



**Association of
American Medical Colleges**

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VIA HAND DELIVERY

June 24, 2005

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

Attention: **CMS-1500--P**

Dear Administrator McClellan:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "*Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates.*" 70 Fed. Reg. 23306 (May 4, 2005). The AAMC represents approximately 400 major teaching hospitals and health systems; all 125 accredited U.S. allopathic medical schools; 96 professional and academic societies; and the nation's medical students and residents.

Our letter comments on the proposed changes to the regulations for Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. We also comment on a number of other proposals that have particular importance to teaching hospitals. In particular, we urge the Agency not to expand the post-acute care transfer policy, and to reduce the proposed outlier threshold to \$24,050. In addition, we believe it is premature to change the labor-related share.

I. IME RESIDENT CAPS FOR FORMERLY INPATIENT PPS-EXCLUDED HOSPITALS AND UNITS

PPS-excluded rehabilitation and psychiatric hospitals and distinct-part units of acute care hospitals do not receive IME payments under the inpatient acute care prospective payment system (PPS) because their payments are determined by different systems.¹

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¹ Until recently, these units and hospitals were paid on a cost-based system. However, they currently are paid based on either the inpatient psychiatric facility PPS or inpatient rehabilitation facility PPS. The psychiatric PPS has its own IME adjustment. CMS has recently proposed to include an IME adjustment as part of the IRF PPS (70 Fed. Reg. 30188 (May 25, 2005)).

Consequently, they do not have inpatient PPS IME resident caps. However, these hospitals and units receive DGME payments and thus have DGME resident caps.

The proposed rule appropriately recognizes that there may be times when a PPS-excluded teaching hospital may have its Medicare status changed such that it would be subject to the inpatient PPS. While not explicitly mentioning PPS-excluded units, the situation is also applicable to them. In both of these situations, the hospitals and units that are training residents are eligible to receive IME payments under the inpatient PPS system. However, because they were not subject to the acute inpatient PPS in 1996--the time frame for determining the IME resident caps--their IME resident counts are not associated with the caps.

We acknowledge CMS' position that, as is true for other inpatient PPS teaching hospitals, PPS-excluded teaching hospitals that become subject to the acute inpatient PPS must also be subject to an IME resident cap.

While the proposed rule does not explicitly mention them, we presume CMS' position also applies to PPS-excluded units. Such a presumption is reasonable given that the situation for PPS-excluded units is the same as PPS-excluded hospitals. For example, if a teaching hospital had residents training in a rehabilitation unit in 1996 that was not PPS-excluded, those residents would be included in its IME cap. If the rehabilitation unit was PPS-excluded, the hospital was not permitted to include the resident counts in its 1996 IME cap calculation. If the PPS-excluded rehabilitation unit subsequently changes its status such that it now receives inpatient PPS payments (including IME payments), it is reasonable that the unit's resident counts should also be subject to an IME cap. Accordingly, the hospital's IME cap should be adjusted to reflect the additional resident counts.²

CMS proposes that for PPS-excluded hospitals that subsequently become subject to the inpatient PPS, the IME cap that would be established for them would equal the resident count that was used to establish their DGME cap--1996 for most teaching hospitals. At the outset, we believe that, at a minimum, the methodology that is ultimately decided upon by CMS must apply to PPS-excluded units as well.

We also believe that 1996 is too far back in time for establishing the IME caps for these facilities. While we recognize the CMS traditionally chooses a historical time period for decisions such as this³, it is important to remember that 1996 was the year chosen for the

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² The only other alternatives would be to a) not subject resident counts in these units to a cap, which seems counter to current law which imposes an IME cap on hospitals subject to the acute inpatient PPS, or b) not adjust the hospital's resident cap when a PPS-excluded unit changes status, which could result in effectively denying hospitals IME payments associated with resident counts in those units. Not only would the result under b) be nonsensical, it would be contrary to statutory intent and current regulations that provide for IME payments under the inpatient PPS.

