, a list of all home health agencies (HHA) that have requested to be on the hospital's list. Hospitals are to maintain documentation of the list provided to the beneficiary in the medical record. Since passage of this provision in the Balanced Budget Act (BBA), Iowa hospital discharge planners have provided HHA information to Medicare beneficiaries upon discharge.

Finally the rule adds another proposed requirement hospitals to disclose to the patient entities with which the hospital has a financial relationship and vice versa.

IHA acknowledges the requirement by the MMA for CMS to make a list of SNFs publicly available and for hospitals to provide this to the beneficiary upon discharge. Also, IHA understands the intent of the proposal to disclose financial relationships to ensure beneficiaries are adequately informed regarding where they choose to receive services. However, IHA would like to express concern regarding the additional administrative burden this places on the part of hospitals to create a database to download CMS' list, updating the database for frequent SNF changes, and to ensure they have identified all the entities with which they have a financial relationship. To alleviate the additional resources associated with implementing this proposal for SNFs, the Iowa hospital community recommends following the same process that is in existence with providing HHA information to Medicare beneficiaries. By requiring SNFs to request to be included on a hospitals' list of post-acute care providers, the hospital will not be burdened with ensuring that each SNF is Medicare-certified since this designation can change periodically, and within the service area in which the patient requests. This approach will allow hospitals to dedicate valuable resources to providing quality care rather than lists of post-acute care providers.

The proposed rule states the proposals under this section apply only to hospitals as defined in sections 1861(e)(1) through (e)(8) which excludes Critical Access Hospitals (CAHs). IHA requests CMS provide clarification as to whether or not this policy is intended to apply to both PPS hospitals and CAHs.

New Technology Threshold

The IHA strongly urges CMS to raise the add-on payment level for new technologies from 50 percent to 80 percent of the difference between the standard DRG payment and the cost of the procedure using the new technology. This change is supported in the MMA's report language. In addition, it would mirror the current 80 percent marginal cost factor for inpatient outlier payments.

ICD-9-CM Code Changes

ICD-9-CM code changes have traditionally been implemented once a year on October 1. The Medicare Modernization Act (MMA) required that new diagnosis and procedure codes be implemented April 1 of

each year (without DRG recalibration of weights or rates) in addition to the longstanding October 1 update.

IHA believes that codes considered for the April 1 update be limited to new technologies that present a strong and convincing case for new technology add-on payment only. The IHA recommends that the annual April 1 update be limited to as few codes as possible for the following reasons:

- The addition of a significant number of new codes outside the traditional October 1 implementation will result in doubling the costs associated with the purchase of new code books and updating encoder software programs, requiring hospitals to purchase new code books twice a year. In anticipation of the twice-yearly ICD-9-CM code update, at least one publisher already has announced that two editions of the code books will be published every year.
- Many health plans, including Medicare, require a significant lead-time to incorporate new codes into their systems. IHA is concerned that payers, such as Medicaid, currently struggling to maintain their systems on the most current code set version will not be able to support a large number of codes being implemented outside the traditional October 1 update.
- A considerable amount of education and coder training takes place every year with the introduction of new and updated codes. Introducing a large number of new codes on a twice-yearly basis, rather than annually, will increase this burden.

In addition:

- New codes should be made publicly available with the same lead-time as currently exists for the October update. Codes for October 1 implementation are currently published in May of the same year (a five month lead time). Codes for April 1 implementation therefore should be published by November of the prior year.
- Since the ICD-9-CM classification is a Health Insurance Portability and Accountability Act (HIPAA) standard code set and applies beyond the Medicare inpatient PPS, CMS should ensure that the new ICD-9-CM update process is communicated to the Office of HIPAA standards, so that all payers, providers and clearinghouses may be notified.
- Traditionally, the new ICD-9-CM codes have been published in the *Federal Register*, as part of the "Proposed Changes to the Hospital Inpatient Prospective Payment Systems" proposed rule. IHA urges CMS to develop a process for the wide dissemination of new/modified ICD-9-CM codes for April 1 implementation. We request that the process be published in the Hospital Inpatient final rule to inform users of the process.

The Association reminds CMS that twice-yearly updates to the ICD-9-CM is only a temporary solution to meeting the coding needs of providers who may need to report new technology. A more permanent and long-term solution would be the implementation of ICD-10-CM and ICD-10-PCS.

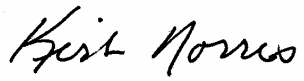
Medical Malpractice Insurance

IHA appreciates CMS' acknowledgement of the impact escalating malpractice insurance premiums have on hospitals. Indeed Iowa hospitals have been financially impacted by this trend particularly in the recent past when one major carrier that provided coverage to 35 Iowa hospitals exited the Iowa market in 2002, leaving only two carriers writing such business in Iowa and both of those companies are faced with capacity and reserve issues. Where hospitals have been successful in gaining a quote from another professional liability carrier, it has not been uncommon for hospital premiums to increase as much as *500 percent*, a prohibitive figure for many institutions. However, hospitals are left with no choice but to pay these premiums.

In response to CMS' inquire as to whether increasing malpractice costs may pose access problems for Medicare beneficiaries, Iowa hospitals are committed to providing healthcare services to their communities and will not deny access to their patients. However, it is becoming increasingly difficult with the lack of reimbursement from government payers and the increased malpractice premiums to continue to offer existing services with hospital reserves depleting. The result is hospitals must make tough strategic decisions on the types of services they provide requiring Medicare beneficiaries to drive further for particular services.

Thank you for your review and consideration of these comments. If you have any questions please contact Heather Olson or Tracy Warner at the Iowa Hospital Association at 515/288-1955.

Sincerely,



J. Kirk Norris
President

cc: Iowa congressional delegation
IHA Board of Trustees
Iowa hospitals
CMS Kansas City regional office

CMS-1428-P-303

Submitter : Dr. Stephen Hartsell **Date & Time:** 07/12/2004 12:07:00

Organization : University of Utah School of Medicine

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

July 12, 2004
Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicine & Medical Services
Department of Health and Human Services
443-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Re: CMS-1428-P: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment System for fiscal year 2005
Dear Doctor McClellan:
The University of Utah School of Medicine, its Graduate Medical Education Office and the Division of Emergency Medicine were pleased that Congress addressed the issue of disparities in residency training opportunities in the MMA (Section 422), and we appreciate CMS. efforts to develop objective implementation criteria. Emergency Medicine has been a recognized board specialty for over thirty years but has been the one major specialty for which there has been no residency-training program at the University of Utah, or in fact within the Intermountain West (Idaho, Montana, Nevada, Wyoming).
The legislative language in the MMA, as well as a draft regulation include in this rule are priority weighted to foster reduction in geographic mal-distribution of physicians by providing more residency training opportunities in rural areas. One of the Utah.s manpower goals as determined by the Utah Medical Education Council has been that residency-trained board certified emergency physicians staff every emergency department in this state. However, in order for those physicians to receive adequate clinical preparation they are required to train in high volume Emergency Departments. Therefore, we take this opportunity to express our concerns with the proposed evaluation criteria in the six-page form . .Application for the Increase in a Hospital.s FTE Caps under Sec. 442 in the MMA..
Top priority goes to rural teaching hospitals. While a laudable goal, not many allopathic specialty programs could meet ACGME accreditation requirements in rural hospitals where the patient volume is low. Emergency physicians in training are required to see a large number of patients to gain experience and clinical expertise across a large range of injuries and illnesses they will need to diagnose and treat. This large volume of patients is not available in rural hospitals. Several new and expanding residency programs in largely rural states including Iowa, Nevada, Oklahoma, and ourselves in Utah, have their teaching hospitals located in the larger metropolitan areas in order to satisfy the patient volume required to meet emergency residency program accreditation. We therefore urge CMS to give priority weight to emergency residency programs that serve largely rural states.
We appreciate the opportunity to offer these comments and look forward to continuing to work cooperatively with CMS in order to address this important issue. Please contact Stephen Hartsell, M.D., FACEP, Division of Emergency Medicine at 801-581-2730 if you have any questions or recommendations.
Sincerely,
Stephen C. Hartsell, M.D., FACEP
Associate Professor
Director, Residency Development
Division of Emergency Medicine
University of Utah School of Medicine
175 North Medical Drive East, 1150 Moran
Salt Lake City, UT 84132

Submitter : Mr. Donald Parseghian **Date & Time:** 07/12/2004 12:07:00

Organization : Greenville Hospital

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document.

