



June 12, 2006

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

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

Dear Administrator McClellan:

The American Dental Education Association (ADEA) appreciates the opportunity to comment on the proposed rule for changes to hospital inpatient prospective payment systems for fiscal year 2007, as published in the April 25, 2005 *Federal Register*. Specifically, we will comment on proposed changes to graduate medical education (GME) policies which will have a very deleterious impact on residency training.

ADEA is the national organization that speaks for dental education. It is dedicated to serving the needs of all 56 U.S. dental schools, 731 U.S. dental residency programs, 266 dental hygiene programs, 259 dental assisting programs, and 25 dental laboratory technology programs, as well as the 11,332 full- and part-time dental school faculty, more than 5,060 dental residents (both hospital- and school-based) and the nation's 36,286 dental and allied dental students.

Comments Regarding Section IV(F)(5) -- Resident Time Spent in Nonpatient Care Activities as Part of Approved Residency Programs (Sections 413.9 and 413.78(a))

We are gravely concerned with the entire discussion in this section of the proposed rule regarding didactic activities that are a seminal component of every residency program. CMS's view regarding the treatment of this issue over the years, in our opinion, bears little resemblance to the actual language in the Medicare statute, regulations, manual and CMS's own correspondence.

We agree with CMS that only time spent by residents training in a nonprovider setting performing "activities relating to patient care" may be counted towards direct graduate medical education (D-GME) and indirect medical education (IME) funding. However, in using this language, it is very clear that Congress intended for more than just direct patient care to be

included. Indeed, as described below, CMS regulations, manual provisions and correspondence also support this conclusion.

The Medicare Statute

In a very misleading fashion in the proposed rule, CMS does not quote the entire section of the relevant portion of the Medicare statute, which reads in full:

“Counting Time Spent in Outpatient Settings. Such rules shall provide that only time spent in activities relating to patient care shall be counted and that all the time so spent by a resident under an approved medical residency training program shall be counted toward the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training in that setting.” (Emphasis added). Section 1886(h)(4)(E) of the Social Security Act.

Congress and CMS itself know what language describes care directly provided to individual patients. That term is “direct patient care”. Congress uses the term “direct patient care” in 42 USC Section 1395m regarding special payment rules for compensation provided to a referring physician for direct patient care services, and again in Section 1395nn, in distinguishing administrative services from direct patient care.

Significantly, however, the statutory language regarding this GME issue does not use the term “direct patient care,” but rather employs the much broader language of “activities relating to patient care.” Further, the law states that “all the time so spent by a resident under an approved medical residency training program shall be counted . . . without regard to the setting in which the activities are performed.” (Emphasis added.)

In addition to Congress using the phrase “direct patient care” when that is what it means, CMS uses the phrase “direct patient care” frequently. Examples include:

- 42 CFR Sections 460.71, 460.62, 418.70, 418.100, 413.106;
- Proposed rule for physician services for 2005 (69 Fed. Reg. 150 at 47491);
- Interim final rule for Programs of All-inclusive Care for the Elderly (PACE) (67 Fed. Reg. 190 at 61499);
- Medicare Provider Reimbursement Manual, Transmittal 13, October 2003;
- Medicare Benefit Policy Manual, Chapter 11, Section 80.2, Physicians’ Services - Outpatient Maintenance Dialysis;
- Medicare Benefit Policy Manual, Chapter 9, Coverage of Hospice Services;
- Medicare Claims Processing Manual, Chapter 3, Section 141.1.3Q, Inpatient Hospital Billing; and
- State Medicaid Manual, Chapter 4, Section 4307 (Payment for Physician Services Under Hospice).

Medicare regulations also define “direct medical and surgical services” of physicians in a teaching setting as “services to individual beneficiaries that are either personally furnished by a physician or furnished by a resident under the supervision of a physician in a teaching hospital ...” 42 CFR Section 415.152.

In all these situations where Congress or CMS used the phrase “direct patient care” or “direct medical and surgical services,” it meant care provided directly to specific patients. To describe hands on care provided directly to individual patients, neither Congress nor CMS has used the phrase “activities relating to patient care.”