³ A past time frame is usually used so that hospitals will not have an opportunity to change their behavior patterns in response to the legislation; for example, to increase resident counts before the imposition of a

DGME caps because it was the most recent year prior to the passage of the Balanced Budget Act of 1997 (BBA), which established the caps. That year was chosen so that the cap numbers would reflect as closely as possible hospitals' situations as of the time the BBA was enacted. To impose a 1996 time frame on a policy that is being implemented in 2006 is counter to this philosophy. Moreover, teaching hospitals have made educational and programmatic decisions regarding expansions of residency training rotations within those hospitals and units since 1996 with the understanding that the hospital is making those decisions absent a financial penalty apart from that associated with Medicare direct GME reimbursement by exceeding the hospital's direct GME cap. To use a cap based on hospitals' situations in 1996--10 years ago, is unfair and wrong.

We urge CMS to make cap determinations based on more current data. The psychiatric and rehabilitation facility prospective payment systems provide cap methodologies that use more recent cost report periods.⁴ Not only are these easily adaptable to the inpatient system, they also would ensure resident cap consistency when an excluded facility converts to an acute inpatient status. Under the inpatient psychiatric facility (IPF) PPS, an IME cap is established based on the number of residents training in the IPF as reported by the hospital or unit in its most recently filed cost report before November 15, 2004 (See IPF PPS Final Rule, 69 Fed. Reg. at 66955). If a psychiatric PPS-excluded hospital or unit subsequently becomes subject to the inpatient acute care PPS, using this same cap would maintain consistency across payment systems.

Under the 2006 inpatient rehabilitation facility (IRF) proposed rule, a resident cap would be established based on the number of residents reported by the IRF on its most recent cost reporting period on or before November 15, 2003 (70 Fed. Reg. at 30243). We believe consistency dictates that for those IRFs which lose or change their status and become subject to the acute care inpatient PPS, the IRF PPS IME cap should be used.

II. DGME INITIAL RESIDENCY PERIOD (IRP) DETERMINATIONS FOR SPECIALTIES REQUIRING A GENERAL CLINICAL TRAINING YEAR

Initial residency periods (IRPs) are used to determine Medicare DGME payments. Residents are counted as 1.0 full time equivalents (FTEs) during the number of years required to achieve first board eligibility, known as the initial residency period (IRP), though no resident can be counted as a 1.0 FTE for more than five years. For any training beyond the IRP, residents are counted as 0.5 FTEs.

CMS historically held the position that the IRP for residents in specialties that require a general clinical training year (for example, radiology, anesthesiology, and dermatology,) is determined based on the specialty of the first residency program they enter, rather than the second year program, which reflects their intended specialty of training. Thus, a

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resident cap.

⁴ We are not opining as to the legality of CMS' decision to impose resident caps under either the IPF or IRF prospective payment systems.

resident who enrolls in a preliminary year internal medicine program is assigned the internal medicine IRP of three years, even if that is not the resident's ultimate specialty choice.

In last year's FY 2005 IPPS final rule, CMS stated that effective for portions of cost reporting periods beginning on or after October 1, 2004, if a hospital can document that a resident "simultaneously matched" for one year of training in a particular specialty residency program and for a subsequent period of training in a different specialty program, the resident's IRP will be determined based on the period of board eligibility associated with the second program.

The proposed rule broadens CMS' policy by allowing hospitals that can document that a resident matched to an advanced residency program beginning in the second year prior to the commencement of any training, the resident's IRP will be determined based on the advanced specialty, even if the resident had not matched for a clinical base year program.

We appreciate and support the proposal. However, we continue to believe that the IRP for residents whose first year of training is completed in a program that provides a general clinical year of training should be based on the specialty the resident enters in the second year of training, regardless of whether, or when, the resident matches to the advanced specialty program.

Not only would this be a much more straightforward--and administratively less burdensome--solution, it also would reflect Congress' statutory intent regarding initial residency periods, as reiterated by the Conference Committee agreement accompanying section 712 of the Medicare Modernization Act (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.

