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HEALTH INDUSTRY ALERT

COURT REJECTS MEDICARE'S "LEAST COSTLY ALTERNATIVE" DRUG PAYMENT POLICY

As health care costs continue to rise, the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) are attempting to curb federal health care program spending, including Medicare spending, through a variety of regulatory and sub-regulatory tools used to lower federal programs' costs. A recent federal court decision found that the Least Costly Alternative (LCA) policy could not be used to set the cost of Medicare covered items and services.

SUMMARY

In *Hays v. Leavitt*, the U.S. District Court for the District of Columbia prohibited the Secretary of HHS from setting Medicare payment rates by applying the LCA policy to a beneficiary's claim for a Medicare Part B drug.[1] The case involved a Medicare beneficiary's challenge to the LCA policy, which, as applied to her prescription inhalation drug, would have provided reimbursement based not on the statutorily mandated payment formula for the drug, but on the cost of the least expensive "reasonably feasible and medically necessary" alternative drugs. The Secretary argued that the applicable statute gave him authority to set "reasonable and necessary" reimbursement rates for drugs covered under Medicare Part B. The court disagreed with the Secretary's interpretation and, in granting the plaintiff's motion for summary judgment, held that the Secretary lacked the authority to apply the LCA policy under the applicable statute.

MEDICARE COVERAGE POLICY BACKGROUND

Medicare covers items and services that are deemed "reasonable and necessary" for the diagnosis or treatment of an illness or injury. Medicare Administrative Contractors (MACs) interpret and apply the "reasonable and necessary" standard when developing Local Coverage Determinations (LCDs) for specific items and services. CMS Regulations state that LCDs may deny coverage for a particular item or service that is not "reasonable and necessary," but may not alter the statutorily required reimbursement for an item or service.[2] According to the relevant statute, the type of drug at issue in *Hays* is reimbursed based upon the drug's average sales price plus six percent (ASP+6%).[3]

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[1] *See* Case No. 1:08-cv-01032-HHK (D.D.C. 2008).
[2] 42 C.F.R. § 400.202 (2008).
[3] 42 U.S.C. § 1395w-3a(b)(1)(A).

CMS had recently issued the LCA policy in informal agency guidelines that required MACs to reimburse covered services and items based on the amount of the least costly "reasonably feasible and medically appropriate alternative pattern of care."[4] The validity of this apparent departure from the statutory ASP+6% formula was at issue in *Hays*.

CASE ANALYSIS

Hays, a Medicare beneficiary, was prescribed DuoNeb, an inhalation treatment for chronic obstructive pulmonary disease that provides a combination of two drugs in one dose. Prior to April 2008, DuoNeb and the two component drugs were each reimbursed at the statutorily set rate of ASP+6%. However, in April 2008, several MACs issued LCDs applying the LCA policy to change DuoNeb's reimbursement rate. The new LCDs set reimbursement for DuoNeb at ASP+6% of the two component drugs, rather than at its own ASP+6%.

Hays' motion for summary judgment asked the court to hold that the Secretary lacked the authority to apply the LCA policy to DuoNeb.[5] Hays originally filed the motion together with Dey, the manufacturer of DuoNeb. However, the court held that the drug manufacturer had no standing because the relevant statute allows only beneficiaries to challenge LCDs, and dismissed Dey from the case.

Hays argued that the plain language of the applicable statute setting forth the specific reimbursement for Part B covered drugs (ASP+6%), limited the Secretary's authority to determine reimbursement rates for particular services and items.[6] Hays further argued that the statutory language providing that "no payment may be made . . . for any expenses incurred for items or services . . . which are not reasonable and necessary for . . . diagnosis or treatment"[7] clearly limited the Secretary's discretion to determine reimbursement rates. According to Hays, the statutory phrase "reasonable and necessary" modifies "items and services," while the Secretary urged that it modifies "expenses." Under Hay's interpretation, where a Medicare statute sets forth a specific method for calculating reimbursement for a covered Part B drug, a Medicare Administrative Contractor's authority in developing an LCD for such a drug is limited to determining whether the drug is covered as "reasonable and necessary." In contrast, under the Secretary's interpretation, the MAC would be permitted to determine whether the expense of the drug is reasonable and necessary, and thus to make a reimbursement decision.

