



**ASSOCIATION OF  
AMERICAN  
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Thomas A. Scully, Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
Room 443-G  
200 Independence Ave, SW  
Washington, DC 20201

Attention: **CMS-1470-P**

Dear Administrator Scully:

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 2004 Rates.*" 68 Fed. Reg. 27154 (May 19, 2003). The AAMC represents approximately 400 major teaching hospitals and health systems; all 126 accredited U.S. medical schools; 96 professional and academic societies; and the nation's medical students and residents.

A primary focus of this letter is to comment on proposed changes to the regulations for Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments that, if finalized, would dramatically and fundamentally change the purpose of these payments.

We also believe the cost threshold under the Medicare outlier payment methodology must be reduced substantially below that published in proposed rule. In fact, we believe that as a result of the changes in the outlier final rule published on June 9, 2003 (68 Fed.Reg. 34494), the outlier threshold for Federal fiscal year (FY) 2004 must be set below the FY 2003 level in order to ensure that the statutorily mandated level of outlier payments is achieved.

We also believe other aspects of the proposed rule must be addressed, including:

- Withdrawing the proposal to expand the post-acute care transfer policy,
- Clarifying the initial residency period for specialties requiring a general clinical training year,
- Reconsidering the nursing and allied health proposals,
- Withdrawing proposals relating to counting beds and patient days for Medicare IME and disproportionate share (DSH) payment methodologies, and
- Addressing wage index, new technology, and drug-eluting stent payment policies.

## **I. THE PROPOSED REGULATIONS RELATING TO COMMUNITY SUPPORT AND REDISTRIBUTION OF COSTS MUST BE WITHDRAWN IN THE FINAL RULE**

A fundamental component in the calculation of both DGME and IME payments is the number of full time equivalent (FTE) residents that a hospital is permitted to count.

The proposed rule has the potential to significantly limit the number of residents a hospital may count by imposing an arbitrary requirement relating to “community benefit” and “redistribution of costs.” According to the proposed rule preamble: “residents training at nonhospital sites may be counted in a hospital’s FTE resident count only where the principles of redistribution of costs and community support are not violated. . . [W]e believe the concepts of redistribution of costs and community support are equally relevant to the counting of FTE residents by a hospital in general.” (68 Fed. Reg. at 27215.)

As discussed below, the law firm of Vinson & Elkins has reviewed the legal basis for the proposed changes. They conclude that the new requirements are contrary to current law and are arbitrary and capricious.

We also urge the Agency to review the comments submitted by Tom Coons, J.D., a partner with Ober, Kaler, Grimes & Shriver, and a former Senior Attorney with the Health Care Financing Administration. In addition to concluding that the proposals are contrary to law, Mr. Coons concludes they are ill-advised from a policy standpoint. We agree with Mr. Coons as well as the conclusions of Vinson & Elkins. Accordingly, we believe the proposals must be withdrawn in the final rule.

### **A. Proposed Rule Changes**

The proposed rule would create a new paragraph and two new regulatory definitions under 42 C.F.R. § 413.86.

The proposed new paragraph (i) is entitled “Application of Community Support and Redistribution of Costs in Determining FTE Resident Counts”:

- (1) For purposes of determining direct graduate medical education payments, the following principles apply:
  - (i) *Community support.* If the community has undertaken to bear the costs of medical education through community support, the costs are not considered graduate medical education costs to the hospital for purposes of Medicare payment.
  - (ii) *Redistribution of costs.* The costs of training residents that constitute a redistribution of costs from an educational institution to the hospital are not considered graduate medical education costs to the hospital for purposes of Medicare payment.
- (2) *Application.* A hospital must continuously incur the costs of direct graduate medical education of residents training in a particular program at a

training site since the date the residents first began training in that program in order for the hospital to count the FTE residents in accordance with the provisions of paragraphs (f) and (g)(4) through (g)(6) and (g)(12) of this section.

The proposed new definitions under 42 C.F.R. § 413.86(b) are:

*“Community Support* means funding that is provided by the community and generally includes all non-Medicare sources of funding (other than payments made for furnishing services to individual patients), including State and local government appropriations. Community support does not include grants, gifts, and endowments of the kind that are not to be offset in accordance with section 1134 of the Act.”

*“Redistribution of costs* means an attempt by a hospital to increase the amount it is allowed to receive from Medicare under this section by counting FTE residents that were in medical residency programs where the costs of the programs had previously been incurred by the educational institution.”

CMS also proposes to modify paragraph (f) of section 413.86 (“Determining the total number of FTE residents”) to incorporate paragraph (i). The seeming effect of this modification would be to subject resident counts associated with DGME payments in any and all sites, including both hospitals and nonhospitals, to the community support and redistribution of costs regulations in proposed paragraph (i).

Because IME regulations on counting residents at nonhospital sites cross-reference the DGME nonhospital site regulations, the proposed rule would also affect IME payments associated with these residents (see 68 Fed. Reg. at 27216). However, it appears that IME resident counts in hospital settings would not be subject to the community support and redistribution of costs provisions, although we request CMS to clarify this interpretation.

## **B. The Proposed Changes are Arbitrary and Capricious and Violate the Administrative Procedures Act**

The attached legal memorandum, prepared by Vinson & Elkins, sets forth the legal and statutory context for the proposed changes. The memorandum concludes that the proposed changes would violate the standards set forth in the Administrative Procedures Act. They are contrary to the plain meaning and intent of the Medicare statute and are in substantial and irreconcilable conflict with the Agency’s long-standing interpretation and implementation of the statutory schemes governing DGME and IME payment policies.

## **C. The Proposed Changes are Bad Policy**

The AAMC has long been a strong voice in support of resident training in ambulatory sites. Through various legislation and regulations, Congress and CMS also have demonstrated their support of ambulatory training by providing Medicare DGME and IME payments for residents training in nonhospital sites. Unfortunately, we believe the proposed rule changes represent a major step backward in this important policy.

Teaching hospitals and their nonhospital residency training partners do not dispute the statutory requirement that when a hospital wishes to receive Medicare DGME and IME payments associated with resident training in nonhospital sites, the hospital must incur “all or substantially all of the costs” of that training. (Sections 1886(h)(4)(E) and (d)(5)(B)(iv) of the Medicare statute.) What we dispute is a proposal to dramatically change this otherwise straightforward legislative requirement to impose a requirement that these costs must have been incurred since “the date the residents first began training in that site.” 68 Fed. Reg. at 27215.

Prior to 1999, “all or substantially all” of the training costs were defined by regulation to be only the resident’s compensation. (See 42 C.F.R. §413.86(f)(3)(ii).) Consequently, if a hospital incurred the resident compensation costs, it could receive the associated DGME and IME payments, even if other costs associated with the training were incurred by another entity. In 1999, the definition of “all or substantially all” was changed in regulation to include both resident compensation and physician supervisory costs. (See 42 C.F.R. §413.86(f)(4).) Nowhere in the regulations promulgated implementing the original statutory requirement, or in the 1999 change, has CMS ever stated that in order to receive DGME and IME payments a hospital must meet an additional requirement of incurring the training costs since the inception of the training program. To impose such a retroactive requirement at this point goes against Agency policy.

Moreover, such a proposal would contravene longstanding financial commitments and arrangements involving training at nonhospital sites. There are situations in which States or other entities have helped to financially support residency training at ambulatory sites. In some instances this support was intended to be for a startup period of time and in other situations the period of support was finite but indeterminate. There also is health profession funding provided under Title 7 of the Public Health Service Act that helps to support residency training at nonhospital sites. We are very concerned about the impact of the proposed rule on these training sites.

Under the proposed rule, a hospital would not be eligible to receive DGME and IME reimbursements for resident training at such sites because it had not been incurring the training costs since the inception of the program. If the proposed rule becomes official policy, one of two alternatives could occur if the party initially providing support can no longer financially support residency training at these sites—both undesirable. The first would be that the hospital would take over financial responsibility for the training costs, but would receive no financial support from Medicare for that training—a result that Congress certainly did not intend when it enacted the nonhospital site residency training legislation. An even bleaker scenario would be that the hospital cannot afford to incur the additional costs without the corresponding Medicare support and the training site would have to shut down. Either of these results would be contrary to the longstanding Medicare commitment to support resident training in nonhospital sites.

