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Eastern District of Michigan Rejects Secretary's Position on IME/Research Time and New Residency Programs

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According to the United States District Court for the Eastern District of Michigan, the Secretary of Health and Human Services (Secretary) may not exclude residents from a hospital's indirect medical education (IME) count simply because they are engaged in research rather than providing direct patient care and may not exclude new programs (for purposes of resident cap adjustments) which are accredited during the time frame specified in the applicable regulations. While not definitive (as this decision may be appealed), *Henry Ford Health System v. Sebelius* is certainly a "win" for providers. No. 09-10195, 2009 U.S. Dist. LEXIS 121443 (E.D. Mich. Dec. 30, 2009). [PDF]

The *Henry Ford* court analyzed both of the provider's issues according to the two pronged analysis of *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994). In that case, the Supreme Court explained that an agency's interpretation of its own ambiguous regulation is due deference. That deference, however, is not due where the interpretation is contrary to the plain language of the regulation or contradicted by evidence of the Secretary's intent at the time of the regulations promulgation. The *Henry Ford* court concluded that the Secretary's interpretation of both its IME regulations and its new program regulations effectively failed both prongs of the *Thomas Jefferson* test.

The Secretary first contended that certain of the provider's IME resident Full Time Equivalents (FTEs) should be excluded because they were engaged in research, rather than providing direct patient care. The applicable IME regulation provided during the cost years in question that, to be counted, residents must be assigned to one of certain identified "areas." These "areas" included the portion of the hospital subject to the Prospective Payment System (PPS) and the hospital's outpatient department. The regulation did not, on its face, make any reference to the activities a resident performs in these "areas." The Secretary, however, argued that "area" and "portion" were ambiguous and that they can be read to mean either "geographic location" or "purpose." Accordingly, the Secretary interpreted the regulation to exclude

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residents who, even where they were assigned to the identified areas of the hospital, were not engaged in direct patient care activities.

The *Henry Ford* court first addressed the argued ambiguity of the words in question. While noting that there have been court decisions cutting both ways, the *Henry Ford* court referenced several cannons of statutory interpretation in its decision that, in context, the words "area" and "portion" cannot be read to describe a "purpose" rather than a "location." Read in context with the remainder of the regulation, the court found the words required that the Secretary count, for IME reimbursement purposes, all residents assigned to appropriate "areas" regardless of the type of work they performed there.

Continuing its analysis, the court also found that the Secretary's current interpretation was contrary to significant evidence regarding her intent at the time of the regulations promulgation. The court noted, for instance, that prior to the current interpretation, there were no manual provisions or other instructions to intermediaries to investigate residents' activities, rather than their location. The court also noted that the Secretary already reimbursed hospitals for the time residents spent "on call" during which they were, indisputably, not engaged in direct patient care. Even were the regulation ambiguous, the court found, the Secretary could not now advance an interpretation so contrary to all other indications of her intent.

The court's analysis of the provider's new programs followed a similar path. The provider had been operating two educational programs that were unaccredited prior to January 1, 1995. They were both initially accredited, however, after this important date. While the applicable regulation states that a program will be considered new if it is "established" between January 1, 1995 and August 5, 1997 or initially accredited on or after January 1, 1995, the Secretary argued that the programs should not be considered new. More specifically, the Secretary argued the programs in question should not be considered new because they were "established" when they began operating (prior to 1995) and therefore could not be new even though they were initially accredited after January 1, 1995, as required by the applicable regulation.

The *Henry Ford* court held that the applicable regulatory language was unambiguous. The language, noted the court, clearly provided that a program should be considered new where it met either of the regulatory criteria. The Secretary's interpretation was, accordingly, "without merit as the plain language of the regulation is clear." Additionally, the court went on to find that the Secretary's interpretation conflicted with evidence of her intent at the time of the regulation's promulgation. At that time, the Secretary specifically published language indicating that a provider could qualify for an increase to its resident cap as a result of an expansion and accreditation of an existing program. Later, a CMS Program Memorandum was issued instructing Intermediaries to follow a simple, two-step inquiry when determining whether a program was new: Intermediaries were told to first ask whether a program received initial accreditation on or after January 1, 1995 and, only then, to inquire whether the hospital had trained residents prior to 1995. Programs that received initial accreditation on or after January 1, 1995 were to be considered "new" even if they had previously trained residents. Taken together, the court held that these indications of the Secretary's intent at the time of the regulation's promulgation demonstrated the Secretary never intended to disallow programs that were "established" before they were initially accredited.

Ober|Kaler's Comments: Both resident research time and new residency programs are hotly contested issues with large reimbursement sums at stake. The *Henry Ford* court's careful analysis will provide strong persuasive support for providers in crafting arguments in relation to these issues.