III. PROPOSALS AFFECTING BOTH DGME AND IME PAYMENTS

A. NEW TEACHING HOSPITALS' PARTICIPATION IN MEDICARE GME AFFILIATED GROUPS

Under current regulations, existing teaching hospitals that meet specified criteria may enter into Medicare GME affiliation agreements by which they combine their respective resident caps and then redistribute them according to their agreement--with the proviso that the sum of the new caps cannot exceed the aggregate combined cap. Currently, 42 C.F.R. §413.79(e)(1)(iv) specifies that new teaching hospitals that are located in urban areas cannot be part of Medicare GME affiliated groups. New rural teaching hospitals may enter into these agreements but only if the rural hospital provides training for at least one-third of the FTE residents in all of the joint programs of the affiliated hospitals.

CMS states that its rationale for the new teaching hospital provision is to prevent “gaming” by current teaching hospitals that might encourage nonteaching hospitals to become teaching hospitals, receive a resident cap, and then enter into a GME affiliation agreement in which they would transfer many of their cap slots to the existing teaching hospital. A more flexible standard is provided for new rural teaching hospitals because rural hospitals may not have sufficient patient volume to support residency training programs.

The proposed rule would allow a new urban teaching hospital to enter into GME affiliation groups but only if there is a “positive adjustment” to its direct GME and/or IME cap; that is, the new teaching hospital’s revised cap pursuant to the affiliated agreement must be higher than its base year cap.

While we favor this proposal, we continue to believe the overall policy is unnecessary. Hospitals do not decide to become teaching institutions and go through the rigors of the accreditation process without extensive thought and analysis. CMS has provided no evidence that so-called “gaming” has occurred. Even if such a concern existed, it could be addressed by limiting the affiliation group exclusion for new urban teaching hospitals to a specified period of time, for example, three years.

B. RESIDENT CAPS FOR HOSPITALS CHANGING GEOGRAPHIC STATUS

Under the resident cap provisions, rural hospitals’ resident caps equal 130 percent of their base year (generally 1996) resident counts and their resident caps are increased to reflect new residency programs. These provisions do not apply to urban teaching hospitals.

As a result of labor market definitional changes, some rural teaching hospitals are now considered urban. Under the proposed rule, these hospitals would retain their 130 percent cap determination, as well as any new program cap expansions that occurred while they were classified as rural. We support both of these proposals.

Also, urban hospitals that received cap increases for rural training track programs may retain those increases even if the rural “track” has been re-designated as urban due to new labor market definitions.

The situation is different for an urban hospital that had applied and been approved to be reclassified as rural under section 1886(d)(8)(E) (codified at 42 C.F.R. §412.103) and then returns to being urban. First, according to CMS, urban hospitals that reclassify to rural under this section may receive the rural cap adjustments (130 percent and new program expansions), but only for their IME cap. This is because under the statute the reclassification affects only payments made under section 1886(d) of the Medicare statute. While IME payments are authorized under this section, DGME payments are authorized under section 1886(h). Consequently, CMS states that only the IME cap is affected by the change to rural status. If the hospital subsequently rescinds its rural

reclassification status and returns to being urban, CMS proposes that the hospital would forfeit any IME cap adjustment that it received during its rural status.

According to the proposed rule, CMS believes it is appropriate to allow rural hospitals that become urban due to labor market definitional changes to retain permanently any upward cap adjustments that occurred while they were considered rural because the labor market changes were not within their control. This is in contrast to those urban hospitals that voluntarily chose to change their status to rural under section 1886(d)(8)(E) and then return to urban status. CMS is concerned that some hospitals would seek rural status for a short period only to receive the upward cap adjustment. While we question this concern, we believe that it is not applicable if a hospital retains its rural status for a significant period before changing back to an urban status. Thus, we recommend that urban teaching hospitals that reclassify to rural status for a significant period of time before returning to urban status (for example, three years) should be permitted to retain any upward cap adjustments that occurred during the period in which they were considered rural.