**D. If The Proposed Policies are Not Withdrawn Entirely, Additional Changes are Necessary**

As discussed above, we believe the proposed regulations on community support and redistribution of costs should be withdrawn. If CMS decides, however, that some form of

these proposals will be included in the final rule, we believe that, in addition to addressing the concerns raised above, the final rule should be modified such that a) resident counting at hospitals is not affected, b) the final regulations focus on “residents” rather than “programs,” c) the administrative burden associated with providing documentation is minimized, and d) any changes are not applied retroactively.

## **1. The Changes Should Not Impact Training That Occurs at Hospitals**

According to the proposed regulatory text, in addition to applying to the nonhospital site regulations (proposed section 413.86(f)(4)), proposed paragraph (i) seemingly applies to the remaining subsections in paragraph (f), as well as paragraphs (g)(4) through (6) and (g)(12).

If the proposed rule changes are retained in some form in the final rule, it is important that CMS specify that the provisions affect only the counting of residents in nonhospital sites and not the count of residents being trained in hospitals, both the inpatient and outpatient settings.

To this end specifically, the regulatory text in proposed paragraph (i)(2) should reference only the nonhospital site regulations of 413.86(f)(4), and the reference to proposed paragraph (i) in paragraph (f) should be deleted. Alternatively, proposed paragraph (i) should be included solely as a subpart to paragraph (f)(4). We believe that such a clarification would make the regulatory text consistent with the Agency’s intent as supported by the preamble statement that “--redistribution of costs and community support, and ‘all or substantially all’--does not occur when counting FTE residents training inside the hospital, since a hospital is not required to incur ‘all or substantially all’ of the costs of the training program inside the hospital.” (68 Fed. Reg. at 27217.)

Such a clarification would also be consistent with current Agency policies regarding the counting of residents at hospitals. For example, in last year’s Medicare inpatient final rule, the Agency clarified that when hospitals are involved, the criterion for determining which entity may count the residents for IME and DGME payments is based on where the actual training occurs, not which hospital is incurring the costs (67 Fed. Reg. at 50077-78 (August 1, 2002)).

## **2. The Proposed Rule Emphasis on “Programs” is Contrary to Current Policy**

The proposed rule attempts to introduce another new concept into Medicare DGME and IME policies by differentiating between situations when the hospital incurs costs for the entire program versus individual residents. The preamble states that in order for a hospital to count residents training in a nonhospital site, it must incur “all or substantially all” of the costs of the residency training *program* at that site (68 Fed. Reg. at 27217).

We believe this change runs contrary to other current Medicare policies that focus on the resident rather than the program. Both the DGME and IME regulations are replete with references to “resident” rather than “program.” Medicare DGME and IME payments have consistently been determined and calculated at the resident level. Under current

regulations, the residency program is referenced only in the criterion requiring that for residents to be counted for DGME and IME payments they must be part of an “approved program” (see 42 C.F.R. §413.86(f)(1)).

The Medicare resident limits in the Balanced Budget Act of 1997 reaffirmed that Congress intended that the focus for calculating Medicare DGME and IME payments be the resident, not the program. A hospital cannot count residents above its resident limit for DGME and IME payments, even if those residents are enrolled in the same training program as other residents for which the hospital receives DGME and IME payments because they are part of the resident count that is within the resident limit.

### **3. The Proposed Rule Changes Would Impose Significant and Unwarranted Administrative Burdens on Hospitals**

According to the preamble, if the proposed rule is finalized, hospitals that wish to receive DGME and IME payments will be required to provide documentation that they have been incurring the costs of residents’ training in particular settings so that the fiscal intermediaries can verify whether redistribution of costs or community support has occurred (68 Fed. Reg. at 27216). It appears such documentation must go back as far as January 1, 1999, but potentially could go back even further.<sup>1</sup> Moreover, it appears that the hospital must somehow be able to demonstrate that it has been “continuously incurring the costs of the training since the date the residents first began training in that program.” (68 Fed. Reg. at 27216.)

Teaching hospitals often have resident training agreements with numerous nonhospital sites. Complying with this requirement for each site would be extremely burdensome, particularly if historical documentation is required. This burden would be additive to a policy that already is fraught with excessive administrative requirements. In particular, we note the controversy relating to demonstrating “reasonable” physician supervisory costs and the related issue of volunteer supervising physicians.

Often, residency training at nonhospital sites occurs in individual physician offices, or in small group practices. The length of time residents spend at these settings may not be significant, which means that Medicare DGME and IME payments also are not significant. Imposing a disproportionate level of administrative burden in order to receive legitimately deserved Medicare DGME and IME payments, particularly in sites such as these, is contrary to a doctrine of fairness.

### **4. Any Changes in the Final Rule Must Be Applied Prospectively**

While it seems from the proposed rule preamble that, if finalized, the proposed changes would be effective October 1, 2003,<sup>2</sup> this date must be reconfirmed because the preamble

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<sup>1</sup> “[I]f the fiscal intermediaries determine that there is a redistribution of costs or community support exists with respect to certain residents prior to January 1, 1999, a disallowance of direct GME and IME payments with respect to those FTE residents would certainly be required.” 68 Fed. Reg. at 27216.

<sup>2</sup> “We are proposing that effective October 1, 2003, in order for a hospital to receive IME and direct GME payments, the hospital must have been continuously incurring the direct GME costs of residents training in a

also states that hospitals must demonstrate that they having been incurring the training costs as of January 1, 1999 (68 Fed. Reg. at 27216). Even more disconcerting is another preamble statement that states “if the fiscal intermediaries determine that there is a redistribution of costs or community support exists with respect to certain residents prior to January 1, 1999, a disallowance of direct GME and IME payments with respect to those FTE residents would certainly be required.” (Ibid.)

As set forth in section IV of the attached legal memorandum, the proposed changes should not be applied retroactively. The U.S. Supreme Court made clear in *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) that the Secretary does not have the authority to promulgate rules with retroactive effect.

Even if the changes could be viewed as clarifications of existing policy, which we dispute, we believe the principles of due process and fair notice require that they be implemented only prospectively.

On this latter point, we would like to emphasize that in written correspondence on policies relating to counting residents in nonhospital sites, CMS never addresses the concepts of community support or redistribution of costs (See, e.g., August 22, 2001 letter from Tzvi Hefter, Director, CMS Division of Acute Care to Richard Ranney, Dean, Baltimore College of Dental Surgery). In fact, the first mention of the applicability of these concepts to resident counting is in the proposed rule.

#### **E. Poor Word Choice in Definition of “Redistribution of Costs”**

While likely unintentional, we are disappointed and object to the choice of words used in the proposed language to define “redistribution of costs” under proposed 42 C.F.R. §413.86(b). The definition begins with the phrase “an attempt by a hospital to increase the amount it is allowed to receive from Medicare.” Such a phrase could be viewed as implying a malevolent intent when none exists. This phrase is completely unnecessary to the definition and should be deleted.

#### **II. CMS SHOULD CLARIFY THE INITIAL RESIDENCY PERIOD FOR SPECIALITIES REQUIRING A GENERAL CLINICAL TRAINING YEAR**

Proposed new subsection (i) would apply to all of section 413.86 (f), which contains the Medicare policy for the counting of residents. As a result, CMS, in effect, has proposed to change how residents are counted. Accordingly, as part of the final rule, we believe CMS should also address how residents are counted when they enter into specialties requiring a general clinical training year.

Certain specialties (for example, radiology and anesthesiology) require that residents spend a year in a general clinical training program, with the remaining years constituting specialty-specific training. A large number of residents meet the general clinical year

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particular program since the date the resident first began training in the program in order for the hospital to count the FTE residents.” 68 Fed. Reg. at 27417.

requirement by entering a preliminary year program in a specialty, such as internal medicine, before entering their specialty of choice.

Medicare's policy for DGME payments is to count residents during the number of years required to achieve first board eligibility as a 1.0 FTE, though no resident can be counted as a 1.0 FTE for more than five years. The period leading to initial board eligibility is called the initial residency period (IRP). For any training beyond the IRP, residents are counted as 0.5 FTE. Under the Medicare statute, the IRP is "determined, with respect to a resident, as of the time the resident enters the residency training program." (underlining added; section 1886 of the Social Security Act).