Medicare Regulations and Provider Manual

The Medicare regulations relating to training in a nonprovider setting state:

“For portions of cost reporting periods occurring on or after January 1, 1999, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physician offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital’s resident count if the following conditions are met: (i) The resident spends his or her time in patient care activities . . .” (Emphasis added). 42 CFR 413.78(a).

Consistent with the statutory language, the reference in the regulations is to patient care “activities” and not to direct patient care.

CMS states that the regulations at 42 CFR Section 413.9 support its position that didactic time is not a patient care activity. Actually, these regulations fully support the interpretation that the costs of didactic training are in fact related to patient care.

Section 413.9 requires that the costs that a hospital places on its cost report be related to patient care to be reimbursed.

“Costs related to patient care Necessary and proper costs are costs that are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities.” (Emphasis added). 42 CFR 413.9

The Provider Manual expands on this language by stating that all costs of an approved Interns and Resident training program are allowable as “Costs Related to Patient Care”. PRM Section 2148.

In addition, “Costs Related to Patient Care” also is defined in the Provider Manual as “all necessary and proper costs which are appropriate and helpful in maintaining the operation of patient care facilities and activities.” PRM Section 2102.2

Moreover, the Provider Manual also lists examples of “Costs Not Related to Patient Care”. (Emphasis added). The Provider Manual states that costs not related to patient care are the cost of meals sold to visitors, cost of drugs sold to other than patients, cost of operating a gift shop, cost of entertainment, cost of educational expenses for spouses or other dependents of providers of services, etc. PRM Section 2102.

Thus, in listing the costs that are not related to patient care, the Provider Manual specifically mentions the education expenses for spouses and other dependents of providers of services. Notably, the Provider Manual does not mention the educational expenses of providers of services, such as residents, themselves. Therefore, the educational expenses of these providers of services must be related to patient care. That is the only reasonable interpretation.

Further, in a recent Q and A that CMS issued on April 8, 2005, entitled “Medicare Policy Clarifications on Graduate Medical Education Payments for Residents Training in Non-Hospital Settings,” CMS defines in its answer to Question #5 what are the teaching supervisory costs that a hospital must incur with respect to training occurring in a nonhospital site in order to qualify for D-GME and IME funding. CMS states that the teaching physician costs that the hospital must incur do not include billable direct patient care time, but rather include time spent on non-billable GME teaching activities, “such as general clinical didactic training or assessing the resident’s performance.” (See Answer #5, at Attachment #1.)

Therefore, according to this CMS instruction, the hospital must incur the cost of the faculty teaching the didactic seminars, but then, according to this proposed rule, the hospital cannot count the time the residents spend in these seminars. Such a result would be absurd policy.

CMS Correspondence

Perhaps most significant, the CMS official who directly oversees GME policy issues, addressed the very question at issue here in 1999. In response to correspondence asking how CMS interprets the phrase “patient care activities” with respect to training occurring in nonprovider settings, Tzvi Hefter, Director, CMS Division of Acute Care, in a letter dated September 24, 1999, attached, responded:

“HCFA interprets the phrase ‘patient care activities’ broadly to include any patient care oriented activities that are part of the residency program. As you stated in your letter, this can include . . . scholarly activities such as educational seminars, classroom lectures, research conferences, patient care related research as part of the residency program and presentations of papers and research results to fellow residents, medical students, and faculty. Therefore, as long as the residents are primarily involved in patient care oriented activities and other program requirements are met, a hospital may include other educational activities as part of the entire time spent by residents in non-hospital settings and include this time in its FTE count and GME/IME payment calculations.” (Emphasis added.) (See Attachment #2).

We do not believe the CMS letter could have been more clear or to the point. Further, as described above, this CMS interpretation of “patient care activities” is supported by the language of the Medicare statute and regulations, neither of which refer to “direct patient care,” but rather mention “activities relating to patient care.”