IV. OTHER PROPOSALS OF PARTICULAR IMPORT TO TEACHING HOSPITALS

A. POST-ACUTE CARE TRANSFER PAYMENT POLICY

Medicare patients who are sent from one acute care hospital to another are viewed as “transfers.” The transferring hospital is paid a per diem rate based on the diagnosis-related group (DRG) payment and the number of days spent at the transferring hospital; the receiving hospital receives the full DRG payment.

In Federal fiscal year (FFY) 1999, in accordance with the BBA, CMS expanded its transfer policy such that hospitals that discharge patients associated with one of 10 specified DRGs to a post-acute care facility – such as rehabilitation hospitals and units, psychiatric hospitals and units, cancer, long-term care and children’s hospitals, skilled nursing facilities, or are discharged home and receive home health services within three days after the date of discharge – would receive payments under the “post-acute care (PAC) transfer” policy. In subsequent years, CMS further expanded the post-acute care transfer policy, and as a result, a total of 30 DRGs were subject to the PAC transfer policy in FFY 2005.

CMS is proposing to expand--again--the post-acute care transfer policy, from 30 to 223 DRGs. DRGs that meet the following criteria would be subject to the PAC policy:

- The DRG has at least 2,000 discharges to post-acute care;
- At least 20 percent of cases in the DRG were discharged to post-acute care;
- Out of the cases discharged to post-acute care, at least 10 percent occur before the geometric mean length of stay for the DRG;
- The DRG has a geometric mean length of stay of at least 3 days; and

- If the DRG is one of a paired set of DRGs based on the presence or absence of a comorbidity or complication, both paired DRGs are included if either one meets the first three criteria above.

According to CMS, this proposed expansion would result in \$880 million less in Medicare program payments to hospitals, the equivalent of a 1.1 percent decrease in payments. Our analyses show a reduction of \$894 million when the effects of IME, disproportionate share, capital and outlier payments are considered.

Simply put, CMS should not implement an expansion of the post-acute care transfer policy. Such a policy penalizes hospitals that ensure that Medicare patients receive care in the most appropriate setting. Moreover, it undercuts the fundamental principle of the PPS, which is that some cases will cost more than the DRG payment, while others will cost less, but on average, the overall payments should be adequate. It also is important to recognize that to the extent there still are cost reductions associated with discharging patients to post-acute care facilities (a debatable presumption given the current low average lengths of stay), such reductions will be reflected in lower DRG case weights during the DRG recalibration process.

We agree with comments by the American Hospital Association (AHA) that this proposal does not comport with the statutory directive that CMS focus on those DRGs that have a *high volume* of discharges to post-acute care and a *disproportionate use* of post-discharge services (emphasis added). (SSA section 1886(d)(4)(J)(ii)). Moreover, contrary to CMS' assertion that the PAC transfer policy levels the playing field for rural hospitals that do not have access to post acute care that is comparable to urban hospitals, AHA analyses show that rural patients have essentially the same access. Consequently, the proposed rule would harm all hospitals. We urge the Agency to rescind this proposal.

B. OUTLIER PAYMENT THRESHOLD

If the costs of a particular Medicare case exceed the relevant DRG operating and capital payment (including any disproportionate share (DSH), IME, or new technology add-on payments) plus a fixed-loss cost threshold, the hospital will receive an outlier payment. This payment equals 80 percent of the case's costs above the threshold calculation.

The cost threshold is set at a level that is intended to result in outlier payments that are between five and six percent. Outlier payments are budget-neutral. Each year the Agency reduces the inpatient standardized amount by 5.1 percent and estimates a cost threshold that will result in outlier payments that equal 5.1 percent.

The proposed rule would increase the fixed-loss cost threshold for outlier payments to be equal to a case's DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus \$26,675, an increase of 3.4 percent over the FFY 2005 threshold of \$25,800.