We understand that CMS is interpreting the statute in such a way that hospitals providing training for residents who select a specialty that requires a general clinical year are not permitted to count those residents as a 1.0 FTE for the full length of the specialty training. This is because CMS views the determination of IRP based on the specialty in the first year of training, regardless of the specialty in which the resident actually intends to train. Under this view, a resident who enrolls in a preliminary year internal medicine program would be assigned the internal medicine IRP of three years. For a resident who intends to train in radiology (many of whom have already been "matched" to a radiology program prior to commencing any residency training), for example, this means that for the first three years of training (preliminary medicine year plus two years of radiology), the hospital counts the resident as a 1.0 FTE and that for the required years four and five of radiology 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 radiology, this would be five years.

CMS' interpretation results in inappropriate differential payments to hospitals for residents who complete their training in the same specialty merely because, as allowed by the residency accrediting organization, they met their general clinical year training requirement in different ways. We believe that for a resident whose first year of training is done in a program that requires a general clinical year, an IRP should be assigned based on the specialty the resident enters in the second year of training.

We urge CMS to include this clarification as part of the final rule. Alternatively, the clarification could be published as an interim final rule at the same time the final rule is published.

### **III. THE OUTLIER COST THRESHOLD MUST BE SUBSTANTIALLY REDUCED FOR FY 2004**

Under Medicare outlier policy, if the costs of a particular Medicare case exceed the relevant diagnosis-related group (DRG) operating and capital payment (including any DSH, IME, or new technology add-on payments) plus a fixed-loss cost threshold, determined by CMS, 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. Each year since 1998, outlier payments have exceeded the six percent level. The high levels of outlier payments during this period was due, in very large part, to a disconnect between the years used for identifying costs and charges for a case. This resulted in a calculation of per case costs that were higher than the actual costs for a large number of cases. In response, each year CMS increased the cost threshold in an attempt to constrain outlier payments to within the mandated level. As a result, between 1997 and 2003, the threshold was increased over 300 percent.

On June 9, 2003, CMS published a final rule that addresses these deficiencies by making a number of significant changes to the outlier payment methodology (68 Fed. Reg. 34494). These changes will ensure a more accurate calculation of a case's costs, which in a large number of cases, will be lower than the results of the previous methodology. Given that under the new methodology, the costs of a large number of Medicare cases will be lower, many fewer cases will qualify for outlier payments. Accordingly, it is necessary to lower the cost threshold so that outlier payments do not fall below the five percent mandated level.

CMS also recognized that the cost threshold must be lowered when it published its proposed cost threshold of \$50,645 for FY 2004--a 50 percent increase over the FY 2003 level. The Agency noted that the proposed threshold did not factor in the outlier final rule changes (because the proposed rule was published prior to the outlier final rule) and that the cost threshold published in the final rule would be different because it would reflect the changes in the outlier final rule.

We agree with CMS. As a result of the outlier final rule changes, the current threshold is now overinflated and must be significantly reduced. According to analyses performed for the American Hospital Association, the most accurate outlier cost threshold for FY 2004 is between \$27,820 and \$30,930. We believe that current law mandates that CMS publish a threshold in this range.

#### **IV. CMS SHOULD RECONSIDER THE PROPOSED CHANGES TO THE MEDICARE NURSING AND ALLIED HEALTH REGULATIONS**

Under 42 C.F.R. §413.85, Medicare pays its share of the costs of approved nursing and allied health education activities that are operated by providers. These costs are not considered part of the hospital's inpatient operating costs. Medicare's payments (known as "pass through payments") are made on a "reasonable cost" basis, separate and apart from DGME and IME payments.

The proposed rule attempts to distinguish between nursing and allied health continuing education programs, which *are not* eligible for pass-through payments, and approved educational payments, which *are* eligible for pass through payments.

Specifically, CMS proposes to change 42 C.F.R. §413.85(h)(3) to state that the following programs would not be eligible for pass-through payments:

Educational seminars, workshops, and continuing education programs in which the employees participate that enhance the quality of medical care or enhance the quality of medical care or operating efficiency of the provider and, *effective October 1, 2003 do not lead to certification required to practice or begin employment in a nursing or allied health specialty.* (Proposed new text in italics.)

The proposed rule would also add a new definition under 42 C.F.R. §413.85(c) for “certification” to mean “the ability to practice or begin employment in a specialty as a whole.”

CMS states that under the regulations, pharmacy residency and clinical pastoral education programs are “inappropriately” receiving pass-through payments (68 Fed. Reg. at 27416).

The Agency provides no evidence that Medicare payments for these programs have been rising excessively or any other rationale for making changes to this longstanding policy. Consequently, we believe the current polices and regulations should not be modified.

**A. The Negative Impact of the Proposed Changes Outweighs Any Potential Savings**

According to CMS’ own estimates, the entirety of Medicare payments for nursing and allied health programs is only about \$230 million annually (68 Fed. Reg. at 27416). This is less than 0.16 percent of total annual Medicare Part A net benefit payments (2003 Medicare Trustees Report). The preamble acknowledges that, any savings realized by the Medicare program as a result of the proposed changes would be only a “small fraction” of this 0.16 percent.

While the proposed rule would have essentially no impact on Medicare expenditures, at the level of the individual hospital and affected nursing or allied health program the loss of Medicare payments would be significant and conspicuous. In response, teaching hospitals might try to continue bearing these costs without the Medicare financial support, but they would do so at a time when they are facing substantial threats to their financial stability. Alternatively, programs no longer eligible for these payments might be curtailed or eliminated. We believe the gravity of both of these alternatives far outweighs the minimal savings associated with these changes if they are finalized.

**B. CMS’ Interpretation of “Continuing Education” is Overly Broad**

Webster’s Dictionary defines continuing education as “formal courses of study for adult part-time students” (Merriam Webster’s Collegiate Dictionary, Tenth Edition). Under this definition, the nursing and allied programs described in the proposed rule would not be considered continuing education because they are full-time programs or equivalents thereof.

Moreover, continuing education programs typically are of short duration with a goal of ensuring that practitioners, regardless of their profession, *maintain* a level of knowledge

throughout their careers that is commensurate with their formalized educational process. By contrast, our understanding of the allied health programs of which CMS expresses concern is that they are of extended duration (generally one to two years) and provide an enhanced educational process for students seeking a particular expertise.

**C. Pharmacy and Pastoral Education Programs Must be Given the Opportunity to Demonstrate Their Eligibility for Medicare Payments**

We believe that the conclusion in the preamble that pharmacy residency and clinical pastoral education programs would no longer qualify for Medicare reimbursement is, at the least, premature. It does not appear that CMS has full and complete knowledge about these programs (as evidenced by the use of phrases such as “it is our understanding” and “we understand that”). These programs should be permitted to demonstrate that they meet the regulatory criteria before they are summarily dismissed.

**V. CMS SHOULD POSTPONE CHANGES TO BED COUNTING POLICIES PENDING FURTHER STUDY**

Medicare IME payments are determined using a calculation that involves a teaching hospital’s intern/resident-to-bed (IRB) ratio. To compute this ratio, there must be an accurate count of both residents and beds. Under current regulations, the number of beds is computed by dividing the number of available bed days during a hospital’s cost reporting period by the number of days in the cost reporting period. 42 C.F.R. §412.105(b). The proposed rule makes a number of changes that would affect the “bed day” component of this calculation.

Over time, there have been a number of discrepancies between hospitals and fiscal intermediaries regarding the bed counting methodology. We appreciate CMS’ intention to try to achieve better clarity in this area. However, we believe the proposed rule falls short of this goal and, moreover, has the potential to create even more confusion. We believe that additional time is needed to study this issue before changes are implemented. Consequently, we urge CMS to not implement any changes to the bed day policies in the final rule and instead announce the Agency’s intention to further study this issue over the coming year. We would be happy to work with the Agency to address bed day issues so that the goal of accurate and appropriate bed counts can be achieved.