CMS-1428-P-305

Submitter : Mr. Frank Pipas **Date & Time:** 07/12/2004 12:07:00

Organization : Meridian Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan,
Please find the attached four comment letters as they each pertain to different portions of the proposed changes to the Hospital Inpatient Prospective Payment System as published in the May 18th Federal Register.
The four attachements are as follows:
1. General Comments on Inpatient PPS provisions
2. Comments specific to wage index provisions
3. Comments specific to DGME provisions
4. Comments specific to LTCH and Hospital within Hospital provisions
Meridian Health System is a three hospital health system located in Monmouth/Ocean counties in New Jersey. We appreciate the opportunity to have our comments considered and look forward to your responses. If for any reason you have difficulty with accessing the attachments or have any follow up questions or concerns you would like to address directly to me, please feel free to contact me at (732) 751-3356.
I thank you in advance for your time in considering Meridian Health System's comments.
Sincerely,
Frank Pipas
Director of Finance
Meridian Health System

CMS-1428-P-306

Submitter : Ms. Anne Cordes **Date & Time:** 07/12/2004 12:07:00

Organization : Amer Academy of Hospice and Palliative Medicine

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1428-P
Graduate Medical Education
Please see attached letter.

CMS-1428-P-307

Submitter : Mr. Brian Riddle **Date & Time:** 07/12/2004 12:07:00

Organization : Oconee Regional Medical Center, Inc.

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

July 12, 2004
VIA ELECTRONIC MAIL
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850
Re: CMS-1428-P Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2005 Rates; Proposed Rule, May 18, 2004 (69 Federal Register 28196).
Dear Ladies and Gentlemen,
On behalf of Oconee Regional Medical Center, I appreciate the opportunity to comment on CMS proposed rule establishing new payment rates, and policies, for hospital inpatient services for fiscal year 2005.
The Medicare Modernization Act of 2003 (MMA) was an acknowledgement by Congress that Medicare payments to hospitals were inadequate. I am troubled that CMS is proposing provisions that would reduce the relief we gained through the MMA. Adequate and equitable Medicare reimbursements to hospitals are critical if the needs of rural communities, such as ours, are to be met.
In general I would like to add my support for the comments made by the American Hospital Association (AHA) made in their letter to Mr. Mark McClellan, M.D., Ph.D., CMS Administrator, dated July 2, 2004. More specifically, I support the AHA comments with two exceptions, as follows:
1) the three year "hold harmless" recommendation proposed by CMS for urban hospitals being reclassified to a rural area is inadequate to alleviate the substantial decline in payments, and
2) the AHA's recommendation to provide a three year "stop loss type/hold harmless" for
hospitals is inadequate for hospitals whose wage rates were impacted by "more than 5 percent" due solely to the MSA/CBSA changes, and will further jeopardize many Georgia hospitals, and hospitals in other states, who lose substantial amounts of money from radical payment shifts for this sudden and unexpected change in payment methodology.
Revised MSAs
Hospitals whose wage indices will be negatively impacted by the proposed change to the revised MSA should be held harmless, just as CMS is proposing to help 72 hospitals which are being reclassified from urban to rural and are proposed to be held harmless for three years. This would not protect hospitals from a decline in the wage rates versus the national average change.
The 5% MSA change stop-loss for the MSA changes only, will help merely 110 hospitals nationwide, with a miniscule budget neutrality impact on the national PPS rate of $10.7 million.
I am very concerned that Georgia rural hospitals, under CMS's proposed policy to help mitigate the MSA impact, receives no relief and that the AHA proposal of 5% stop-loss provides only a small amount of help.
CMS is essentially proposing to cut 35 Georgia rural PPS hospitals Medicare payments by 1% next year, and AHA's proposal to help only the worst off only cuts that to a negative 0.3% payment loss. It was only a few month ago that Congress passed the MMA drug bill, with provisions to specifically help small rural hospitals and small urban area hospitals. Further, in May 2004 CMS stated that hospitals would see additional financial relief in 2005, averaging 6% for rural hospitals and 4.7% for urban
The MMA impact for Georgia hospitals was additional DSH payment to rural hospitals of $30 million in FY 2005; plus $8.8 million for a lower labor share when the hospitals area wage index was below 1.0; and $19.8 million for bringing all areas up to the Atlanta urban standardized rate. Were there a 2.5% stop-loss for the MSA impact implemented next year, Georgia rural hospitals would realize a 1.1% payment increase for FY 2005 Medicare payments. The 1% loss, or a -0.3% loss, or a 2.5% gain do not compare favorably with the figures CMS touted on in its May 11, 2004 Medicare News Release that for FY 2005 rural hospitals will see an average increase of 6.0%, and urban hospitals will see an average increase of 4.7%. The first line of the news release stated the FY 2005 would&."offer a

CMS-1428-P-308

Submitter : Mr. Paul Rowland **Date & Time:** 07/12/2004 12:07:00

Organization : Nassau Suffolk Hospital Council

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See the attached comment letter.

CMS-1428-P-309

Submitter : Mr. William Delahunt **Date & Time:** 07/12/2004 12:07:00

Organization : US House of Representatives

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

see attached PDF File Re:
CMS-1428-P; Medicare Program, Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates

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Congress of the United States
House of Representatives
Washington, DC 20515–2110

COMMITTEE ON THE JUDICIARY
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COMMERCIAL AND ADMINISTRATIVE LAW

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SUBCOMMITTEES ON:
WESTERN HEMISPHERE
EUROPE

CO-CHAIR:
CONGRESSIONAL COAST GUARD CAUCUS
OLDER AMERICANS CAUCUS

July 12, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1428-P
P. O. Box 8010
Baltimore, MD 21244-1850

Re: CMS-1428-P; Medicare Program, Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates

Dear Dr. McClellan:

Last Friday, I met with the hospitals in my District, and like many other regions, the proposed rule for the FY 2005 Inpatient Prospective Payment System (IPPS) promises both positive and negative impacts for our hospitals. Given that, it is important that we adhere to specific principles that balance the interests of all stakeholders, especially the seniors who are truly the customers of the services funded through the IPPS.

In analyzing the proposed rules, I believe the following guiding principles will help ensure the long-range return to a healthy system of reimbursement that ensures quality benefits for Medicare beneficiaries:

1. The Medicare wage index adjustment should accurately reflect wage level differences among labor market areas throughout the nation.
2. Wage areas must recognize labor market realities – specifically, that area borders are somewhat arbitrary and that reclassifications must be allowed to avoid inequities among hospitals competing in the same labor markets, but that may fall in different wage areas.
3. When significant changes are made in the wage index there should be a transitional "hold-harmless" provision that cushions any significant and sudden reduction in a hospital reimbursement to allow adequate time for adjustment.
4. Relief for hospitals that are negatively impacted by the changes should not come at the direct expense of those hospitals that benefit.

Given these principles, I support the CMS proposal to update wage areas in line with the revised statistical areas reflecting data from the 2000 census, but believe that modifications are required to accommodate realities in the labor market and avoid sudden financial dislocations that could threaten many financially fragile hospitals.

Imputed Rural Floor

In Massachusetts, the rural wage index is critically important, because labor costs in rural areas often exceed those in urban areas. While I support the CMS proposal to establish an Imputed Rural Floor for All-Urban States, the proposed methodology needs to be modified to reflect the *actual* experience of Medicare providers in rural Massachusetts.

Last year, CMS excluded from the calculation of the 2004 Area Wage Index data for hospitals that were subject to the PPS in the year that wage data are collected, but subsequently converted to Critical Access Hospital (CAH) status. As a result, there was a 7.5% *decrease* in the rural Massachusetts AWI, the most significant drop in the nation. This led to a 0.6% decrease in payments per case in New England, compared to the national average decrease of 0.2%.

Last year, rural Medicare providers located in the high wage counties of Dukes and Nantucket in my District had their payments adjusted by an artificially low rural wage index. Because that index was based on data from only *one* low wage rural hospital located in Franklin county, it resulted in a 2004 rural AWI that in no way reflects the labor market in Dukes and Nantucket counties.