CMS proposes an increase to the threshold even though the Agency estimates that outlier payments for FFY 2005 will represent only 4.4 percent of actual total DRG payments. Further, CMS estimates that outlier payments represented only 3.5 percent of total DRG payments in FFY 2004. Because outlier payments were less than the 5.1 percent reduction to the standardized amount, the result is less total Medicare payments to hospitals in both of these years, contrary to the intent of the outlier payment policy.

We believe the FFY 2005 cost threshold must be reduced. CMS relies only on charge inflation to determine projected increases in per case costs, which determines outlier payment outlays. In conjunction with the American Hospital Association and Federation of American Hospitals, we conducted an analysis that incorporates both cost and charge inflation, which we believe makes the threshold calculation more accurate and reliable. Using this methodology, the threshold should be \$24,050 for FFY 2006. We would be happy to discuss this methodology with CMS and provide further details.

C. LABOR-RELATED SHARE

The proportion of the PPS standardized rate to which the wage index is applied is known as the “labor-related share.” CMS defines labor-related share as “the national average proportion of operating costs that are related to, influenced by, or vary with local labor markets. We believe that the operating cost categories that are related to, influenced by, or vary with local labor markets are wages and salaries, fringe benefits, professional fees, contract labor, and labor intensive services” (70 Fed. Reg. at 23391).

CMS proposes to decrease the labor related share from 71.1 percent to 69.7 percent. Such a reduction would reduce payments for hospitals with wage indices above one, but would not increase payments for hospitals with wage indices below one since the labor share for these hospitals is legislatively set at 62 percent.

We believe the labor share should remain at 71.1 percent. In the FFY 2003 rulemaking process, CMS analyses supported increasing the labor share to 72.5 percent, but the Agency ultimately withdrew its proposal to implement the increase citing a need to conduct further analyses (67 Fed. Reg. at 50042).

We agree with the American Hospital Association that more analyses are needed before making a change to the labor share. The large drop in the “other labor-intensive services” category merits further attention. We also believe the suggestion by the Greater New York Hospital Association to re-designate professional liability insurance as a labor-related cost deserves serious consideration.

D. SUBMISSION OF HOSPITAL QUALITY DATA

The Medicare Modernization Act requires that in order for hospitals to receive their full market basket update, they need to submit quality data on ten quality measures established by the Secretary. AAMC supports public reporting of hospital quality data and as a result most of the AAMC’s Council of Teaching Hospitals and Health Systems

(COTH) participated in the Quality Initiative and all eligible COTH hospitals have submitted their data on the 10 starter measures for the update.

The proposed rule sets forth a process that changes the criteria for receiving the full market basket update by tying the update to not only the reporting of the quality data, but passing the validation criteria as well. We support the idea of submitting and displaying clinically valid data on the Hospital Compare website; however, the proposed validation process is new and needs further refinement before it can be tied to a hospital's payment.

We recognize all of the work that was done by CMS in the Quality Initiative to establish a framework to facilitate the proper submission of quality data. The early days of the Quality Initiative provided much information on how to modify processes in order to ensure an efficient operation at a time where there was minimal risk to the hospitals. If nothing else, we learned that anything new needs time to be vetted, tested and refined before it is ready for codification.

There already has been data to reinforce the fact that all of the problems have not been worked out of the proposed validation system. For example, the latest preview of quality data by hospitals showed that many hospitals failed their validation due to a data error by the Clinical Data Abstraction Center (CDAC). This is the same center that is used to calculate the validation results for payment. This process is obviously too new and needs further testing before any kind of payment system can be linked to it.

We also have concerns about several aspects of the proposed validation process. First, the number of charts that are pulled in order to calculate the percent match rate is five. It is questionable whether five charts will provide a statistically significant test of validity. It also is much easier for hospitals to fail validation or have a lower score due to a data mismatch error or missing data with such a small sample size. We recommend that the sample size be increased.