**A. Unoccupied Beds**

Under the proposed rule, a hospital’s bed day count would exclude bed days associated with “beds in units unoccupied for the previous 3 months.” (Proposed §412.105(b)(2).) The preamble explains this proposal:

If any of the beds in the unit were used to provide an IPPS level of care at any time during the preceding 3 months, all of the beds in the unit are counted for purposes of determining available bed days during the current month. If no patient care of a type generally payable under the IPPS was provided in that unit during the 3

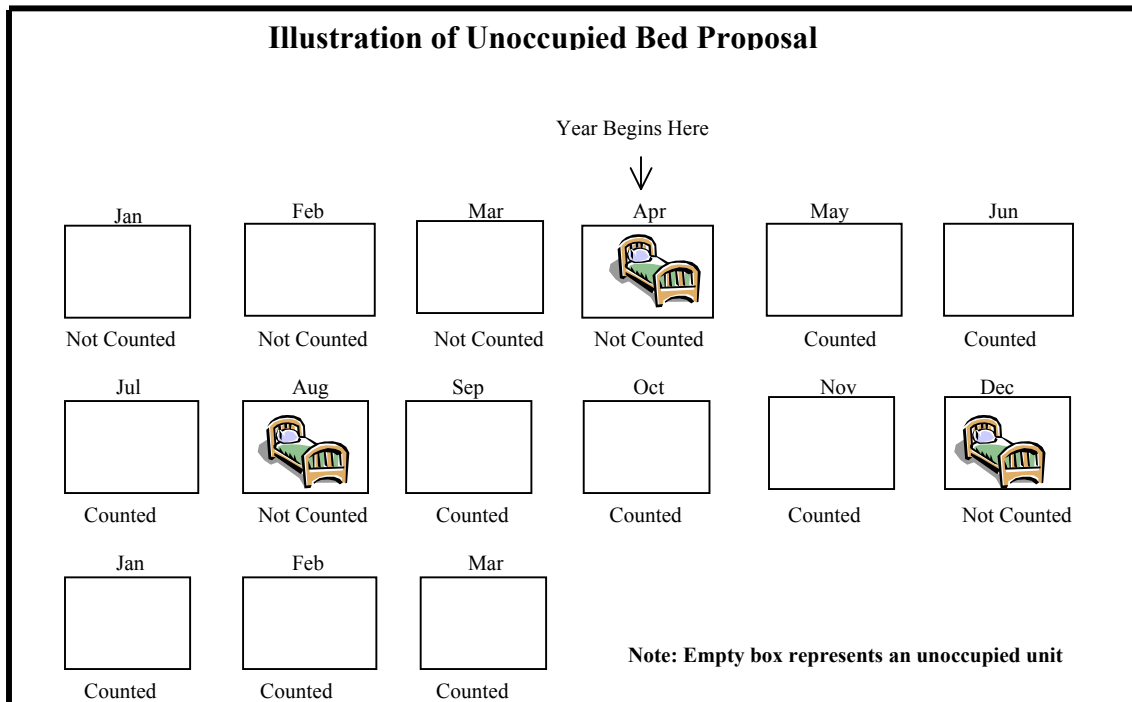
preceding months, the beds in the unit are to be excluded from the determination of available bed days during the current month.

68 Fed. Reg. at 27203.

We find this proposal confusing and arbitrary. First, it is unclear why the Agency is focusing on the month as the unit of analysis, rather than the cost reporting year—which is the time frame specified in the current regulations.

Second, we believe that the combination of using a “look back” and “rolling” month methodology is confusing and would be difficult to implement. Moreover, we believe that setting three months as the threshold for determining whether the beds in a unit may be counted is arbitrary and could result in significantly inaccurate counts.

To illustrate, consider a situation in which a hospital unit undergoes periodic renovation throughout a year. Assume a unit is being renovated for nine out of the 12 months of a given year. The unit, therefore, is occupied for only three months of the year---April, August and December (see the following chart).



For purposes of this illustration, assume the fiscal year begins in April. As an initial consideration, it would seem that the unit’s beds in January, February and March prior to the April start date would be excluded from the bed count because they are unoccupied and would be subject to the current methodology since April would be the start date for the new regulations.

According to the proposed rule and preamble, it seems that in April the unit’s beds would not be counted, even though the unit was occupied in that month, because it was

unoccupied in the three preceding months (January-March). However, the beds would be counted in May, June and July, even though the unit was unoccupied in those months because it was occupied at some point during the previous three months (in this example it is April). If this interpretation is applied throughout the year, it would mean that the beds in the unit would be counted for the nine months in which the unit *was not* occupied but would not be counted for the three months in which the unit *was* occupied—this is counterintuitive.<sup>3</sup>

We appreciate CMS' dilemma in dealing with units that are unoccupied for various time periods. As we stated above, we believe CMS should consider withdrawing the proposed policies and conduct further study and consultation with the hospital community throughout the coming year. We believe such a process can result in regulatory changes that will meet the purpose of the IME and DSH policies, while being clear and capable of consistent application across hospitals.

#### **B. Excluding Nonacute Care Beds and Days**

Under the proposed regulatory text, a hospital's bed day count also would exclude any bed days associated with beds in hospital units "where the level of care provided would not be payable under the acute care hospital inpatient prospective payment system." (proposed 42 C.F.R. §412.105(b)(1)).

This language seems duplicative of current paragraph (b)(3) which excludes beds associated with PPS-excluded distinct part units. The preamble seeks to clarify the Agency's intention by stating that the bed days are to be excluded if "the nature of the care provided in the unit or ward is inconsistent with what is typically furnished to acute care patients" regardless of whether these units or wards are separately certified or located in the same general area as acute care units (68 Fed. Reg. at 27204). The preamble goes on to say that the unit would be excluded even if some patients would be receiving acute care.

While this proposed regulation could result in reduced bed counts for hospitals (which could result in higher IME payments), we believe that this change requires subjective determinations, which could further confuse both providers and fiscal intermediaries and obfuscate the goal of obtaining accurate bed counts. This confusion is further compounded by the preamble statement that included beds are those associated with allowable costs payable under the IPPS that are reported on the Medicare cost reports (68 Fed. Reg. at 27202).

#### **C. Labor, Delivery, Recovery and Postpartum Beds and Days**

Increasingly, hospitals do not move patients during the childbirth process, such that labor, delivery, recovery and postpartum occur in the same room (these rooms are labeled "LDRP" rooms). CMS' proposes to require hospitals to distinguish the labor and delivery portions of the patient's stay from the recovery and postpartum portions. This

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<sup>3</sup> Our interpretation also is based on the statement in the preamble that says "beds in an otherwise unoccupied unit that are occupied . . . at any time during the 3 preceding months would be counted as available for the current month." 68 Fed. Reg. at 27203.

apportionment apparently is necessary because only the recovery and postpartum portions of the stay are included in the hospital's calculation of total days, bed days and Medicaid days (where applicable) for IME and DSH payment purposes.

We believe CMS underestimates the administrative burden associated with this proposal as well as the potential discrepancies that could result between fiscal intermediaries and hospitals regarding the assumptions on which the apportionment is based. We believe that with further study and consultation, a process can be developed that will meet CMS' needs with less administrative burden.

#### **D. Including Observation Days that Result in Inpatient Stays**

CMS' proposal to count observation days in the bed day count if the patient is subsequently admitted for acute inpatient care does not seem unreasonable. This change, though, will require administrative changes for hospitals to count these days as part of their reporting processes.

If this change is finalized, it is important that it be included in any and all Medicare policies that rely on calculations of Medicare days and length of stay. So, for example, these days should be included in the Medicare inpatient share calculation when determining Medicare DGME payments. In addition, these days should be included when determining the length of stay for patients in those DRGs that are subject to the post-acute care transfer policy. This latter inclusion is necessary because it may be determinative as to whether a case is paid at a per diem or full DRG rate, as discussed below.

#### **VI. THE POSTACUTE CARE TRANSFER PAYMENT POLICY SHOULD NOT BE EXPANDED**

Medicare patients who are sent from one acute care hospital to another are viewed as "transfers." Under Medicare's transfer payment policy, a full DRG payment is made to the final discharging hospital and each transferring hospital is paid a per diem rate for each day of the stay, not to exceed the full DRG payment.