Now, the current CMS proposal to incorporate Franklin County, home of the only remaining rural PPS hospital in the state, into the Springfield CBSA will entirely eliminate the rural wage index in Massachusetts. This means the imputed rural floor is crucial for other providers (home health, etc.) in my District. However, it is imperative that the imputed rural floor reflect the narrow range of wage variation in the state. Therefore, it must either incorporate the wage data for the hospitals in rural Massachusetts, or modify the proposed methodology to account for the historically higher rural wage index in the state. One way of ensuring that this happens is to calculate the imputed rural floor for Massachusetts using the average Lowest-to-highest AWI ratio in states where the rural floor applies that are *similar* to Massachusetts, i.e. those where the rural floor *greater* than one. The appropriateness of using this calculation is increased further by the fact that a provision of the MMA provides for the reduction of the labor share to 62 percent for hospitals with a wage index of less than or equal to one. The lower labor share cushions hospitals with a less than 1 wage index from the full impact of decreases in the AWI, therefore it would be unfair to compare Massachusetts to those states. I ask that CMS modify the proposed methodology for imputing a rural floor in the manner described above to adequately compensate hospitals for their true labor costs.

Transitional Hold-Harmless:

When significant changes are made in the wage index there should be a transitional "hold-harmless" provision that cushions any significant and sudden reduction in a hospital reimbursement to allow adequate time for adjustment. Hospitals that would be negatively impacted by the proposed changes had no advance warning that these drastic changes would be proposed by CMS and therefore these hospitals had no opportunity to apply for reclassification for 2005.

A hold harmless provision would give hospitals time to consider other alternatives, such as obtaining reclassification, available to them for relief for 2006, while protecting them from a sudden, unexpected drop in payments in 2005. In order that relief for those hospitals that are adversely affected by the CBSA changes does not come at the expense of those benefited, I support the Massachusetts Hospital Association recommendation that CMS calculate *two* wage indices, one consisting of those hospitals in the new CBSA and a second wage index calculated by using data from all hospitals in counties formerly included in the NECMA but now in separate CBSAs.

Geographic Reclassification:

Wage areas must recognize the realities of labor markets notably that area borders are somewhat arbitrary and that reclassifications must be allowed to avoid inequities among hospitals competing in the same labor markets, but that may fall in different wage areas. Criteria could be designed to facilitate this process, such as allowing reclassification if: the county is contiguous to the requested area of reclassification; there is a two way commuting percentage of at least 20% to the former area; the county's hospitals have an average hourly wage of at least 82% of the area to which they request reclassification and there is a stronger two way commuting exchange to the former area than to any adjacent county to which the county has been combined into a different MSA.

With the modifications described above, the proposed rule for the FY 2005 Inpatient Prospective Payment System will more accurately respond to the realities of today's market environment and help ensure the delivery of quality Medicare services. Thank you for the opportunity to provide comment on these important changes.

Sincerely,

William D. Delahunt

Submitter : Mrs. Sharon Hall **Date & Time:** 07/12/2004 12:07:00

Organization : Charleston Area Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Graduate Medical Education Comments

Submitter : Ms. DeChane Dorsey **Date & Time:** 07/12/2004 12:07:00

Organization : American Academy of Ophthalmology

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

see attached file

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

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FEDERAL AFFAIRS DEPARTMENT

July 12, 2004

ELECTRONICALLY SUBMITTED
Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

RE: DIRECT GME INITIAL RESIDENCY PERIOD

Dear Dr. McClellan:

The American Academy of Ophthalmology (Academy) appreciates the opportunity to comment on the issue of direct graduate medical education (DGME) payment for the initial residency period (IRP), often referred to as the preliminary year issue, as addressed in the proposed Hospital Inpatient Prospective Payment Rule (Inpatient PPS Rule). The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States.

The proposed Inpatient PPS Rule addresses the IRP determinations used, in determining Medicare DGME payments. See 69 Fed. Reg. at 28310. A clarification is necessary because CMS' interpretation of the requirements for determining the IRP does not reflect Congressional intent and results in inequitable payments to teaching hospitals for residents training in certain specialties. The most recent statement of Congressional intent with regard to the IRP clearly supports our position. As stated by conference report language accompanying section 712 of the Medicare Modernization Act of 2003 (P.L. 108-173):

> The conferees also clarify that under section 1886(h)(5)(F), the initial residency period for any residency for which the ACGME requires a preliminary or general clinical year of training is to be determined in the resident's second year of training.

We urge CMS to address the IRP issue in the inpatient final rule (or in an interim final regulation) and to interpret the statute to reflect Congressional intent—thereby creating a system that more equitably addresses the issue of hospital GME

payments for residents whose first year of training is completed in a program that provides a general clinical year.

Certain specialties, including ophthalmology, require residents to spend a year in general clinical training, with the remaining years comprising specialty-specific training. Under requirements established by the Accreditation Council for Graduate Medical Education (ACGME), the organization that accredits allopathic residency programs, the general clinical year requirement can be met through one of two pathways: by 1) spending the first year in internal medicine, pediatrics, or surgery, or 2) participating in a one-year, freestanding "transitional year" program. Ophthalmology residents typically meet the general clinical year requirement by entering a preliminary year internal medicine, neurology, pediatrics, surgery, family practice, or emergency medicine program before entering their specialty of choice. Residents are accepted for one year into a preliminary general clinical year program with the understanding that they will enter a specialty in which they wish to train in their second year.

To determine DGME payments, residents are counted as 1.0 full time equivalents (FTEs) during the number of years required to achieve first board eligibility (the IRP), though no resident can be counted as a 1.0 FTE for more than 5 years. For any training beyond the IRP, residents are counted as 0.5 FTEs. Under the Medicare statute, the IRP is "determined, with respect to a resident, as of the time the resident enters the residency training program." The statue also states that: " 'the period of board eligibility' means, for a resident, the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training." (See Social Security Act Section 1886(h)(5)(F) and (G)).

Under the proposed rules' interpretation of the statute, hospitals providing specialty training for residents who select a specialty that requires a general clinical year may not be able to count those residents as a 1.0 FTE for the full length of the specialty training. This is because using the IRP based on the specialty in the general clinical year of training, regardless of the specialty in which the resident actually trains, may yield an incorrect labeling of the resident that does not reflect the resident's clear intent with regard to specialty training. For example, a resident who enrolls in a preliminary year internal medicine program is assigned the internal medicine IRP of 3 years. For a resident who intends to train in ophthalmology this means that for the first 3 years of training (preliminary medicine year plus 2 years of ophthalmology), the hospital counts the resident as a 1.0 FTE and that for the remaining year of ophthalmology training, the resident is counted as only a 0.5 FTE. By contrast, a resident who meets the general clinical year requirement through a "transitional year" program is assigned an IRP based on the specialty in which the resident is training in the

second year—for residents entering ophthalmology, this would typically be a period of three years.

MMA does not support the interpretation described in the proposed rule. The statute requires that the IRP be determined according to the date the resident enters the residency training program. The statute does not require assignment of an IRP to a resident during the first year of the resident's training. If the statute did mandate such a requirement, then a resident training in a separately accredited transitional year program would not be eligible to have the IRP determined in the second year of training. CMS' longstanding policy of allowing the IRP to be determined in the second year for residents training in transitional year programs is clear evidence that such a timeframe is permissible under the statute.

We urge CMS to interpret the statute in a manner reflective of Congressional intent, as expressed in the MMA 2003 conference report language, by allowing residents whose first year of training is completed in a program that provides a general clinical year (pursuant to ACGME requirements) an IRP based on the specialty the resident enters in the second year of training.

It is our hope that CMS will give strong consideration to these recommendations. We appreciate the opportunity to comment and look forward to hearing from CMS regarding its decision.

Sincerely,

William L. Rich, III, M.D.
Secretary of Federal Affairs

Cc: Tommy Thompson, Secretary of Health and Human Services
Josh Bolton, Director of Office of Management and Budget
Robert Dickler, Association of American Medical Colleges

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

July 12, 2004

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FEDERAL AFFAIRS DEPARTMENT

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

RE: CMS-1428-P (Residents Training in Nonhospital Settings; Reductions of and Increases in Hospital's FTE Resident Caps for GME Payment Purposes; Direct GME Initial Residency Period)

Dear Dr. McClellan:

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the proposed changes to the Medicare Hospital Inpatient Prospective Payment System. The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed Hospital Inpatient Prospective Payment System Rule (Inpatient PPS).