Secondly, there were many issues with the initial submission of data on the 10 starter measures due to a misalignment between CMS and JCAHO. The interim fixes that were put in place were still causing errors and required manual review for those data elements. A very tedious process was undertaken to make sure that all CMS and JCAHO measures were in complete alignment effective January 1, 2005. Due to the known data problems with the measure misalignment, this is further evidence that validation should not be used on third and fourth quarter data and certainly should not be used for purposes of calculating the payment update. Therefore, we recommend that the first quarter FFY 2005 should be the first quarter in which the validation process is used for calculating full payment update that would occur in FFY 2007.

E. MEDICARE PAYMENTS FOR NEW TECHNOLOGIES

Pursuant to the Benefits Improvement and Protection Act of 2000 (BIPA), in a September 7, 2001 final rule (66 Fed. Reg. 46902), CMS established a methodology that would provide additional payments to hospitals for new technologies that they use that are not

yet reflected in the DRG payment system. In order to qualify for the additional payments the new service must meet three criteria under the DRG system:

- The medical service or technology is considered “new” until such time as data are available to reflect the cost of the technology in the DRG weights through recalibration – usually 2 to 3 years beginning with FDA approval,
- It must be inadequately paid under the DRG system. The adequacy of payment is established based on a threshold for each DRG (a list of qualifying thresholds by DRG can be found in Table 10 of the Addendum), and
- It must represent an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

The additional payment is based on the hospital’s cost for the new medical service or technology. Medicare pays the lesser of a) 50 percent of the difference between the cost of the case with the new technology and the DRG payment, or b) 50 percent of the cost of the new technology.

Payments for new services and technology were initially subject to a budget-neutrality factor. However, the law was subsequently amended and add-on payments from FFY 2005 forward are no longer budget-neutral.

In FFY 2005, hospitals could receive additional payments for three new technologies.

For FFY 2006, CMS proposes add-on payments for only one technology-- Kinetra® Implantable Neurostimulator for Deep Brain Stimulation. This technology currently receives add-on payments; payments for the other two technologies were discontinued. Moreover, the Agency proposes to deny five of the eight applications it received. For two technologies, CMS will make a decision in the final rule, and for one device, CMS is not making a decision at this time.

We are dismayed about the number of applications that are being submitted for new technology payments. We also are concerned about CMS’s decisions to not approve payments for new technologies for which applications have been submitted. Given the pace of innovation, it is somewhat incredulous that only one new technology merits additional payments. We urge CMS to conduct a study of this issue. It may be that the criteria should be modified to ensure that hospitals that utilize expensive new devices in the treatment of Medicare beneficiaries are adequately compensated for this cutting edge care.

F. DRG RECLASSIFICATION FOR CASES INVOLVING EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)

We appreciate CMS’s analysis of the average charges associated with cases that involve Extracorporeal Membrane Oxygenation (ECMO) and support the proposal to assign these cases to DRG 541 (one of the tracheostomy DRGs). ECMO is a procedure to

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create a closed chest, heart-lung bypass system by insertion of vascular catheters. It is used for severely ill patients; often these patients are children.

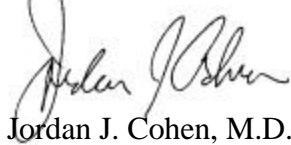
We appreciate CMS' recognition that often other insurers use Medicare DRG classifications and payment rates. Consequently, its efforts to ensure accurate DRG classifications for all cases, even those that are predominantly non-Medicare, help to ensure that hospitals are paid appropriately.

V. CONCLUSION

Thank you for this opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic health care community.

If you have questions concerning these comments, please feel free to call Robert Dickler, Senior Vice President, Health Care Affairs, or Karen Fisher, Senior Associate Vice President. These individuals may be reached at (202) 828-0490.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jordan J. Cohen".

Jordan J. Cohen, M.D.

cc: Robert Dickler, AAMC
Karen Fisher, AAMC