In FY 1999, CMS expanded its transfer policy such that hospitals that discharge patients in one of 10 specified DRGs to either a PPS-exempt hospital or unit, skilled nursing facility, or home health agency, receive per diem payments, not to exceed the full DRG payment.

This year's proposed rule would expand the postacute care transfer policy to include 19 additional DRGs. According to CMS, this option would result in \$160 million less in Medicare program payments to hospitals. We also note that half of the current DRGs subject to the post-acute care transfer policy do not meet the criteria CMS used to select these additional DRGs.

We agree with the comments of the American Hospital Association and believe that 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.

On a related matter, as discussed above, to the extent observation days are counted as bed days if the patient is ultimately admitted as an inpatient, those days should be included in the calculation of inpatient length of stay for purposes of calculating whether a per diem or full DRG payment is appropriate.

## **VII. THE PROPOSALS AFFECTING PATIENT DAY COUNTS FOR MEDICARE DSH PAYMENTS SHOULD BE MODIFIED IN THE FINAL RULE**

The methodology for calculating Medicare disproportionate share (DSH) payments involves two fractions: 1) inpatient days associated with Medicare patients receiving supplemental security income (SSI) divided by total Medicare inpatient days, and 2) inpatient days associated with Medicaid patients divided by total inpatient days. Patient days associated with patients eligible for both Medicare and Medicaid (so called “dual eligibles”) currently are included in the Medicare SSI inpatient day count and not the Medicaid count.

### **A. Dual-Eligible Patient Days**

The proposed rule would include the patient days of dual eligible Medicare patients whose Medicare coverage has expired in the Medicaid fraction of the DSH methodology. They currently are included in the Medicare fraction.

CMS acknowledges that the current policy is consistent with statutory intent (68 Fed. Reg. at 27208). Thus, it appears that the proposed rule change is due solely to practical considerations regarding fiscal intermediaries’ abilities in obtaining data on Medicare SSI beneficiaries.

We find CMS’ rationale for making this change unconvincing, particularly given the new administrative burden it will place on hospitals to provide documentation to fiscal intermediaries that a patient’s Medicare Part A coverage has been exhausted.

### **B. Patient Days Associated with Medicare+Choice Beneficiaries should be Considered Medicare Days**

Under the proposed rule, patient days associated with Medicare beneficiaries enrolled in Medicare+Choice plans would not be included in the Medicare fraction of the DSH methodology since the Medicare benefits for these patients are administered under Medicare Part C, rather than Part A.

We strongly disagree with this proposed change and accompanying rationale. Medicare+Choice patients are just as much Medicare beneficiaries as beneficiaries enrolled in the fee-for-service program. Under current law, teaching hospitals receive DGME and IME payments associated with Medicare+Choice enrollees. There is no reason to create a distinction between the treatment of Medicare+Choice enrollees under DGME and IME policies and their treatment under DSH policies. CMS' proposal is unnecessary, unwise, and should be abandoned.

## **VIII. PAYMENTS FOR NEW TECHNOLOGIES**

Pursuant to current law, CMS established a methodology that would provide additional payments to hospitals for new technologies that are not yet reflected in the DRG payment system. In order to qualify for the additional payments, the new service must meet thresholds related to new, significant improvement over the current service, and inadequate payment under the DRG system. The policy is required to be budget neutral, achieved by funding the additional payments through reducing the standardized payment.

Only one item has yet to qualify for additional payments—Xigris®, which was approved for additional payments in FY 2003. However, due to systems problems it is unclear whether any additional payments for this drug have been received by hospitals. Given that the standardized payment amount has been reduced in order to finance these additional payments, it is critical that the Agency act expeditiously to correct any problems to ensure that hospitals using this drug receive the intended payments.

In the proposed rule, CMS proposes to change the “high-cost” threshold for a new technology to qualify for additional payments. Specifically, CMS is proposing to reduce the cost threshold from one standard deviation to 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the DRG to which the new medical service or technology is assigned (proposed 42 C.F.R. §412.87(b)(3)).

We appreciate CMS' proposal to lower the threshold. We believe that there are more new technologies that merit additional payments than have currently been identified. However, it is unclear whether the reduced threshold achieves the goal of identifying these technologies.

We recognize CMS' concern about establishing a threshold that would result in inappropriate technologies becoming eligible for additional payments. To gain further insights into an appropriate threshold, we suggest that CMS conduct a historical review of technologies that likely would have met the “new” and “substantial improvement” criteria and determine the relationship between the costs of those items and the Agency's cost threshold. Such an analysis may provide useful insights as to whether a more flexible cost criterion is needed.

We also have concerns that the new technology payment methodology does not ensure payment equity for hospitals that use new technologies and, perhaps more importantly, may not comply with the current law requirement that the additional payment “adequately reflects the estimated average cost of the service or technology.” If the criteria for identifying cutting-edge technologies are implemented appropriately, we

believe only a limited number of technologies will qualify for additional payments. For these limited technologies, we believe current law requires that hospitals receive an additional payment that much more closely approximates average costs than the current amount; eighty percent, for example, rather than the current fifty percent level.

#### **IX. THE OCCUPATIONAL MIX ADJUSTMENT TO THE WAGE INDEX**

Current law mandates that, beginning in FY 2005, the hospital wage index is to be adjusted to reflect the occupational mix of employees. On April 4, 2003 CMS published a proposed survey instrument to gather data on hospitals' occupational mix. As we stated in our comment letter on the proposed survey instrument, we urge the Agency to publish the methodology it is contemplating for incorporating occupational mix into the current wage index and provide ample opportunity for public comment on that methodology.

#### **X. PAYMENTS FOR DRUG ELUTING STENTS**

In the FY 2003 Medicare inpatient PPS final rule, the Agency created two temporary DRGs, DRGs 526 and 527, to reflect cases involving the insertion of a drug-eluting coronary artery stent. In this year's proposed rule, CMS states that the FY 2004 relative weights for these two DRGs will be determined using the "best available" data as of the final rule. (68 Fed. Reg. at 27172.)

We appreciate the Agency's continued monitoring of the weights for these two important DRGs. Given the "break through" nature of drug eluting stents, it is important that the relative weights be as accurate as possible to ensure adequate payments to hospitals that use these stents. We understand that the costs of drug-eluting stents are higher than what is reflected in the current weights, and the number of stents used per procedure often is more than the 1.5 average CMS used in calculating the weights. We believe that upon review of the "best available" data, the FY 2004 weights for DRGs 526 and 527 should be higher than current weights.

#### **XI. 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.

Thomas A. Scully  
July 8, 2003

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

Sincerely,

Jordan J. Cohen, M.D.

cc: Robert Dickler, AAMC  
Karen Fisher, AAMC  
Ivy Baer, AAMC



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## M E M O R A N D U M

June 30, 2003

TO: Association of American Medical Colleges

FROM: Dennis M. Barry  
Christopher L. Keough

RE: Analysis of Retroactive “Redistribution” Theory Presented in the Proposed IME and GME Payment Rules (May 19, 2003 Federal Register)

This memorandum responds to your request for analysis of the proposed changes to the Medicare regulations governing the full-time equivalent (“FTE”) resident counts used to calculate the direct graduate medical education (“GME”) payment under section 1886(h) of the Social Security Act (the “Act”) and the indirect medical education (“IME”) adjustment under section 1886(d)(5)(B) of the Act. Briefly, we conclude that the proposed changes are substantively invalid and in any event should not be applied retroactively for the reasons discussed below.<sup>4</sup>

### **I. Summary of Proposed Rule**

In the May 19, 2003 *Federal Register*, CMS proposes to amend the GME regulation to incorporate certain Medicare reasonable cost principles in the determination of a hospital’s allowable number of residents for purposes of both the GME payment methodology and the IME adjustment.<sup>5</sup> 68 Fed. Reg. 27,154, 27,211-18, 27,231-33. More specifically, if the proposed rule is

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<sup>4</sup> The proposed rule is also procedurally invalid. Section 1871(b)(1) of the Act requires the Secretary to allow 60 days after publication of notice in the *Federal Register* for public comment on a proposed rule. Notice of the proposed changes was not published in the *Federal Register* until May 19, 2003, and the period for public comments on the proposed rule has been abridged to July 8, 2003.