Several of the changes addressed in the proposed rule could potentially have a detrimental affect on the efficacy of ophthalmology residency programs. Included among these changes are recommendations affecting: 1) payment for supervisory teaching activities at non-hospital sites; 2) re-allocation of vacant residency slots; and 3) determining the initial residency period (IRP). The Academy urges CMS to reconsider its current position on these issues in light of our comments.

Residents Training in Nonhospital Settings

Residents in many specialties complete part of their training at non-hospital sites. This training is currently provided under a requirement that the hospital counting the resident enter a written agreement with the non-hospital site wherein the hospital agrees to pay reasonable costs to the non-hospital site for supervisory teaching activities. The proposed rule would eliminate the requirement that a written agreement be executed between the hospital and nonhospital site, and

replace it with a requirement that the hospital pay all or substantially all of the costs of the training in a nonhospital site by the "end of the month following a month in which the training in the nonhospital site occurred." (69 Fed. Reg. at 28316). As a result, the resident count associated with training at nonhospital sites would be determined on a month-to-month basis and would depend on whether the hospital had paid for the training costs of the previous month.

The Academy is concerned that the new requirement will be administratively onerous for teaching hospitals and could adversely impact residency programs. While we appreciate CMS' recognition of the administrative burden associated with the written agreement requirement, the payment time frame associated with CMS' current proposal is too short and would result in more, rather than fewer, disallowances of resident counts. The billing arrangements of complex organizations such as teaching hospitals and their business partners often exceed 30 and even 60 days. Moreover, the fiscal offices for many hospitals cannot send a payment to any entity without first receiving an invoice from that entity. Often these invoices do not arrive at the hospital within the 30-day proposed deadline.

Adoption of the proposed rule will result in additional administrative burdens for the teaching hospitals involved in sending residents to non-hospital sites for training. This could very well lead to decisions by teaching hospitals not to allow their residents to take advantage of this type of training.

Ophthalmology residents receive training and provide services at non-hospital sites. These non-hospital sites are often free or low-cost clinics whose patients would otherwise be deprived of access to specialty care. Requiring hospitals to provide proof of payment to these non-hospital sites on such short notice, at the risk of jeopardizing their residency program funding and slots, creates a disincentive for them to allow their residents to train at non-hospital facilities. Consequently, the proposed changes may result in reduced access to care by patients at non-hospital facilities.

We believe that a reasonable alternative to the proposed 30-day payment rule would require hospitals to demonstrate proof of payment to non-hospital sites when their cost reports are audited or within a time frame consistent with CMS' policy regarding other provider payment obligations. Either of these alternatives will achieve CMS' goal of ensuring that hospitals make required payments to non-hospital sites--but in a less burdensome manner.

We urge CMS to adopt one of these options in the final rule. If CMS rejects these comments, we believe teaching hospitals should be given the option of continuing to operate under the existing policy (maintaining a written agreement) **or** making

payments according to CMS' proposal. Otherwise, we believe that CMS should rescind this proposal pending further study of this issue.

Reductions of and Increases in Hospital's FTE Resident Caps for GME Payment Purposes

The proposed rule's stance on reallocation of unused residency slots concerns the Academy. Though ophthalmology residency programs are typically filled, we are troubled by the possibility that programs located in hospitals that have trouble filing vacancies in other specialties may lead to reduced funding because of cap reductions thereby impacting the available number of residency slots in all specialties. The residency slot re-allocation process should further analyze its impact on other specialties. The Academy encourages CMS to give further consideration to the impact that cap reductions will have on the overall availability of services to patients and to the number of residency training slots available within all specialties located at a particular hospital facility. In order to avoid the problems associated with tracking the number of resident slots used by a particular specialty the Academy would suggest that CMS evaluate the distribution of residency slots on a more frequent basis. This would ensure better tracking and allocation of residency slots to specialty training programs within particular facilities.

We are also concerned with the evaluation criterion, established in the proposed rule, that gives hospitals with existing or planned geriatric residency programs a higher priority with regards to receiving additional residency slots. The proposed regulation creates a mechanism for increasing residency slots for geriatrics programs but does not provide additional slots to ophthalmology programs. See 69 Fed. Reg. at 28302. Ophthalmologists provide a large percentage of care to geriatric patients.[1] In lieu of designating geriatrics as the sole specialty that will benefit based on its provision of services to Medicare beneficiaries, we think it would be prudent for CMS to give consideration to ophthalmology and other specialties who provide a high percentage of services to geriatric patients when determining how to re-allocate residency slots. We would encourage CMS to consider prioritizing the allocation of additional residency slots to include ophthalmology residency programs based on the high number of Medicare beneficiaries benefited by this specialty.

[1] In 1998 48.1% of the Medicare fee for service population used eye care services. An ophthalmologist evaluated approximately 67.1%. Archives of Ophthalmology p. 804 (June 2002).

Direct GME Initial Residency Period (IRP)

The proposed Medicare Inpatient PPS rule addresses the IRP determinations used in determining Medicare DGME payments. See 69 Fed. Reg. at 28310. A clarification is necessary because CMS' interpretation of the requirements for determining the IRP does not reflect Congressional intent and results in inequitable payments to teaching hospitals for residents training in certain specialties. The most recent statement of Congressional intent with regard to the IRP clearly supports this position. As stated by conference report language accompanying section 712 of the Medicare Modernization Act of 2003 (P.L. 108-173):

> The conferees also clarify that under section 1886(h)(5)(F), the initial residency period for any residency for which the ACGME requires a preliminary or general clinical year of training is to be determined in the resident's second year of training.

We urge CMS to address the IRP issue in the inpatient final rule (or in an interim final regulation) and to interpret the statute to reflect Congressional intent—thereby creating a system that more equitably addresses the issue of hospital GME payments for residents whose first year of training is completed in a program that provides a general clinical year.

Certain specialties, including ophthalmology, require residents to spend a year in general clinical training, with the remaining years comprising specialty-specific training. Under requirements established by the Accreditation Council for Graduate Medical Education (ACGME), the organization that accredits allopathic residency programs, the general clinical year requirement can be met through one of two pathways: by 1) spending the first year in internal medicine, pediatrics, or surgery, or 2) participating in a one-year, freestanding "transitional year" program. Ophthalmology residents typically meet the general clinical year requirement by entering a preliminary year internal medicine, neurology, pediatrics, surgery, family practice, or emergency medicine program before entering their specialty of choice. Residents are accepted for one year into this preliminary general clinical year program with the understanding that they will enter a specialty in which they wish to train in their second year.

To determine DGME payments, residents are counted as 1.0 full time equivalents (FTEs) during the number of years required to achieve first board eligibility (the IRP), though no resident can be counted as a 1.0 FTE for more than 5 years. For any training beyond the IRP, residents are counted as 0.5 FTEs. Under the Medicare statute, the IRP is "determined, with respect to a resident, as of the time

the resident enters the residency training program." The statue also states that: " 'the period of board eligibility' means, for a resident, the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training." (See Social Security Act Section 1886(h)(5)(F) and (G)).

Under the proposed rule's interpretation of the statute, hospitals providing specialty training for residents who select a specialty that requires a general clinical year may not be able to count those residents as a 1.0 FTE for the full length of the specialty training. This is because using the IRP based on the specialty in the general clinical year of training, regardless of the specialty in which the resident actually trains, may yield an incorrect labeling of the resident that does not reflect the resident's clear intent with regard to specialty training. For example, a resident who enrolls in a preliminary year internal medicine program is assigned the internal medicine IRP of 3 years. For a resident who intends to train in ophthalmology this means that for the first 3 years of training (preliminary medicine year plus 2 years of ophthalmology), the hospital counts the resident as a 1.0 FTE and that for the remaining year of ophthalmology training, the resident is counted as only a 0.5 FTE. By contrast, a resident who meets the general clinical year requirement through a "transitional year" program is assigned an IRP based on the specialty in which the resident is training in the second year— typically three additional years for ophthalmology residents.

MMA does not support the interpretation described in the proposed rule. The statute requires that the IRP be determined according to the date the resident enters the residency training program. The statute does not require assignment of an IRP to a resident during the first year of the resident's training. If the statute did mandate such a requirement, then a resident training in a separately accredited transitional year program would not be eligible to have the IRP determined in the second year of training. CMS' longstanding policy of allowing the IRP to be determined in the second year for residents training in transitional year programs is clear evidence that such a timeframe is permissible under the statute.

