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Hospitals Suffer Setback in IME Research Case

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The issue of whether hospitals are entitled to Medicare Indirect Medical Education (IME) payment for time spent by residents in "pure research" has a turbulent history. Initially, federal district courts in Ohio, Arizona, Rhode Island, Illinois, and Michigan all ruled that such reimbursement is appropriate. In 2008, however, the U.S. Court of Appeals for the First Circuit in *Rhode Island Hospital v. Leavitt*, 548 F.3d 29 (2008) issued a contrary decision and upheld the Secretary's disallowance of IME for such activities. A year and a half later, the U.S. Court of Appeals for the Seventh Circuit reached a contrary conclusion, deciding that reimbursement for such expenses is allowable. *University of Chicago Med. Ctr. v. Sebelius*, 618 F.3d 739 7th Cir. (2010). Now, the U.S. Court of Appeals for the Sixth Circuit has added its voice to the tumult, upholding the Secretary's position and her denial of reimbursement for such expenses. Henry Ford Health Sys. v. Department of HHS, No. 10-1209 (6th Cir. Aug. 18, 2011) [PDF]

The single issue in the district court cases and in the Rhode Island case was how to read the regulation at 42 C.F.R. § 412.105(f), which specifies that a resident's time may be included in the IME FTE count if the resident is (1) enrolled in an approved teaching program and (2) assigned to a "portion" of the hospital subject to the prospective payment system. The dispute principally focused on whether the word "portion" as used in the regulation refers to a geographic location within the hospital, as the hospitals have contended, or to a function that the resident is performing within the hospital irrespective of physical location, as the government has argued.

In 2001, the Secretary attempted to buttress her position by amending the regulation to "reiterate" the "long standing" policy that "time spent by a resident in research not associated with the treatment or diagnosis of a particular patient" may

not be included in the IME count. 42 C.F.R. § 412.105(f)(iii)(B). The district courts, including the district court in the *Henry Ford* case, all rejected the Secretary's position that the 2001 policy applied to periods prior to that date, and all concluded that the word "portion" refers to a geographic location, not to some "patient care" requirement. The First Circuit, however, adopted a contrary view and agreed with the Secretary's position.

While this matter was brewing in the courts, Congress entered the fray. As part of the Affordable Care Act (ACA), Congress addressed a variety of non-patient care activities and whether those activities could be reimbursed for IME. In § 5505(b) of the ACA, Congress provided that "all time spent by an intern or resident in an approved medical residency program in non-patient care activities, such as didactic conferences and seminars, as such time and activities are defined by the Secretary, that occur in the hospital" is to be counted effective January 1, 1983. Congress also specified in the ACA, however, that for periods after October 1, 2001, all time spent by an intern or resident in "an approved medical residency training program in research activities that are not associated with the treatment or diagnosis of a particular patient … shall not be counted." ACA § 5505(c)(3). Congress specifically left open the question of whether, under the ACA, time spent in research activities prior to October 1, 2001, should be allowed, stating that the new section regarding research time "shall not give rise to any inference as to how the law in effect prior to such date should be interpreted." Id.

The ACA was helpful, but it did not end the conflict for periods beginning prior to October 1, 2001, periods that the ACA purported not to affect. For that time, the litigation continued, with the first post-ACA case addressing pre-October 1, 2001 IME research time being issued by the Seventh Circuit in the University of Chicago case. In that case, the court of appeals acknowledged that the issue of reimbursement under the pre-ACA regulation was "less than clear," and stated that where there is an ambiguous regulation, the agency's construction of the regulation is entitled to deference. The court went on to conclude, however, that research time should be considered to be a non-patient care activity, just as didactic conferences and seminars are, when performed in the hospital, and that such time

should be counted, under the ACA, for periods beginning January 1, 1983. The court then concluded that the "no inference" provision in the ACA is unclear and does not "contradict the clear meaning of the earlier language allowing reimbursement for non-patient care activities during the time relevant to the present appeal."

The Seventh Circuit's reasoning, however, did not persuade the Sixth Circuit, which recently issued a contrary decision. In framing the issue, the Sixth Circuit noted that in the ACA, Congress has required the Secretary to reimburse hospitals for *"all the time spent by an intern or resident … in non-patient care activities … as such time and activities are defined by the Secretary"* (emphasis supplied). The court noted that the Secretary recently promulgated a regulation that implements this provision and excludes from hospitals' Medicare IME reimbursement the time spent by residents conducting pure research, see 75 Fed. Reg. 71,800, 72,261 (Nov. 24, 2010). The court then concluded that, in promulgating the regulation, the Secretary had reasonably exercised the authority delegated to her under the Act. The court stated that the term "non-patient care activities" is ambiguous; that the qualifying examples of didactic conferences and seminars "say nothing about whether pure research qualifies"; and that the statute delegates to the Secretary the authority to "define[]" eligible "non-patient care activities." Furthermore, the court concluded, the distinction that the Secretary has made appears reasonable. Didactic conferences and seminars, according to the court, differ from pure research rotations in that conferences and seminars touch on patient care, thereby increasing the benefit to current patients. Accordingly, the court concluded, the Secretary's exclusion of pure research comports with the relevant statute and must be given controlling weight.

The court then dealt with the provider's contention that the Secretary's regulation was impermissibly being applied to past periods. The court cited the Supreme Court's decision in Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) in which the Court recognized that express congressional authorization for an agency to regulate retroactively will defeat the general presumption that agency regulations must be applied prospectively. Here, the court said, Congress gave such

retroactive authorization in §§ 5505(b) and 5505(c)(i), allowing the Secretary to "define[]" eligible "non-patient care activities," and to do so retroactively to periods beginning on or after January 1, 1983. Thus, according to the court, the Secretary's new regulation implementing the ACA may properly be applied retroactively, thereby denying the reimbursement of IME research time.

Ober|Kaler's Comments

The Sixth Circuit's decision in Henry Ford is the first ruling on the validity of the Secretary's November 2010 ACA regulations and their application to claims for IME research time prior to October 1, 2001. The court treated the issue as one in which the Secretary, post-ACA, was writing on a clean slate and one where, given the language of the statute, the Secretary was acting pursuant to a broad grant of authority. The court concluded that, in circumstances such as these, the Secretary's administrative authority is at "its apex." The Sixth Circuit's decision on this issue will probably not be the last. There will likely continue to be further litigation, and whether other courts will agree with the Sixth Circuit is open to question.