CMS’s main argument in the proposed rule is that the plain meaning of “patient care activities” clearly means direct patient care. If the meaning was not plain to the CMS Director overseeing GME issues himself, how then could it have been plain to hospitals and medical and dental schools?

As CMS is well aware, and contrary to its implication in the proposed rule, this 1999 CMS correspondence was distributed widely to many hospitals and universities. Indeed, ADEA explained this to CMS officials in a meeting in April of 2004. Many hospitals and medical and

dental schools have relied upon the CMS letter's unequivocal language, which states that hospitals could include resident didactic time in a nonhospital setting in calculating FTEs for D-GME and IME.

Federal District Court Opinion in *Riverside*

In a case involving Riverside Methodist Hospital in Ohio, the fiscal intermediary denied IME payments to the hospital for time the family practice residents were in journal club, practice management seminars, ob/gyn seminars, and psychiatric seminars. The basis for the intermediary's denial was that this time was not related to "hands-on patient care." All of these activities, however, were required components of the family practice residency program under the ACGME standards.

The hospital appealed the fiscal intermediary's denial to the Provider Review Reimbursement Board (PRRB), and the PRRB sided with the hospital, concluding that this didactic time should be counted. The CMS Administrator reversed the PRRB's decision in November of 2001, however, and the hospital appealed to Federal District Court.

A Federal District Court in 2003 reversed the CMS Administrator's position that didactic time couldn't be counted for IME payments at least for training occurring in a hospital setting, in *Riverside Methodist Hospital v. Thompson*, 2003 U.S. Dist Lexis 15163 (S.D. Ohio, July 31, 2003). In *Riverside*, the Court held that in the hospital setting there was no requirement that a resident's time be counted only if it involved patient care.

The Court did not need to resolve or decide the question of whether this didactic time was related to patient care. However, the Court did take note of the issue in footnote 11, stating:

"It could be very difficult to define exactly what is included in the Secretary's phrase 'patient care costs.' For example, if a resident suspects that a patient has a mental disorder, and does some research in order to better understand the patient's condition and treatment, is this time spent for 'patient care'? If the same resident, for the same purpose, attends a psychiatric seminar, is this time spent for 'patient care'?"

Didactic Activities Are Relating To Patient Care

Lastly, the didactic activities that are included in all ACGME and CODA accredited residency programs are activities relating to patient care as the Medicare statute and regulations require. In conferences and seminars, the residents are encouraged to discuss how the material relates to patients whom they are treating. The journal clubs, literature reviews, case presentation, laboratory techniques are related to patients who are being treated. Even seminars on communication skills are related to patient care, as communication with patients, family, and other professionals is discussed in the context of how to care for patients presently.

Conclusion

As described above, the Medicare statute and regulations do require that residents be involved in activities relating to patient care for the time to be counted towards D-GME and IME in a nonhospital setting. However, the Medicare statute, regulations, manuals, and CMS's own correspondence make very clear that "activities relating to patient care" include more than just direct patient care and that didactic time that is part of an ACGME- or CODA-accredited program is an activity relating to patient care. Therefore, this didactic time meets the statutory

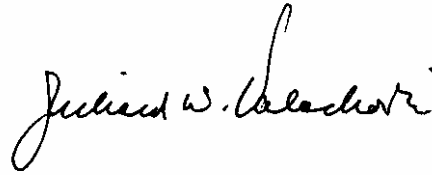
and regulatory definition of activities related to patient care and should be counted for both D-GME and IME purposes.

We look forward to working with CMS staff to resolve this critical issue. If there are any questions concerning these comments, please contact Jack Bresch, Associate Executive Director and Director of the Center for Public Policy and Advocacy, American Dental Education Association, at 202/289-7201, Ext. 169.

Respectfully submitted by,

Handwritten signature of Kenneth L. Kalkwarf DDS in black ink.

Kenneth L. Kalkwarf, D.D.S.
President

Handwritten signature of Richard W. Valachovic in black ink.

Richard W. Valachovic, D.M.D., M.P.H.
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