<sup>5</sup> The preamble to the proposed rule suggests that CMS is proposing to apply the community support and redistribution principles only with respect to the determination of a hospital’s allowable number of residents in a non-provider setting. See 68 Fed. Reg. 27,215. It appears, however, that the proposed amendments to section 413.86(f) could be applied,

adopted in final form, the determination of a hospital's total number of residents for the direct GME payment would be subject to the community support and redistribution principles currently set forth in the reasonable cost reimbursement regulation codified at 42 C.F.R. § 413.85(c). *See* 68 Fed. Reg. 27,231-33 (proposing amendments to paragraphs (f) and (f)(4) and adding a new paragraph (i) in section 413.86). The same limitations would apply with respect to the determination of a hospital's allowable number of residents in a non-provider setting for IME purposes. *See* 68 Fed. Reg. 27,216; 42 C.F.R. § 412.105(f)(1)(ii)(c).

In effect, the proposed rule would preclude a hospital from counting a resident in the determination of its payment for GME and IME if the cost of the resident's training in a particular setting was borne by an entity other than a hospital, at any time since at least January 1, 1999. The preamble to the proposed rule states that the Medicare intermediaries would be required only to verify compliance with the new standard since January 1, 1999. Intermediaries would not be required to verify whether a hospital was incurring the cost of program prior to January 1, 1999; but, an intermediary "certainly would be required" to disallow GME and IME payments if it determines that there was a redistribution of cost or community support for a program prior to that date. 68 Fed. Reg. 27,216.

The proposed effective date of the proposed rule is October 1, 2003. 68 Fed. Reg. 27,417 ("We are proposing that effective October 1, 2003, in order for a hospital to receive IME and direct GME payment, the hospital must have been continuously incurring the direct GME costs of residents training in a particular program since the date the resident first began training in the program in order for the hospital to count the FTE residents.") It is unclear, however, whether CMS would apply the community support and redistribution principles to determine GME and IME payments due for periods prior to the proposed effective date.

The preamble to the proposed rule suggests that CMS is proposing these amendments in response to certain "inappropriate" practices that purportedly have been adopted, particularly with respect to dental programs, in response to earlier changes in the rules governing the count of residents training in a non-provider setting, which were effective January 1, 1999. 68 Fed. Reg. 27,212-13. CMS asserts that the new rule is a permissible exercise of the Secretary's "broad discretion to implement policy on FTE resident counts." 68 Fed. Reg. 27,215. In addition, CMS argues that the proposed rule is consistent with Congressional intent to encourage hospitals to move residents' training from hospital settings to non-provider settings, without shifting non-provider costs to hospitals, and that "Medicare would only share in the costs of medical education until the community assumes the costs." *Id.*

## **II. The Proposed Rule Is Inconsistent with the Secretary's Long-Standing Interpretation and Implementation of the Act.**

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however, to the determination of a hospital's total number of residents training in all settings. *See* 68 Fed. Reg. 27,231. Moreover, the preamble to the notice states CMS' purported belief that "the concepts of redistribution of costs and community support are equally relevant to the counting of FTEs residents [*sic*] by a hospital in general." 68 Fed. Reg. 27,215.

Congress clearly delegated the Secretary a measure of discretion in the implementation of the prospective GME payment method and the IME payment adjustment. Nevertheless, the agency's exercise of that discretion is bounded by the Administrative Procedure Act ("APA"). The APA directs a reviewing court to "hold unlawful and set aside agency action" that is arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, in excess of statutory authority or otherwise contrary to law. 5 U.S.C. § 706(2).

If adopted in final, the proposed rule, in our view, would not survive review under the APA. The proposed rule is contrary to the plain meaning and intent of the applicable provisions of the Act. In addition, the proposed rule conflicts in substantial and irreconcilable respects with the agency's long-standing interpretation and implementation of the statutory schemes governing the prospective GME payment method and the IME adjustment.

A. GME

As noted above, section 1886(h) of the Act established a prospective payment method for direct GME costs. The per resident amount method applies "[n]otwithstanding section 1861(v)" of the Act" (emphasis added), and the amount determined under the prospective method is paid in lieu "of any amounts that are otherwise payable under [title XVIII] with respect to the reasonable costs of hospitals for direct graduate medical education costs. . . ." Section 1886(h)(1) of the Act. Consistent with the Secretary's long-standing interpretation of section 1861(h)(1), CMS has argued, and the courts have agreed, that Medicare reasonable cost principles have no effect with respect to the direct GME payment method prescribed by section 1886(h) of the Act. Thus, in a case where the Secretary's calculation of a hospital's base payment rate resulted in no GME payment at all for the allowable costs incurred by a hospital in later cost reporting periods, a federal district court upheld the Secretary's determination that section 1861(v) of the Act, and its proscription against cross-subsidization, do not have "any effect on regulations or agency decisions regarding the prospective payment system that now applies to GME reimbursement." *Episcopal Hospital v. Shalala*, [1997-2 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 45,433 (E.D.Pa. 1997).

Inasmuch as section 1861(v) of the Act is of no effect with respect to the direct GME payment method established in section 1886(h), as the Secretary has previously determined, then the redistribution and community support principles are equally inapposite in the determination of a hospital's resident count for GME. As discussed above, these principles implement the statutory provision in section 1861(v) of the Act for payment of reasonable costs. Indeed, these principles originally were derived from the legislative history of that very section of the statute, and under the Secretary's long-standing construction of the GME statute section 1861(v) of the Act and the reasonable cost established therein are inapplicable to the direct GME payment method.

The proposed rule is also incompatible with the Secretary's prior implementation of the statute in another significant respect. The Secretary has interpreted the GME statute from the outset to preclude the consideration of allowable cost in the determination of a hospital's resident count for GME. Since its initial adoption in 1989, the implementing GME regulation has stated:

“Residents . . . working in all areas of the hospital complex may be counted.”<sup>6</sup> 42 C.F.R. § 413.86(f)(1). By its plain terms, the regulation construes the GME statute so as to preclude consideration of allowable costs incurred in connection with a resident’s training. The Secretary repeatedly acknowledged this principle in the preamble to the September 29, 1989 final rule implementing the GME statute, stating:

- “no consideration [is] given to actual costs incurred for these programs during a cost reporting period,” (54 Fed. Reg. 40,288);
- “[n]othing in section 1886(h) of the Act indicates that the bearing of certain types of costs in connection with particular residents is a factor in determining who should be counted,” (*id.* at 40,298);
- “section 1886(h) of the Act [does] not take into account the various types of financial arrangements that teaching hospitals have made for their GME programs,” (*id.*);
- “We believe that Congress intended to establish a payment method . . . which is not based on actual costs incurred for GME programs in any year [after the base year], (*id.* at 40,309); and
- “As such, the payment method is neutral with regards to hospital-specific costs. For example, a hospital could change its arrangements with its teaching physicians in such a way that the physicians are no longer receiving a salary for their services associated with the GME programs. These hospitals could conceivably make a profit on their GME programs since they would continue to receive per resident amounts based on costs they no longer incur.” (*Id.*)

Consistent with these principles, the Secretary determined in the 1989 final GME rule that while the costs attributable to non-reimbursable activities must be excluded from the GME costs used to compute a hospital’s base-year average per resident amount for GME, the residents’ time associated with such activities must be included. See 42 C.F.R. § 413.86(e)(1)(A)-(B) (emphasis added). For example, while non-allowable costs associated with residents’ research were excluded from the calculation of a hospital’s average per resident amount for the 1984 base year, the residents’ research time was required to be included. See *University of Iowa Hospitals & Clinic v. Blue Cross & Blue Shield Ass’n / Blue Cross & Blue Shield of Iowa*, [1996-1 Transfer Binder] MEDICARE & MEDICAID GUIDE (CCH) ¶ 43,940 (HFCA Adm’r Nov. 27, 1995) (concluding that “nothing in section 1886(h) of the Act indicates that the bearing of certain types

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<sup>6</sup>As noted above, a 1986 amendment to the statute permits a hospital to count residents’ time in a non-provider setting if the hospital incurs all or substantially all of the cost of the residents’ training at the non-provider site.

of costs in connection with particular residents is a factor in determining who should be counted.”)<sup>7</sup>

Similarly, a hospital was required to include in the calculation of its average per resident amount time spent in the hospital by residents who were paid by other entities, such as a medical school, notwithstanding the community support and redistribution principles. This construction of the GME statute applied not only to the resident counts used to compute the 1984 base payment rates for GME but also to the resident counts to be determined for the later cost reporting periods subject to the prospective payment method for GME. Indeed, the 1989 GME rule was modified after publication of the proposed rule in order “to require Medicare hospitals to count residents who are working in their facility even if the residents’ salaries are fully paid by other entities, either Federal or non-Federal. This revised counting policy will apply to both the GME base period and cost reporting periods subject to the new payment methodology.” 54 Fed. Reg. at 40,299 (emphasis added).