We urge CMS to interpret the statute in a manner reflective of Congressional intent, as expressed in the MMA 2003 conference report language, by allowing residents whose first year of training is completed in a program that provides a general clinical year (pursuant to ACGME requirements) an IRP based on the specialty the resident enters in the second year of training.

Conclusion

It is our hope that CMS will give strong consideration to the Academy's recommendations regarding reconsideration of the payment policy for residents

training at non-hospital sites and will preserve patient access to care. We also urge CMS to strongly consider making changes to its current proposal regarding re-allocation of residency slots. The modifications that we have proposed will better enable achievement of the ultimate objectives of the regulation while protecting other residency programs within the same teaching hospital. Lastly, we would encourage CMS to adopt a more equitable system for determining the IRP applicable to residents in specialty programs that require a general clinical year. We appreciate the opportunity to comment and look forward to hearing from CMS regarding its decision.

Sincerely,

William L. Rich, III, M.D.
Secretary of Federal Affairs

Submitter : Ms. Karen Ryan **Date & Time:** 07/12/2004 12:07:00

Organization : Geisinger Health System

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter outlining Geisinger Health System comments

Submitter : Mr. Philip Besler **Date & Time:** 07/12/2004 12:07:00

Organization : BESLER Consulting

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment for comments.

Submitter : Mr. Sarah Wells **Date & Time:** 07/12/2004 12:07:00

Organization : Boston Scientific

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Pls find attached second comment letter from Boston Scientific on Coronary Stent Procedures

Submitter : Ms. Yvette Hayes **Date & Time:** 07/12/2004 12:07:00

Organization : Mountain States Health Alliance

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Comments attached on separate file.

CMS-1428-P-316

Submitter : Mr. John Tierney **Date & Time:** 07/12/2004 12:07:00

Organization : US Representative, MA-06

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments. Thank you.

CMS-1428-P-317

Submitter : Mr. Bob Thompson **Date & Time:** 07/12/2004 12:07:00

Organization :

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

We just became aware of the MED Pac.s July 9th recommendation. We are concerned that it might lead to an overall of lowering of payment for ICDs. This would be contrary to the spirit of the new technology add .on payment we are seeking. We ask you to not take an action that would lower payment in an area that is already experiencing inadequate payment.
Our letter of July 2 highlighted the rationale for CMS to find that CRT-D meets the newness criteria for an add-on payment. We want to note one final point to CMS on this issue. In the Medicare Prescription Drug, Improvement and Modernization Act (MMA), Congress passed a reduction in the new-tech cost threshold to enable more technologies to qualify. Prior to the enactment of MMA, CRT-D did not meet the payment inadequacy criterion, so consequently Medtronic did not apply for add-on payment. The new cost threshold has made it possible for CRT-D to qualify. Had Congress acted earlier to reduce the cost threshold, Medtronic would have applied for an add-on payment earlier, eliminating the issue CMS has now raised regarding newness. We applied for the CRT-D add-on payment at the earliest possible date in coordination with the enactment of the new thresholds in MMA. We believe a finding of newness and approval of the add-on payment for CRT-D is consistent with Congress. intent to ensure more new technologies qualify for the add-on payments.
We appreciate your consideration of these comments on the CRT-D add-on payment amount. If you have questions on the information above, please contact

Submitter : Ms. Terri Straub **Date & Time:** 07/12/2004 12:07:00

Organization : Greater New York Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Hard Copy with Signature will follow.

GREATER NEW YORK HOSPITAL ASSOCIATION
GNYHA

Greater New York Hospital Association
555 West 57th Street, 15th Floor
New York, N.Y. 10019
Phone: (212) 246-7100
Fax: (212) 262-6350

Kenneth E. Raske, President

July
Twelve
2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

Dear Dr. McClellan:

I am writing in response to the *Federal Register* notice dated May 18, 2004, "Reporting of Hospital Quality Data for Annual Hospital Payment Update." Greater New York Hospital Association (GNYHA) and our members thank you for the continued opportunity to comment on the Hospital Public Reporting Quality Initiative. The purpose of this letter is to provide a series of recommendations in response to the May 18 *Federal Register* notice.

GNYHA members are committed to quality and public reporting of hospital performance and continue to support Centers for Medicare and Medicaid Services (CMS) efforts to develop a public reporting system that all health care consumers can easily access and understand. Nonetheless, we continue to be concerned about the resource requirements to accomplish this initiative and the additional validation burden placed upon an already financially constrained health care system.

Although GNYHA is supportive of the concept of public reporting and transparency of quality data, we continue to have concerns in regard to the challenge faced by hospitals to commit the significant resources needed to collect, report, and validate the data. On behalf of the members of GNYHA, we encourage CMS to carefully consider the resource requirements for this initiative and the cumulative impact of adding additional measures and validation requirements. As mentioned in past comments letters to CMS in regard to the resource requirements, GNYHA believes that any calculation of time spent collecting data for this initiative must include resources for accessing administrative data, identifying cases for review, pulling medical records,

data abstraction, reliability testing, developing internal and external reports, administrative oversight, and ongoing quality improvement efforts. Of greater concern is that the public reporting initiative's impact will be diluted if the data collection and reporting burden outweighs the hospitals ability to improve quality. GNYHA encourages CMS to incorporate these factors into its assessments of the resource requirements and carefully consider the effort required to make improvements.

GNYHA also recommends that CMS reconsider some of the clinical evidence underlying several of the measures, and make modifications as appropriate. For instance, there continues to be professional debate regarding the use of angiotensin converting enzyme inhibitors as opposed to angiotensin receptor blockers in acute myocardial infarction and heart failure. GNYHA encourages CMS to provide a timely process to allow flexibility to measures when there is growing evidence that they do not reflect current clinical practice or where there is lack of clinical consensus.

In addition to the concerns we have described, GNYHA respectfully requests that CMS consider the following proposed recommendations to the validation process:

- GNYHA requests that the validation reports and process delineate standards that account for data entry transcription errors as opposed to errors of omission. CMS has called for an agreement between Central Data Abstraction Center (CDAC's) abstraction of all data elements and the hospital's abstraction of the same information, without regard to whether the difference in information is meaningful. The goal of the validation process should be to determine whether the standard of care has been met.

- GNYHA encourages CMS to differentiate the validation process for the market basket adjustment data from the other CMS initiatives. It is our understanding that currently the data abstracting guidelines used by CDAC instruct it to validate measures that go beyond those required for the market basket update, such as 7th Scope of Work measures. Furthermore, CMS is calculating the hospital validation score based on measures that are not required for hospital reporting.

- GNYHA encourages CMS to phase in the validation process for hospitals during the initial data collection period and as new quality indicators are developed. While over the majority of GNYHA members have been submitting data on some of these 10 quality measures, less than 25% have been submitting data on all 10 quality measures. Hospitals will begin submitting data on all 10 measures starting with patients discharged during the first quarter of 2004. Even with the best of intentions, there is the potential that the data abstraction process may have some flaws during the first round of data collection. It is also critical that hospitals have written feedback as to the exact failures in the validation process to avoid duplication of errors moving forward. We encourage CMS to consider allowing 60% agreement for the data that will affect the fiscal year (FY) 2006 payment rate and phasing up to 80% agreement for FY 2007. In addition, we would request that there be a phase-in period as additional measures are identified or as quality indicators are revised.

- CMS also has indicated that it would assess the completeness of a hospitals' data submission by checking to see if the number of cases submitted corresponds to the number for whom they have bills. In addition, since the cases reported for quality purposes are for all patients, regardless of payor, and the bills submitted to CMS are only for Medicare patients, it is clear that the number of cases reported may not match with the number billed to CMS. CMS needs to re-evaluate its process to assess completeness and provide greater clarity about how it will assess the completeness of the data submission. It is clear that in some cases the larger hospitals are using sampling techniques when submitting the quality data, and therefore there would not be a direct match with the billing records.

- The current validation process calls for validation of five charts per measure. GNYHA is concerned that a sample size of five charts is not adequate to assess an 80% compliance rate regardless of the number of cases submitted. If CMS chooses not to modify this number, GNYHA recommends that CMS provide a mechanism for hospitals to request that additional charts be reviewed if the initial sample reveals a less than 80% agreement.

