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D.C. Circuit Rules That Medicare Coverage Determinations Cannot Set Reimbursement Rates

by Robert Wanerman and Stuart Gerson

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On December 22, 2009, the United States Court of Appeals for the District of Columbia Circuit issued a decision confirming the distinction between Medicare coverage and reimbursement by ruling that the Medicare statute precludes the Secretary of the Department of Health and Human Services ("Secretary") from issuing a coverage determination that sets the reimbursement rate for a covered drug based on the "least costly alternative." *Hays v. Sebelius*, No. 08-5508 (D.C. Cir., Dec, 22, 2009). This decision limits the Secretary's discretion to determine reimbursement rates for covered pharmaceuticals, and potentially affects any administrative proposal to limit reimbursement for medical devices, supplies, and procedures as well.

In this case, a Medicare beneficiary challenged local coverage determinations that set the Medicare reimbursement rate for a nebulizer drug based on the "least costly alternative" policy in the Medicare Program Integrity Manual instead of using the formula in the Medicare Statute,[1] which directs the Secretary to set the reimbursement for such drugs at 106 percent of the average sales price for that drug as reported quarterly to the Secretary.[2] The District Court rejected the Secretary's argument that the coverage provision in the Medicare Statute that refers to items and services that are "reasonable and necessary" also authorized her to make determinations setting reimbursement up to the "least costly alternative" for that item or service.[3]

Although the Secretary appealed and repeated the arguments raised before the District Court, the D.C. Circuit agreed with the District Court's decision. It held that Medicare coverage determinations cannot incorporate reimbursement rates. The Court determined that (1) the "reasonable and necessary" standard in the Medicare statute was unambiguous and that it could not defer to the Secretary's interpretation;[4] (2) nothing in the statute authorizes the "least costly alternative" policy; and (3) once an item or service is covered because it is reasonable and necessary, it must be reimbursed as specified elsewhere in the Medicare statute. The Court relied on several factors to reach its conclusion. First, the Court explained that the phrase "reasonable and necessary" in the statute refers to "items and services" and not to expenses.

Second, the Court noted that while "items and services" can be "reasonable and necessary for the diagnosis or treatment of illness or injury," expenses cannot. Third, the Court found that the title of the statute, which refers to "items and services specifically excluded" confirmed that items and services must be reasonable and necessary to qualify for Medicare coverage, not expenses.

The Court also agreed that the distinction between the portions of the Medicare statute that address coverage and reimbursement was consistent with the separate statutory reimbursement formula in Section 1395w-3a that requires that Medicare reimbursement for multiple source drugs covered under Part B be set at 106 percent of the average sales price for that drug using a volume-weighted average. The Court concluded that this set of formulas is so detailed that the Secretary could neither ignore the formula nor exercise any discretion to impose a different reimbursement rate or methodology. As a result, the Court observed that if it accepted the Secretary's argument that reimbursement could be based on 106 percent of the "least costly alternative" for a specific drug, this "would permit an end-run around the statute."

This decision reaffirms the basic distinction between coverage, which is a binary decision based on whether an item or service is reasonable and necessary, and reimbursement for that item or service, which is determined based on methodologies contained in other sections of the Medicare statute. This decision also limits the Secretary's discretion when making coverage determinations by foreclosing any consideration of the reimbursement for the particular item or service, which is consistent with the Secretary's own regulations.[5]

The Medicare beneficiary - Appellee was represented by Stuart Gerson and Robert Wanerman of EpsteinBeckerGreen.

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This Client Alert was authored by **Robert Wanerman** and **Stuart M. Gerson**. For additional information about the issues discussed in this Client Alert, please contact one of the authors or contributors or the EpsteinBeckerGreen attorney who regularly handles your legal matters.

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Lynn Shapiro Snyder, Esq.
EDITOR

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Endnotes:

[1] 42 U.S.C. § 1395w-3a.

[2] The district court's decision is summarized in an EBG Client Alert, which is available at: http://www.ebglaw.com/showclientalert.aspx?Show=9324

[3] 42 U.S.C. § 1395y(a)(1) states that "no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services . . . which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ."

[4] *See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984).

[5] 42 C.F.R. § 400.202.