Finally, and in the same vein, the preamble to the 1989 final rule made clear that a hospital’s resident count may also include residents for whom community support was received through a state or local grant. 54 Fed. Reg. at 40,302. Responding to a comment that it would be inappropriate for medical school costs to be passed-through to a hospital insofar as medical schools “often are adequately funded by grants from State and local governments,” the Secretary stated that these alternative sources of funding do not preclude GME payment because the “policy that restricted grants could be offset against allowable costs incurred by providers was changed effective October 1, 1983.” *Id.* Consequently, “any grant monies received by a provider could not be offset against the reimbursable amounts due the provider under Medicare.” *Id.*

As noted above, the 1989 final rule also established that the resident counts for all cost reporting periods subject to the prospective GME payment method must be determined consistently with resident counts for the 1984 base year. *See, e.g.*, 54 Fed. Reg. 40,298. Thus, while the Supreme Court upheld the Secretary’s application of the redistribution principle to disallow costs incurred by a teaching hospital for its 1984 base year, *Thomas Jefferson University Hospital v. Shalala*, 512 U.S. 504 (1994), the Secretary’s long-standing and contemporaneous construction of the GME statute also required the related residents’ training time to be included in the hospital’s FTE counts, not only for the base year itself, but also for subsequent cost reporting periods subject to the prospective GME payment methodology. That consistency principle is necessary to maintain the balance of the statutory payment formula for GME. The proposed change to the rules midstream, and only with respect to subsequent payment years, distorts the balance on which the established payment formula depends. Accordingly, to the extent that the proposed rule would now require disallowing direct GME payments for any program for which a hospital has not continuously incurred the training costs, it is arbitrary, capricious, and an abuse of discretion.

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<sup>7</sup> In an unpublished decision, a federal district court subsequently reversed the Secretary’s determination that the research costs at issue in this case were not allowable. *See University of Iowa Hospitals & Clinics v. Shalala*, No. 3-96-CV-10012, slip. op. at 30 (S.D. Iowa, Feb. 12, 1997). The above-quoted portion of the Administrator’s decision as to the count of FTE residents was not disturbed, however, by either the district court’s decision or the later decision by Eighth Circuit in *University of Iowa Hospitals & Clinics v. Shalala*, 180 F.3d 943 (1999).

B. IME

When Congress adopted the PPS for inpatient operating costs, it also directed the Secretary to provide an adjustment for IME. *See* section 1886(d)(5)(B) of the Act. Except as otherwise provided in the statute, the amount of that adjustment must be “computed in the same manner as the adjustment for such costs under regulations (in effect as of January 1, 1983)” governing the TEFRA cost limits established under section 1886(a) of the Act. *Id.*

According to CMS, “there were no regulations in effect on January 1, 1983 that specifically described how the IME adjustment was computed,” but the prescribed methodology for calculating the adjustment was published in the *Federal Register* on September 30, 1982. *See* 55 Fed. Reg. 35,990, 36,061 (Sep. 4, 1990). Under that methodology, the IME calculation included all residents employed at a hospital for 35 hours or more per week and one half the number of residents who worked less than 35 hours per week. 47 Fed. Reg. 43,296, 43,310 (Sep. 30, 1982).

Thus, except as otherwise provided in the statute, the rules in the 1982 *Federal Register* set forth the basic methodology on which the terms of the statutory IME payment formula rule are premised, and nothing in the 1983 methodology excluded residents involved in a program previously supported by the community or an educational institution. Moreover, nothing in section 1886(d)(5)(B) of the Act supports the application of reasonable cost principles in the determination of a hospital’s resident count for IME. To the contrary, Congress amended the statute to require the inclusion of residents “who furnish services to a hospital but are not employees of such hospital.” Section 1886(d)(5)(B)(iii) of the Act. To the extent that this provision requires the inclusion of residents who are paid by a medical school or are otherwise supported by the community, the statute clearly dispels the proposed application of the redistribution and community support principles in determining a hospital’s resident count for IME. Accordingly, the proposed rule is contrary to the plain meaning and manifest intent of section 1886(d)(5)(B) of the Act.

The proposed change in the methodology for calculating the resident count for IME is also invalid for another reason. The fixed terms of the statutory payment formula for IME (*e.g.*, the values assigned to “c” and the “nth power”) are premised upon, and fixed in relation to, the basic methodology for counting residents as prescribed in the 1982 *Federal Register* and as further modified by the statute. Thus, the Secretary’s proposal to alter that methodology by applying new limitations on the count of FTE residents is no more within the agency’s statutory authority than a proposal to modify by regulation the values assigned by Congress to “c” or “nth power” in the statutory payment formula for IME. *See* section 1886(d)(5)(B)(ii) of the Act. Here again, the Secretary’s proposal to change the rules for counting residents in midstream is arbitrary, capricious in beyond the Secretary’s statutory authority.

Finally, we note that CMS’ discussion of the proposed rule points to no evidence, and we are aware of none, indicating that a teaching hospital’s operating costs bear any relation whatsoever to past or present sources of funding for residents’ training. As noted above, the IME adjustment is intended to serve as a proxy measure for the intensity of teaching in hospital and the statistically-correlated operating costs attributable to the specialized services rendered by a teaching hospital and additional tests ordered by residents in training. Congress’ concerns about

the adequacy of the PPS case-classification system to account accurately for these higher-than-average operating costs, H.R. Conf. Rep. No. 98-25 at 140-41, stands quite apart from, and is not impacted by, the source of funding for residents' training. Accordingly, we conclude that the proposed application of the community support and redistribution principles is arbitrary, capricious, and not based upon substantial evidence.

C. Changes to Non-Provider Setting Rules for GME and IME

The fallacy of CMS' current assertion of a long-standing policy of applying the redistribution and community support principles in the determination of a hospital's resident counts for GME and IME is particularly well illuminated by CMS' prior changes to the rules governing residents' time spent in non-provider settings.

Congress amended the GME statute in 1986 and the IME statute in 1997 to permit a hospital to count a resident's time spent in a non-provider setting if the hospital incurred all or substantially all of the training costs. In the original rule implementing the GME amendment, CMS adopted the requirement that a hospital must have a written agreement with each non-provider entity stating only "that the resident's compensation for training time spent outside of the hospital setting is to be paid by the hospital." *See* 42 C.F.R. § 413.86(f)(3)(ii). Nowhere in that rule, nor in the preamble to the rule, did CMS discuss an additional requirement that a hospital must have continuously incurred the costs of the residents' training in the non-provider since the inception of the training program. *See* 54 Fed. Reg. 40,286-321 (Sep. 29, 1989).

Similarly, when CMS changed the IME and GME rules to require a written agreement indicating that the hospital is also providing reasonable compensation for physicians' supervision of residents' training in the non-provider setting, nothing was said about an additional requirement that a hospital must have continuously incurred this additional cost, as well as the residents' compensation required under the prior regulations, since the inception of the training program. *See* 63 Fed. Reg. 40,954, 40,986-97 (July 31, 1998). Quite to the contrary, in response to a comment "that hospitals did not compensate nonhospital sites for supervisory teaching physician costs and it would not be fair to shift these costs to teaching hospitals," CMS responded:

hospitals and nonhospital sites will have 5 months following publication of this final rule to negotiate **agreements that will allow hospitals to continue counting residents training in nonhospital for indirect and direct GME**. These arrangements are related solely to financial arrangements for training in nonhospital sites. **We do not believe that the agreements regarding these financial transactions will necessitate changes in the placement and training of residents.**

In response to the comment that it is unfair to shift costs to the hospital, we believe that it is appropriate to include supervisory costs in the nonhospital site as part of 'all or substantially all' of the costs that hospitals must incur to count the resident. **Currently, the hospital is able to count the resident even though the costs for that resident may be lower during the time when the resident trains**

**outside the hospital.** At the same time, the nonhospital site may have incurred costs for which it received no compensation. We believe that requiring the hospital to incur the costs associated with training in the nonhospital site is equitable to both the hospital and the nonhospital site and is consistent with the statutory requirement that the hospital must incur ‘all or substantially all’ of the costs.