- GNYHA recommends that CDAC abstractor training be a priority and if the abstractors are given a specific set of rules on how to abstract these charts, the hospitals should be given the same instructions so they have a clear understanding of how the charts are being reviewed. This process may also help hospitals identify best practices in data abstraction and create some efficiencies in the process.

- With the proliferation of multiple report cards and variations in data collection guidelines, CMS should ensure that 100% of the measure definitions, inclusions, and exclusions are aligned between CMS and JCAHO. There are several measures, including those for heart failure and pneumonia, where differences exist that are creating inaccurate validation results.

As always, thank you for considering our comments and recommendations to the public reporting initiative.

My best,

Sincerely,

Kenneth E. Raske

cc: Nancy Foster, Senior Associate Director, Policy, American Hospital Association
Steve Jencks, M.D., M.P.H., Centers for Medicare and Medicaid Services Quality Improvement Group

Submitter : Mrs. Lovelyn Robinson **Date & Time:** 07/12/2004 12:07:00

Organization : American Medical Rehabilitation Providers Association

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

Please find attached comments on behalf of the American Medical Rehabilitation Providers Association on the Proposed Changes to the Hospital within a Hospital Rule.
Thank you very much for the opportunity to submit these comments.

American Medical Rehabilitation Providers Association

Felice Loverso, Ph.D.
President and C.E.O
Casa Colina Centers for Rehabilitation
AMRPA Chairman of the Board

Monday, July 12, 2004

Mark McClellan, M.D. Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 443-G
Attention: CMS -1428-P
Hubert H. Humphrey Building
200 Independence Ave. S.W.
Washington, D.C. 20201

Re: CMS-1428-P Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal 2005 Rates, Hospitals within Hospitals, pg. 28323 et seq.

Dear Dr. McClellan:

This letter is submitted on behalf of the American Medical Rehabilitation Providers Association (AMRPA). AMRPA is the national trade organization representing freestanding rehabilitation hospitals, rehabilitation units of general hospitals, and outpatient rehabilitation services providers. Most, if not all, of our over 350 members are Medicare providers. Several of our members are also long term care hospitals that deliver rehabilitation services. A few of our members, both long-term and rehabilitation, utilize the hospital within a hospital model.

We have reviewed the proposals pertaining to the criteria for classification of hospitals within hospitals (HWH) on pages 28323-28327 of the above referenced proposed rule.

Under the current rule, a HWH must meet the criteria in 42 CFR 412.22(e). CMS has expressed concern that the HWH model, particularly for long term care hospitals, is being used to maximize reimbursement and/or prematurely discharge patients from acute care. The rules apply to a hospital that occupies space in a building also used by another hospital or in one or more entire buildings located on the same campus as buildings used by another hospital.

Currently a HWH must meet a test regarding separateness and control of the HWH from the host hospital or third party entity that controls both. These requirements are found at 42 CFR 412.22(e) (1)-(4):

1. The hospital has a separate governing body from the "host" hospital or "any third entity that controls both hospitals."
2. The hospital has a separate chief medical officer who is not employed by or under contract with the "host" hospital or any third entity that controls both hospitals.
3. The hospital has a separate medical staff which is separate from the medical staff of the host hospital. The medical staff is accountable to the governing body.
4. The hospital has a separate chief executive office who is not employed by or under contract with the host hospital or any third entity that controls both hospitals.

In addition it has to meet one of three other criteria's regarding basic hospital functions and organizational separateness at 42 CFR 412.22(e)(5).

1. Specific functions are not performed by employees or through contracts from or with the host hospital. There are exceptions for certain services.
2. For at least 6 months prior to the exclusion being sought, and for the same six months used to determine age compliance for children's hospitals and length of stay compliance for LTCHs, the cost of services under contracts with the host hospital or a third entity that controls both hospitals did not exceed 15% of the HWH's total inpatient operating costs, or
3. For the same 6 month period, at least 75% of the inpatients were referred from sources other than the host hospital.

CMS believes that HWHs have been abusing the 15% rule and that there are arrangements whereby there is no true complete separation from the host hospital or hospital system. It states:

> "We believe that the 15-percent policy is being sidestepped through creative corporate reconfigurations. Therefore, if the LTCH is nominally complying with the 15-percent requirement, it has not been required to meet the basic hospital function requirements at existing Sec. 412.22(e)(5)(iii). Thus, it is free to accept even 100 percent of patients from the onsite host, and share the same basic hospital functions as the host. Reliance on meeting the 15-percent criterion has enabled the creation of LTCH hospitals-within-hospitals that rely upon affiliated entities both for their operations and for their patient referrals. The result is a situation very similar to the hospital-within-a-hospital serving as a LTCH unit of the acute care hospital, which is precluded by the statute.
>
> One of the reasons we are proposing revisions to the existing criteria for hospital-within-a-hospital is because we believe that determining whether a hospital has complied with the 15-percent criterion is burdensome for a fiscal intermediary on an ongoing basis. Presently, review of corporate arrangements represents a snapshot in time that may assess a particular set of business transactions but does not provide

relevant details to reveal the extent of the unity of interests between the parties over time. Further, the widespread existence of such complex configurations, as well as the ongoing creation of new business arrangements, convinces us that a hospital-within-a-hospital's compliance with Sec. 412.22(e)(5)(ii) may be fluid, unreliable, or, in some cases, nonexistent."

As a result of these concerns CMS is now proposing that in order to be excluded from the IPPS, a HWH must:

1. Meet the existing criteria regarding common control;
2. Meet a new criterion such that it is not owned wholly or in part by a person or party that has any ownership interest in the hospital occupying space in the same building or on the same campus or of any third party entity that controls both hospitals; and
3. Meet the 75% referral rule (i.e. at least 75% of its admission must come from a source other than the host hospital).

Furthermore, CMS is proposing three payment options to "diminish the possibility of a hospital-within-a hospital actually functioning as a unit of an acute care hospital and at the same time generating unwarranted payment under the more costly LTCH PPS." Please note that while the text of the rest of the preamble is not specific to LTCH HWHs, the reference to payment is. **The agency may wish to review this statement**.

They are:

1. If the separateness and control criteria under 412.22.(a) and the 75% rule are not met, pay the hospital as an acute care hospital under the IPPS for all patients.
2. If the 75% rule is not met, pay the excluded rate only for patients referred from the non-host hospital and pay for all other patients under the IPPS. Services provided by the HWH would be treated as provided "under arrangements."
3. If the 75% rule is not met, pay the lesser of the DRG payment for patients admitted from the host hospital or what would be paid to the HWH under the applicable excluded hospital payment system. For patients, from other than the host hospital, the HWH would be paid under the applicable excluded payment system "without adjustment."

We ask that the agency clarify what is meant by "without adjustment" with respect to the reference to applicable excluded payment systems. IRFs are paid under the IRF PPS. LTCHs are paid under the LTCH PPS. Psychiatric hospitals and units continues to be paid under TEFRA as do children's hospitals.

We have reviewed these proposals at length. **After due deliberation we find that we must oppose the proposed rule in that it would limit access to services.**

Separate Ownership

We note that the term "ownership" has not been used before in the discussions pertaining to HWH facilities. We question whether it is appropriate for CMS to try to dictate the type of entities in which another provider can invest. Starting down this road could be very dangerous and lead to multiple reorganizations at greater costs for health care in general as well as Medicare. For example, would a hospital no longer be able to own a SNF? Or would it affect a separate rehabilitation hospital in a joint venture or that is physically removed from the "campus" but still near by?

We find no precedent or authority for the Secretary to prohibit any person or entity from owning a Medicare provider type because that person or entity has an ownership interest in another provider.

75% Criterion

Second, we find the proposed 75% criterion to be bad policy. It would lead to a series of highly convoluted referral patterns at a minimum. For example, Hospital A with a HWH would now refer to Hospital B across town with a HWH. Hospital B with an HWH would now refer patients to Hospital A just to stay open. Most of the patients served by LTCHs and IRFs are fairly fragile and moving them unnecessarily is not only bad patient care clinically, but it is also just plain cruel. Additionally, it creates an administrative burden on the facilities.

