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DC CIRCUIT INVALIDATES MEDICARE "LEAST COSTLY ALTERNATIVE" POLICY

On December 22, 2009, the US Court of Appeals for the DC Circuit issued a decision in a closely-watched case that could have significant implications for Medicare payment policy. In *Hays* v. *Sebelius*, the court struck down a policy based on the "least costly alternative" (LCA) approach, in which Medicare pays for a covered item or service based on the payment rate for a less costly item or service that is deemed a medically appropriate alternative.[1] That is, when a Medicare contractor determined that two or more covered items or services were clinically comparable it would limit payment to the payment rate prescribed for the least costly item or service, and not pay the additional cost of the more expensive item or service. In striking down the LCA policy, the DC Circuit held that the Medicare statute requires Medicare to pay for covered items and services at statutorily prescribed rates, where applicable.[2]

BACKGROUND

At issue in *Hays* was whether the "reasonable and necessary" provision in the Medicare statute authorizes LCA policies. Under this provision:

> [N]o payment may be made under part A or part B of [Medicare] for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.[3]

As discussed in this advisory, the government argued that this sentence bars Medicare coverage for "expenses" that are not "reasonable and necessary," while the plaintiff argued that the sentence bars coverage for "items and services" that are not "reasonable and necessary." The government's interpretation suggests that the Centers for Medicare and Medicaid Services (CMS) or its claims-processing contractors could pay for a covered item or service at a lower payment rate than would be otherwise applicable. Under this interpretation (which is not set forth in any regulations), when applying an LCA, the Medicare program would not cover the excess payment for the more expensive, clinically comparable, alternative. The payment rate would still be determined by the governing statutory formulas—but at the rate for the least costly alternative

1 *See Hays* v. *Sebelius*, No. 08-5508, 2009 WL 4912383 (D.C. Cir. 2009).
2 *Hays*, 2009 WL 4912383, at *1.
3 42 U.S.C. § 1395(y)(a)(1)(A) (Social Security Act (SSA) § 1862(a)(1)(A)).

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therapy (e.g., the payment rate for a Part B drug that was subject to an LCA policy would be 106 percent of the Average Sales Price (ASP) for the lower-priced drug that was considered a medically appropriate alternative). One consequence of this interpretation was that Medicare beneficiaries who wish to receive the more expensive item or service may be liable for increased out-of-pocket costs (i.e., to gain access to the more expensive item or service, beneficiaries may have to pay the excess, in addition to paying Medicare's standard cost-sharing amounts for the least costly alternative).[4]

CMS' sub-regulatory guidance has long required that Medicare contractors apply the LCA approach to durable medical equipment (DME). This guidance also provides that contractors have the discretion to apply LCA to other items and services.[5] As a result, LCA policies have been used in the DME area; more rarely, this approach has also been extended to drugs. *Hays* is the first case that has squarely addressed the question of whether the Medicare statute allows the use of LCA policies.

LEGAL ARGUMENTS IN *HAYS*

In April 2008, four Medicare contractors issued local coverage determinations (LCDs) that applied LCA principles to DuoNeb, an inhalation drug used in the treatment of chronic obstructive pulmonary disease. DuoNeb provides a combination of albuterol and ipratropium bromide in one dose. These LCDs provided:

> The medical necessity for administering an FDA-approved unit dose combination of albuterol and ipratropium (J7620) compared to the separate unit dose vials of albuterol and ipratropium has not been established. Therefore . . . payment [for DuoNeb] will be based on the allowance for the least costly medically appropriate alternative—2.5 units of J7613 [albuterol] and 0.5 units of J7644 [ipratropium bromide].[6]

In other words, under these LCDs, payment for DuoNeb would equal the sum of the payments for separate doses of albuterol and ipratropium bromide. Ilene Hays, a Medicare Part B beneficiary, challenged the LCA policy, arguing that it exceeded CMS' statutory mandate. The district court agreed and granted Hays' motion for summary judgment. The government appealed.

The government defended LCA based on the theory outlined above as an application of the Medicare statute's "reasonable and necessary" provision. Specifically, the government argued that: (1) the phrase "reasonable and necessary" in SSA § 1862(a)(1)(A) modifies the word "expenses" and thereby authorizes Medicare to determine that some or all of a product's costs are not reasonable and necessary; and (2) because Medicare could deny coverage for all of a product's costs, it should also have the "lesser" authority to deny coverage for part of a product's costs under an LCA policy.

Hays countered that the phrase "reasonable and necessary" in § 1862(a)(1)(A) modifies the words "items or services" rather than "expenses." Accordingly, she argued that in making a coverage decision, CMS or its contractors have a binary choice to make: namely, to cover an item or service because it is medically necessary or not to cover it. Moreover, she argued that § 1862(a)(1)(A) is not a payment provision and does not allow the option of covering only part of the item's otherwise-statutorily prescribed payment rate; if the item was covered, then Medicare must pay the full payment rate specified in the applicable statute for that category of the item. For Part B drugs like DuoNeb, the statutorily-prescribed payment formula is generally 106 percent of ASP.[7]

THE DC CIRCUIT'S OPINION

The court analyzed CMS' interpretation under the standards set forth in *Chevron USA* v. *Natural Resources Defense Council*, which requires reviewing courts to determine whether a statute is clear on its face and, if it is not, whether the agency's interpretation of

4 Conversely, if LCA were a payment policy (which would require new legislation), Medicare beneficiaries would owe only the normal Medicare copayment amount.