The court examined the Secretary's arguments in light of the standards set forth in *Chevron v. Natural Resources Defense Council*, the leading Supreme Court case regarding deference to agency interpretations of statutes.[8] In *Chevron*, the Supreme Court held that if Congress has "directly spoken to the precise question at issue" through statutory language, the courts may not defer to agency interpretations that diverge from the statute. However, if the statute does not directly address the issue, the courts must defer to "permissible" constructions of statutory provisions by the agency charged by law with administering the statute.

Given the explicit and detailed language in the statute regarding reimbursement formulas, the court in *Hays* determined that Congress clearly did not intend to convey such broad authority or discretion to the Secretary. Under the framework for analyzing agency action where Congressional intent is clear, the court determined that the Secretary does not have

[4] *See* Medicare Benefit Policy Manual § 110.1; Medicare Program Integrity Manual § 13.4.
[5] Hays originally filed the motion together with Dey, the manufacturer of DuoNeb. However, the court held that the drug manufacturer had no standing because the relevant statute allows only beneficiaries to challenge LCDs, and dismissed Dey from the case. *Hays* at 8.
[6] 42 U.S.C. § 1395w-3a(b)(1)(A).
[7] 42 U.S.C. § 1395y(a)(1)(A) (2008).
[8] 467 U.S. 837 (1984). *See also Methodist Hosp. v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994) (holding that additional deference is due in the Medicare context due to the complexity of the Medicare program).

discretion to set a different reimbursement rate for drugs covered under Part B, because Congress clearly set the statutory reimbursement rate. The court emphasized that adopting the Secretary's reading of the statute would give the Secretary "enormous discretion" to set payment for covered items and services and thus, in essence, to ignore Medicare's existing payment provisions.

The court held that according to the most natural reading of the statutory language, the statute authorized the Secretary to evaluate whether particular "services and items" were "reasonable and necessary," but not to evaluate whether the "expenses" for such services and items were reasonable and necessary. Thus, the court granted the plaintiff's motion for summary judgment and held that the Secretary lacked the authority to apply the LCA policy to DuoNeb.

IMPACT OF THE HAYS DECISION

With budget pressures dominating discussions about Medicare reform, CMS will continue to look for ways to reduce Medicare costs, including payments for drugs. Although CMS withdrew an earlier LCD applying the LCA policy to another inhalation drug after a legal challenge by Medicare beneficiaries,[9] CMS officials have indicated in the wake of the *Hays* decision that the agency continues to believe that its statutory interpretation is correct. It is unclear if CMS will appeal the *Hays* decision.

Significantly, however, language in the *Hays* decision may provide a clue regarding CMS's possible reaction to the decision, as follows—

> Defendants' argument that nothing in [the statute] precludes the Secretary from interpreting the "reasonable and necessary" standard as permitting considerations of cost misses the point. The point *in this case* is not whether the Secretary may consider cost when determining whether an item or service is reasonable or necessary, but whether the Secretary, once she has decided that an item is reasonable or necessary and thus covered by the Act, may set the payment rate by deciding which expenses, associated with the covered item, are reasonable and necessary.[10]

[9] *Coakley v. Cigan Gov't Servs.*, Case No. 1:08-cv-00976-EGS (D.D.C. 2008).
[10] *Hays* at 17 (emphasis added).

This language suggests a possible avenue for CMS to achieve its cost-reduction goals without applying the disputed LCA policy. Specifically, it appears to indicate that although CMS may not alter statutory payment formulas for covered drugs it considers too expensive, it may decline to cover such drugs in the first place on the grounds that they are unreasonably expensive. If this is the case, it may turn out that the plaintiff's victory in *Hays* is only temporary.

CONTACT INFORMATION

If you have any questions regarding this Alert, please contact:

Jorge Lopez, Jr. ..... jlopez@akingump.com ..... 202.887.4128 ..... Washington, D.C.
Eugene E. Elder ..... gelder@akingump.com ..... 202.887.4149 ..... Washington, D.C.
Mara B. McDermott ..... mmcdermott@akingump.com ..... 202.887.4336 ..... Washington, D.C.
Anna R. Dolinsky ..... adolinsky@akingump.com ..... 202.887.4504 ..... Washington, D.C.