We believe that CMS is trying to solve a problem that it sees as occurs primarily with respect to long term care hospitals within hospitals (LTCHs-HWHs). CMS notes, as has MedPAC, that there has been considerable growth of LTCHs overall with most of that growth coming from LTCHs using the HWH model. Since this appears to be the key problem, we recommend that CMS address it instead, as we recommend below. One commenter on this rule notes that if this criterion were applied to freestanding LTCHs and freestanding IRFs and hospital based IRFs, very few would qualify. We believe it is inappropriate to compare the rule to IRFs and freestanding LTCHs in that they are statutory excluded and such referral patterns are standard clinical practice and precede the DRGs and all other prospective payment systems. HWHs have followed this clinical practice pattern.

Furthermore for any type of post acute care provider CMS can address its concerns regarding premature discharge and payment by further refining the DRG weights and transfer policy. Furthermore other payment policies exist to minimize substitution of services. They include the IPPS outlier policy, LTCH short stay payment and the IRF-PPS short stay and transfer policies.

Finally, any potential percentage cap on patient admissions from the host hospital is unreasonable because it would affect HWHs and their patients based on the size of a community and the number of acute care hospitals in a geographic area. It also would affect both discharge planning and acute hospital utilization review functions. A community with one major hospital effectively would be forced to engage in expensive construction of a new freestanding hospital or create a unit. It therefore, appears that one outcome of the 75% rule on patient admissions may be to deprive small and medium size communities of services.

On June 15, the Medicare Payment Advisory Commission (MedPAC) issued its report to Congress, "Report to Congress: New Approaches in Medicare." MedPAC has studied the LTCH field extensively in developing the recommendations in the report. It recommends:

> **"5A** The Congress and the Secretary should define long-term care hospitals by facility and patient criteria that ensure that patients admitted to these facilities are medically complex and have a good chance of improvement.
>
> - Facility-level criteria should characterize this level of care by features such as staffing, patient evaluation and review processes, and mix of patients.
> - Patient-level criteria should identify specific clinical characteristics and treatment modalities.
>
> **COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1**
>
> **5B** The Secretary should require the Quality Improvement Organizations to review long-term care hospital admissions for medical necessity and monitor that these facilities are in compliance with defining criteria.
>
> **COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1"**

AMRPA recommends that if CMS is trying to address incentives that lead to growth in the LTCH field that it accept and develop the MedPAC recommendations regarding patient and facility characteristics and criteria.

Furthermore AMRPA notes that there has not been increase in the number of inpatient rehabilitation facilities than there has been in the LTCH field. For example, the data from RAND analyzing the first year of the IRF-PPS show the following, confirming that, over the years, there has not been rampant growth in the IRF field.

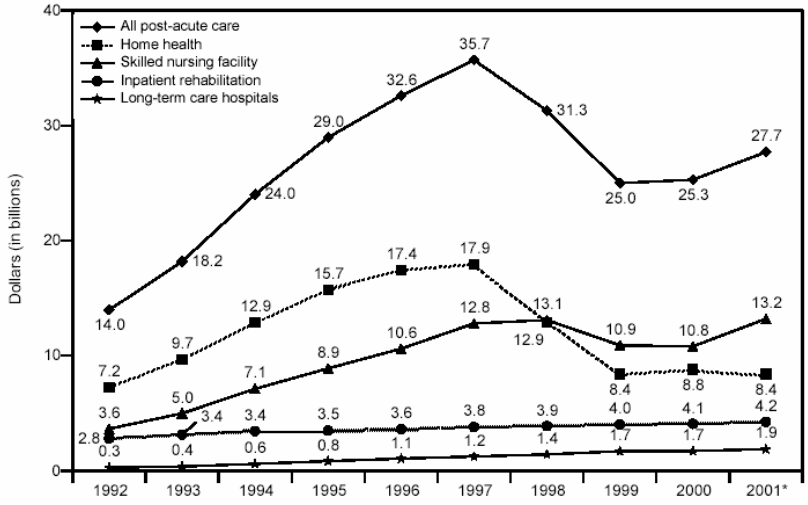
Year	Facilities % Annual Increase	Discharges % Increase
1996		
1997	**3.9**	**4.3**
1998	**2.8**	**3.2**
1999	**0.9**	**5.3**
2002 est.	**0.7**	**6.0**

Hence, the growth in inpatient rehabilitation facilities has been restrained and disciplined. In the initial year of the IRF PPS – which started January 1, 2002 CMS estimated expenditures at about $4.3 billion. Since then, it has increased the payment amount by 3% for FY 2003 and 3.2% for FY 2004 and expects to increase it by 3.2 – 3.2% for FY 2005. It estimates total expenditures through July 2005 of about $5.89 billion.

Hence, overall expenditures have not increased dramatically since implementation of the IRF-PPS.

Moreover, a review of historical Medicare post-acute care expenditures reveals that only the inpatient rehabilitation sector has maintained moderate and steady growth. Although Medicare spending for IRFs did increase somewhat in the early 1990s (from $1.9 billion in 1990 to $3.7 billion in 1993), by the mid-1990s IRF spending had stabilized. For the five-year period from 1992 through 1997, Medicare spending for IRFs increased by only about 6% annually. This contrasts sharply with average annual growth rates of 35%, 29% and 20% during the same period for long-term acute care hospitals (LTCHs), SNFs and home health, respectively. *See* MedPAC, *A Data Book: Healthcare Spending and the Medicare Program* at 126 (June 2003). The following chart (based on CMS data) is illustrative:

Chart 8-2. Medicare spending for post-acute care, by setting, 1992–2001



Note: Dollars are program spending figures and do not include beneficiary copayments.
*Spending for 2001 is estimated.

Source: CMS, Office of the Actuary.

As the above chart indicates, from 1997 to 2001, Medicare spending for IRFs increased by just 2.5% annually. During this same period, IRF operating margins declined by 58%, from 7.4% to 3.1%. *Id.* at 135. Hence again, Medicare spending on IRFs – and IRF profit margins – have not soared in recent years.

Therefore, we recommend that for other excluded facilities there be no change to the current regulations pertaining to hospitals within hospitals.

Patient Choice

The proposed cap on referrals also leads to a denial of patient choice and access, as do other arbitrary rules such as the 75% Rule which is a criterion IRFs must meet to be excluded from the IRF-PPS.

The imposition of a percentage as a barrier to admission for necessary hospital care is contrary to the freedom of choice provisions of the Medicare program. Full freedom of

choice of access to providers and physicians cannot be extended to Medicare beneficiaries only to be withdrawn or restricted by this limit applicable to HWHs. The notion that patients who qualify for services will be diverted to a non HWH, to an acute hospital or a skilled nursing facility, needs to be re-examined and explained in any final rulemaking.

Finally, and more critically, these proposals will further eliminate access to HWH patients needing these specialized services. We believe this rule continues to reflect a bias in CMS that these patients should be sent to and can be served by SNFs. CMS should instead look at quality of care and medical and functional outcomes at a minimum before making such assumptions. We have several ideas on how such an examination should occur and would be pleased to discuss them both with you. This rule is devoid of such considerations.

New Facilities

The rule would penalize facilities in the process of development. Any entity under development, as of the effective date of any final rule if CMS retains these proposals, should also be allowed to be certified. Section 507 of the Medicare Prescription Drug Improvement and Modernization Act of 2003, provided for a moratorium on future development of physician owned specialty hospitals. It also provides an exception where architectural plans were completed, capital funding arranged and state approvals for the establishment of a new hospital have been received, e.g., certification of need, if applicable. CMS recently implemented these provisions. The Secretary should also consider these factors and allow for the continued development of such facilities if this rule goes forward.

We would be pleased to discuss these issues with you at your convenience.