63 Fed. Reg. 40,995 (emphasis added).

The above-quoted explanation of the changes to the GME and IME rules, effective January 1, 1999, belies CMS’ current assertion of a long-standing policy of applying the redistribution and community support principles in the determination of the resident counts used to compute payment for GME and IME. Application of those reasonable cost reimbursement principles in this context would not have allowed a hospital “to continue counting residents training in nonhospital for indirect and direct GME,” after January 1, 1999, if the hospital had not previously incurred the cost of supervising teaching compensation costs, consistent with earlier version of the regulations. Likewise, application of the redistribution and community support principles would not have allowed a hospital to count a resident, under the prior rules, “even though the costs for that resident [were] lower during the times when the resident train[ed] outside the hospital.” In short, nothing in the existing regulations precluded the cost “shift” that CMS intended when it amended the regulations effective January 1, 1999.

### **III. The Proposed Rule Thwarts Congressional Intent to Support Residents’ Training in Non-Provider Settings.**

The proposed rule is also inconsistent with the legislative intent of the Act. The proposed rule does not find support in the 1986 and 1997 amendments concerning the count of residents working in non-provider settings and is inconsistent with the amendments establishing limits on the resident counts for GME and IME.

#### **A. Non-Provider Setting Rules**

The 1986 and 1997 amendments to the Act, permitting hospitals to count residents’ time spent in non-provider settings for GME and IME purposes, certainly are intended to support residents’ training in non-provider settings. For example, the legislative history of the 1986 amendment states that the change relating to the patient care settings, such as a family practice center, in which a resident may be counted for GME purposes is “designed to enhance the incentives for training in primary care” because “it is difficult to find sufficient other sources of funding for the costs of such training.” See H.R. Rep. No. 99-727, 99 Cong., 1st Sess., 69-70 (1986), *reprinted in*, 1986 U.S.C.C.A.N. 3607, 3659-60. Accordingly, the Conference committee report states that “*all* of the time that a resident spends in activities related to patient care is to be counted towards full-time equivalency, without regard to the setting in which those activities take place, so long as the hospital is incurring costs for that resident’s training. *Id.* at 70 (emphasis added).

To the extent that the proposed rule would disallow Medicare payment for at least some programs operated in a non-provider setting, it cannot be said, as CMS now asserts, that the proposed rule is consistent with Congress' intent to support residents' training in non-provider settings. If anything, the proposed rule runs counter to Congress' intent to support that training by cutting off funding for some of these programs. And, it certainly does not further Congress' intent to "enhance the incentives for training in primary care," nor does it address Congress' concern about the difficulty in finding other "sources of funding for the costs of such training," nor is it consistent with Congress' intent to permit hospitals to count "all" residents' time spent training in a non-provider setting for which the hospital incurs the cost.

Finally, there is no support in the legislative history of the non-provider setting amendments for the Secretary's view that these changes were not intended to shift new costs to hospitals in support of on-going training in non-provider settings. This construction of the Congress' intent ignores the existing state of affairs when the amendments were adopted and Congress' awareness the pre-existing regulatory scheme. As reflected in the legislative history of the 1997 amendments, Congress was well aware of the pre-existing regulations that precluded a hospital from counting residents' time spent in a non-provider setting. Moreover, it had been well-established when the amendments were enacted that at least some residency training programs, such as family practice, required clinical training in an ambulatory care setting as condition for accreditation (irrespective of Medicare funding for training in those settings). *See, e.g., University of Cincinnati v. Bowen*, 875 F.2d 1207 (6th Cir. 1989). Legislating against this backdrop, it can be reasonably inferred that Congress was aware, and even intended, that some costs of existing residency training programs in non-provider settings would be shifted to hospitals in order for the hospitals to qualify for direct GME and IME funding under the 1986 and 1997 amendments to the Act.

#### B. Resident Limits

As noted in the preamble to the proposed rule, Congress previously enacted limits on a teaching hospital's allowable number of allopathic and osteopathic residents (excluding dental and podiatric residents). 68 Fed. Reg. 27,212. The caps are derived, in part, from the number of residents trained in a 1996 base year. *See* sections 1886(h)(4)(F) and 1886(d)(5)(B)(v) of the Act. As CMS has acknowledged in the notice of the proposed rule, the caps reflect "an attempt to end the implicit incentive for hospitals to increase the number of FTE residents." 68 Fed. Reg. 27,212.

Thus, through the enactment of the 1996 caps, Congress already has dealt with the problem, if there is one, that CMS is attempting to revisit through the proposed rule. Moreover, Congress' approach with respect to dental residencies, which are the focus of the proposed rule, was to exempt them from the caps. Congress' exemption of dental programs reflects legislative intent not to ratchet down GME payments to hospitals for dental residency training, as CMS proposes, but to encourage increased GME funding to hospitals for dental residency training

programs, and to do so irrespective of whether a hospital starts a new program or begins to support an existing program.<sup>8</sup>

#### **IV. The Proposed Rule Should Not Be Applied to GME or IME Payments for Periods or Discharges Occurring Prior to the Proposed Effective Date.**

For the foregoing reasons, we conclude that the proposed rule is invalid in several respects; but, even if the proposed rule were otherwise valid, it should not be applied to disallow GME or IME payments received before or after the proposed effective date in respect to periods or discharges occurring prior to that date.

Retroactivity is disfavored in the law, and it is well-established that the Secretary does not have authority to promulgate rules with retroactive effect. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). In this instance, the application of the proposed rule in respect of cost reporting periods or discharges occurring prior to its proposed October 1, 2003 effective date would be impermissibly retroactive, and therefore invalid, because it would attach “new legal consequences to events completed before its enactment.” *Landgraf v. USI Film Prods.*, 511 U.S. 244, 270 (1994); *see also Health Insurance Ass’n of America, Inc. v. Shalala*, 23 F.3d 412, 425 (D.C. Cir. 1994) (the Secretary may not rely upon rules that were not in effect when relevant transactions occurred), *cert. denied*, 513 U.S. 1147 (1995).

Moreover, even if the proposed rule were only a clarification of existing policy (which it is not), the clarification should be applied only prospectively. *See P.I.A. Michigan City, Inc. v. Thompson*, 292 F.3d 820 (D.C. Cir. 2002) (affirming the Secretary’s decision that 1992 amendments that clarified an earlier version of CMS’ regulation should be applied only prospectively after the effective date of the clarification). It is well-established that “[e]lementary considerations of fairness dictate that individuals should have an opportunity to know what the law is and to conform their conduct accordingly; settled expectations should be lightly disrupted.” *See, e.g., Landgraf*, 511 U.S. at 265. Never before has CMS stated that the reasonable cost redistribution and community support principles would be applied to the determination of a hospital’s allowable resident count for GME or IME. Indeed, as noted above, the agency’s prior construction of the statute and regulations in the preambles accompanying earlier amendments to the rules, and in court, reasonably would be construed to mean that the redistribution and community support principles are inapplicable in this context. Hospitals, therefore, have entered into agreements with nonhospital entities to incur not the costs of residents’ compensation and supervision in non-provider settings with the settled expectation that they will receive GME and IME payments for that training. And, in view of the lack of prior notice as to CMS’ current view as to the application of the redistribution and community support principles, hospitals should not be financially penalized by the application of these principles with respect to periods or discharges occurring prior to the proposed October 1, 2003 effective date of the proposed rule.

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<sup>8</sup>In addition, as noted above, the language of the proposed rule reaches beyond the problem identified in the preamble with respect to dental residents training in non-provider settings. The language of the proposed rule could reach all residents training in a non-provider setting and might even be applied to residents training in an inpatient hospital setting.

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