5 *See* Medicare Program Integrity Manual, Publication 100-08, Chapter 13-Local Coverage Determinations, Section 13.4.A.

6 *See Hays* v. *Leavitt*, 583 F.Supp.2d 62, 65 (D.D.C. 2008).

7 42 U.S.C. §§ 1395w-3a(b)(1), 1395u(o)(1)(G)(ii).

ambiguous statutory language is reasonable and therefore requires deference.[8] Applying that test, the court held that "[s]everal features of the Medicare statute . . . unambiguously foreclose" the interpretive theory the government offered to defend LCA.[9]

First, the court noted that "only a dependent clause separates 'reasonable and necessary' from the phrase 'items or services.' 'Expenses,' by contrast, appears earlier in the sentence."[10] Although the "Rule of the Last Antecedent," is not an absolute and can be overcome, in this case the court held that the "Rule of the Last Antecedent" applied and concluded that the phrase "reasonable and necessary" modifies only the immediately preceding phrase—"items or services"—and not "expenses."[11]

Second, because the succeeding subparagraphs of the statute describe items or services that Medicare covers (not expenses that it covers), the court reasoned that the statutory language applying the "reasonable and necessary" limitation "except for items and services described in a succeeding subparagraph" similarly meant that the "reasonable and necessary" standard applies only to "items or services" that are covered, and not to "expenses."

Third, the court held that the phrase "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" foreclosed the government's interpretation, because "[i]tems and services diagnose, treat, and improve; expenses do not."[12]

Fourth, the court cited the title of § 1862(a), "Items or service specifically excluded," which does not mention expenses and, according to the court, "confirm[ed] the obvious: that items or services, not expenses, must be reasonable and necessary to qualify for Medicare coverage."[13]

Finally, the court analyzed the drug reimbursement provisions in the Medicare statute (which it characterized as "mandatory") and noted that these detailed payment provisions would have little meaning if CMS and its contractors could simply decide that part of the statutorily-specified payment rate was not "reasonable and necessary":

> Section 1395w-3a [SSA Section 1847A] provides that for multiple source drugs like DuoNeb "the amount of payment . . . *is*" 106 percent of the average sales price, as determined under the statutory formula. 42 U.S.C. § 1395w-3a(b)(1) (emphasis added). The statutory formula is in turn based on the volume-weighted average of the average sales prices of drugs within the same Healthcare Common Procedure Coding System (HCPCS) billing and payment code. 42 U.S.C. § 1395w-3a(b)(6). DuoNeb's HCPCS code includes neither component drug.[14]

Based on this combination of interpretive factors, the court rejected the LCA approach. The court held that the statute authorizes CMS to determine that an item or service is reasonable and necessary (in which case it must be reimbursed under the governing statutory payment formula), or is not reasonable and necessary (in which case no payment can be made)—but the statute does not give CMS a third, "partial coverage," option.

The court noted that "the Secretary would have the authority to refuse payment for the difference in cost between a prescribed item or service and its least costly alternative" if the statutory provision in question was rewritten or "if the reimbursement formulas were either discretionary or based on the cost of an item or service's therapeutic equivalents."[15] However, in the *Hays* case, none of these hypotheticals applied so LCA was foreclosed.

IMPLICATIONS OF THE DECISION

It is not yet clear whether the government will ask the DC Circuit to reconsider the *Hays* decision, or seek Supreme

8 467 U.S. 837, 843 (1984).
9 *Hays*, 2009 WL 4912383, at *2.
10 *Id.* (citation omitted).
11 *Id.*
12 *Id.* at *3.
13 *Id.*
14 *Id.*
15 *Id* at *4.

Court review. Assuming the decision stands, it could place the future of LCA policies in great doubt. Given the DC Circuit's prominence in administrative law cases, its holding likely will be followed by other courts. Moreover, although the *Hays* case only involved an LCA policy for a drug, the court's reading of the statute appears to extend to all items and services, including DME. More specifically, the decision implies that Medicare can use LCA only in circumstances where the statutory provisions that establish payment rates for items or services specifically allow an LCA approach; in the case of DME, it appears that CMS would need to identify a DME payment provision that specifically contemplates this approach in order to continue applying LCA to payment for items of DME.

The opinion referenced in this Advisory, *Hays* v. *Sebelius*, No. 08-5508, 2009 WL 4912383 (DC Cir. 2009), can be accessed at http://pacer.cadc.uscourts.gov/common/opinions/200912/08-5508-1221815.pdf.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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