Sincerely,

Felice Loverso, Ph.D.
AMRPA President

Ken Aitchison
AMRPA PPS Task Force Chair

Marsha Lommel
AMRPA Rehabilitation Post Acute Care Committee Chair

CMS-1428-P-320

Submitter : Ms. Phyllis Wang **Date & Time:** 07/12/2004 12:07:00

Organization : New York State Association of Health Care Providers, Inc

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please accept these comments andf disregard the first set sent - we had a problem with our email Thank you

Submitter : Mr. John Skelly **Date & Time:** 07/12/2004 12:07:00

Organization : Palisades Medical Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attached file

CMS-1428-P-322

Submitter : Mr. Jay Hoffman, Jr **Date & Time:** 07/12/2004 12:07:00

Organization : Houston Healthcare

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attached file for comments

Submitter : Mr. Scott Barnes **Date & Time:** 07/12/2004 12:07:00

Organization : HealthSCOPE Benefits, Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Submitter : Dr. Zachary Levine **Date & Time:** 07/12/2004 12:07:00

Organization : Washington Brain & Spine Institute

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Re: New Technology Applications y Kinetra
I am a neurosurgeon with extensive experience with deep brain stimulation (DBS). I have implanted over 80 DBS devices over the past 3 years. I have used the technology on parkinson's disease as well as tremor and dystonia. Kinetra offers a safer, less invasive manner of producing the same or better results than Soletra (the older device). Kinetra aloows for fewer incisions. The battery will last longer and there avoids frequent procedures to change the device. Staged implantation is still important in that the priamry surgery is done under local and the tunneling and implantation of the pulse generator requires general due to the pain and postioning needed. This second surgery can be done as an outpatient as APC as soletra has been done

CMS-1428-P-325

Submitter : Mr. Richard Jones **Date & Time:** 07/12/2004 12:07:00

Organization : The Stamford Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached comment letter regarding the proposed FY05 inpatient rules.

CMS-1428-P-326

Submitter : Ms. Carolyn Aldige **Date & Time:** 07/12/2004 12:07:00

Organization : Cancer Research and Prevention Fdn.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter

Submitter : Mrs. Jean Herrmann **Date & Time:** 07/12/2004 12:07:00

Organization : Dr. Wilson Asfora Incorpporated/Sioux Falls Neurosurgery

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I would like to express our concern that the present reimbursement for the Kinectra deep brain stimulator system does not address the significant improvements in technology provided. With the new Kinectra patients are now able to do a small amount of self programming of the stimulators at home. To do this of coarse has required additional training of of physicians and nurses to complete a more complex initial programming and some increased time doing the programming following surgery. However the additional time and cost is well worth while to the patient as it decreases the frequency of followup visits and decreases their travel expenses. Thus the Kinectra system also decreases the amount of followup visits that would potentially be filled to Medicare or insurance. The patient is now able to attempt reprogramming of the deep brain stimulator by increasing the amplitude within parameters that have been preset. This has enabled patients to become more involved in the care of dealing with their disease process and more motivated and satisfied with the product. I hope this will help you with your decision.
Sincerely, Jean Herrmann, CNRN, BA Movement Disorder Specialist and programmer

CMS-1428-P-328

Submitter : Mr. Neil Heyman **Date & Time:** 07/12/2004 12:07:00

Organization : Southern New York Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please find comment letter attached for your review regarding the proposed changes to the Hospital Inpatient Prospective Payment System. Thank you.

CMS-1428-P-329

Submitter : Dr. Michael V. Drake **Date & Time:** 07/12/2004 12:07:00

Organization : University of California, Office of the President

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

July 12, 2004
Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850
RE: Centers for Medicare and Medicaid Services. (CMS) Direct GME Initial Residency Policy
I write on behalf of the University of California (UC), which operates the nation's largest health science and medical training program, with an annual enrollment of over 12,000 students, including more than 4,000 medical residents. UC requests that CMS implement in the FY 2005 Medicare inpatient final rule, or in an interim final regulation, a policy allowing the initial residency period to be determined in the second year of residency training based on the specialty the resident enters. We believe that this policy is equitable and reflects accurately Congressional intent with respect to initial residency period (IRP) determination for the purpose of calculating Medicare Direct Graduate Medical Education (DGME) payments to teaching hospitals.
The Conference Committee report language that accompanied the Medicare Modernization Act (MMA) of 2003 (PL 108-173) outlines Congress. intent on this issue. In reference to section 1886, it said that the initial residency period for any residency for which the Accreditation Council for Graduate Medical Education (ACGME) requires a preliminary or general clinical year of training be determined in the resident.s second year of training. This approach addresses the inequity resulting from the current CMS policy that makes DGME payments to hospitals in differing amounts for residents who complete a broad based clinical year prior to beginning training in their selected specialty.
Determining the IRP based on the specialty in the first year of training, regardless of the specialty in which the resident actually trains, may not reflect the resident.s intent with regard to specialty training. For example, some specialties, like radiology, require that a resident complete a broad-based clinical year of training as a prerequisite to entering specialized training. Often, this base year residency requirement is met by entering a .transitional year. program or by entering a .preliminary. slot in an internal medicine program. Under current policy, Medicare treats these two types of programs differently, resulting in inequitable reimbursement for residents completing similar requirements.
We urge that CMS adopt a FY 2005 inpatient final rule (or an interim final regulation) for residents whose first year of training is completed in a program that provides a general clinical year as required by the ACGME for certain specialties (i.e., a transitional or preliminary year). For this purpose, we believe that the IRP should be assigned based on the specialty the resident enters in the second year of training.
Sincerely,
Michael V. Drake
Vice President for Health Affairs
University of California

Submitter : Mr. Daniel Lohr **Date & Time:** 07/12/2004 12:07:00

Organization : The William W. Backus Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

July 12, 2004
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850
Re: CMS-1428-P; Medicare Program; Proposed Changes to Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates; Hospital Reclassifications
Dear Sir or Madam:
The William W. Backus Hospital in Norwich, Connecticut appreciates the opportunity to submit these comments regarding the above-referenced Centers for Medicare and Medicaid Services (CMS) proposed rule. We believe that if implemented, the changes proposed in the rule will result in a significant cut in funding to all Connecticut hospitals, threatening hospital financial viability and access to care for Medicare beneficiaries. Our belief is based on the significant analysis prepared by the Connecticut Hospital Association on behalf of its member hospitals.
The significant unintended adverse consequence for Connecticut hospitals is due to the adoption and application of the new Core Based Statistical Areas (CBSAs) for purposes of hospital geographic classifications. The proposed rule would increase hospital inpatient rates by 3.3% for inflation while cutting funding for wages by 7% for most Connecticut hospitals. The net effect of the new wage indices is that: 2005 IPPS payments to Connecticut hospitals will be $46.6 million lower than they were in 2004 and outpatient payments will be $11.6 million lower than they were in 2004. The impact of the other rule elements, i.e. transfers, outliers, and IME, are estimated to cut funding to Connecticut by another $11 million. In sum, these changes would reduce current Medicare funding to Connecticut hospitals by about $70 million dollars.
The specific impact of the proposed rule on The William W. Backus Hospital is to effectively hold our reimbursement flat as compared to FY 2004 under a payment system which already reimburses the Hospital at a rate less than cost and at a time when our resources are scarce and our costs continue to rise. If the CMS published increases were also to be applied in Connecticut, our FY 2005 payments would increase approximately 4.7%. We must receive some increase in payments in order to cover our anticipated increases in wage and benefit costs. Holding our reimbursement flat under the proposed rule will only result in the long-term to a decrease in services available in our community.
I urge you to act on the recommendations submitted as formal comments by the Connecticut Hospital Association. Specifically:
o Allow Connecticut hospitals that were unable to reclassify to elect to adopt the wage index of the next nearest hospital that was able to reclassify, similar to what is being proposed by CMS for hospitals in states with low population density.
o Given the unpredictability of wage indices and their seemingly counterintuitive effect in Connecticut, set as a floor for the next three years those values that were established as of April 2004.
o Include the hospitals of Litchfield County, i.e., The Charlotte Hungerford Hospital, New Milford Hospital, and Sharon Hospital, in Hartford County for wage index purposes, as they have been since 1979.
o Allow hospital groups in Combined Statistical Areas to be able to seek group reclassification, and/or allow hospital groups to be in either a Core-Based Statistical Areas or Consolidated Metropolitan Statistical Area to seek group reclassification.
o Hold harmless those five Connecticut hospitals that have routinely been granted a wage reclassification to prevent any reduction in their wage index for the next three years.
o Hold harmless the hospitals that were able to reclassify under section 508 of MMA for any reduction to their wage index for the next three years.
Sincerely
Daniel E. Lohr
Senior Vice President & CFO

CMS-1428-P-331

Submitter : Mr. Tom Davis **Date & Time:** 07/12/2004 12:07:00

Organization : RehabCare Group

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter