

Federal Court Enjoins CMS From Applying the “Least Costly Alternative” Payment Policy to Covered Medicare Part B Pharmaceuticals

by Ted R. Mannen and Robert E. Wanerman

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On October 16, 2008, the United States District Court for the District of Columbia permanently enjoined the Secretary of Health and Human Service from implementing coverage policies that would have based Medicare reimbursement for a covered Part B inhalation drug on the “least costly alternative”. *Hays v. Leavitt*, No. 08-01032(HHK)(D.D.C., Oct. 16, 2008).

The plaintiffs, a Medicare beneficiary and the manufacturer of an inhalation drug, challenged four local coverage determinations that set the Medicare reimbursement rate based on the “least costly alternative” policy in the Medicare Program Integrity Manual instead of using the formula in 42 U.S.C. § 1395w-3a, which directs the Secretary to set the reimbursement for such drugs at 106% of the average sales price for that drug as reported quarterly to the Secretary.

The court rejected the Secretary’s argument that the coverage provision in 42 U.S.C. § 1395y(a) prohibiting payment for items and services that are “reasonable and necessary” also authorized him to make payment determinations based on that standard. Instead, the court applied the test taken from *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984) and concluded that Congress had expressly addressed both Medicare coverage and payment for covered Part B drugs in the statute, and that the “reasonable and necessary” language of § 1395y(a) was limited to coverage and did not authorize the Secretary to determine reimbursement using a formula that deviated from the comprehensive payment language of § 1395w-3a.

The court found that the phrase “reasonable and necessary” refers only to coverage for items and services, and not to expenses for those same items and services. In determining that the Secretary had exceeded his statutory authority, the court noted that “[i]f the Secretary had broad discretion to determine what expenses are reasonable and necessary under section 1395y(a), the Secretary may re-write these formulas to

her liking whenever she believes they provide for an unreasonable or unnecessary expense simply by stating that any payment of expenses above her desired payment amount are barred as unreasonable or unnecessary under section 1395y(a).”

This decision reaffirms the limits on administrative discretion in the Social Security Act, and may directly affect the introduction of new drugs and therapies for Medicare beneficiaries.

The plaintiffs were represented by Stuart Gerson and Robert Wanerman of Epstein Becker & Green, P.C., and were assisted by Ted Mannen, Paul Campbell, and John Benevelli of EBG Advisors.

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