MEDICARE DRUG COST SAVINGS THROUGH "LEAST COSTLY ALTERNATIVE"

This article explains how Congress can lower the cost of drugs for Medicare beneficiaries by enacting a law to allow CMS to apply "least costly alternative" payment policy to selected drug groups.

Background:

Through 2008, CMS' Medicare Administrative Contractors (MACS) had the authority to apply a least costly alternative (LCA) payment to a higher cost Medicare B covered injected drug (e.g. Lupron®) when a lower cost equally safe and effective alternative injected drug (e.g. Zoladex®) is FDA approved for the same indication (e.g. prostate cancer). Under LCA, the Medicare contractor would pay the allowed amount of the lower cost drug when a higher cost drug is billed, unless the specific beneficiary could not take the lower cost drug.

In 1999, encouraged by the OIG HHS, I and other Contractor Medical Directors used LCA authority to save Medicare about $630 million per year and beneficiaries about $126 million per year for the drug Lupron. At the time Lupron was about $100 per monthly dose more costly than Zoladex, yet enjoyed about 80% of the market. When a MAC implanted the LCA policy, TAP pharmaceuticals, the manufacturer of Lupron lowered its price by about $100 to preserve its market share. The result was no change in prescribing, but lower Medicare payments and beneficiary co-payments. In effect, the MACs became the "purchasing agents" for all the Medicare beneficiaries within their respective jurisdictions. All but one MAC implemented LCA for Lupron. NHIC New England did not.

In 2008 the federal courts found that CMS does not have authority to apply "least costly alternative." Attached is the ruling. Thereafter, CMS instructed its MACs to discontinue any local coverage decision (LCD) that utilized the LCA authority to save money for Medicare and its beneficiaries.

During the last 9 years, despite lobbying from Medicare advocates, Congress has elected NOT to grant the LCA authority to CMS, which would require a minor revision to the Statue: Section 1862(a)(1)(A) of the Social Security Act of 1965.

If CMS were to have the LCA authority again, its contractors would likely apply it to biosimilar drugs. The result would be a reduction in the allowance for the predicate drug to that of the allowance of the biosimilar, exempting those patients who must use the predicate drug due to patient specific medical necessity reasons.

Biosimilar drugs are large molecules. They are not generic equivalents, but typically are equally as safe and effective as the predicate drug for each specific indication listed in the products label, which is approved by the FDA. An example is Neupogen® (filgastrim) – the predicate drug—v. Granix® (tbo-filgastrim) and Zarxio® (filgastrim-sndz) – the biosimilar drugs.

Typically, the Average Sales Price (ASP) of the biosimilar drug is 30% less than the ASP of the predicate drug. Accordingly, the Medicare allowances may be 30% less for the biosimilar. CMS has issued a new

HCPCS code for each biosimilar family (one or more biosimilars) in order to auto-pay the lower amount when the biosimilar is prescribed.

Physicians and their patients may choose to use the biosimilar drug and save what may be an unnecessary expense.

Manufacturers of predicate drugs are motivated to protect market share without a price reduction. The success of their efforts would be substantially blocked by enactment of LCA authority.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ILENE HAYS **and** **DEY, L.P.,** **Plaintiffs,** **v.** **MICHAEL O. LEAVITT, Secretary of the United States Department of Health and Human Services, et al.,** **Defendants.**	**Civil Action 08-01032 (HHK)**

MEMORANDUM OPINION

Ilene Hays ("Hays"), a Medicare beneficiary, and Dey, L.P. ("Dey"), a drug manufacturer (collectively, "plaintiffs"), bring this action against Michael O. Leavitt, Secretary of the United States Department of Health and Human Services (the "Secretary"), Kerry Weems, the Acting Administrator for the Centers for Medicare and Medicaid Services, each in their official capacity, and four Medicare administrative contractors, National Heritage Insurance Company, National Government Services, CIGNA Government Services, and Noridian Administrative Services (collectively, "defendants"). Plaintiffs allege that defendants unlawfully limited the reimbursement rate under the Medicare Act (the "Act") for the inhalation drug DuoNeb.

Before the court are the parties' cross-motions for summary judgment [##16, 17]. Upon consideration of the motions, the oppositions thereto, and the record of this case, the court concludes that plaintiffs' motion [#16] must be granted and defendants' motion [#17] must be denied.

I. BACKGROUND

Hays is eligible for benefits under Part B of the Medicare Program on the basis of her disability. She suffers from Chronic Obstructive Pulmonary Disease for which her doctor has prescribed DuoNeb, an inhalation drug manufactured by Dey that is taken through a nebulizer. DuoNeb provides a combination of albuterol and ipratropium bromide in one dose.

The Secretary administers Part B of the Medicare program through Medicare contractors, who may issue local coverage determinations specifying whether a particular drug will be covered in their geographic area under the Medicare program. In this case, the four Medicare contractors named as defendants issued local coverage determinations for DuoNeb declaring that reimbursement for DuoNeb would be based not on the cost of DuoNeb, as it had in the past, but on the payment allowance for the least costly medically appropriate alternative, separate doses of albuterol and ipratropium bromide. Plaintiffs challenge these determinations.

A. The Medicare Act and the Department of Health and Human Services Regulations

The Act, codified at 42 U.S.C. § 1395, *et seq*., furnishes health benefits, including hospital services, medical devices and equipment and drugs, for the elderly and disabled. Medicare Part B authorizes payment for non-institutional services and items such as durable medical equipment, including nebulizers and the inhalation drugs used with nebulizers. *Id*. § 1395u(o)(1)(G)(ii); 1395x(n). The Act bars payment for items or services that are not "reasonable and necessary": "no payment may be made . . . 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." 42 U.S.C. § 1395y(a)(1)(A).

The Secretary may delegate her responsibilities under section 1395y(a) to Medicare contractors. 42 U.S.C. § 1395h. Medicare contractors may make determinations of what payments are barred under the "reasonable and necessary" standard in local coverage determinations. Local coverage determinations are defined as "determination[s] by a fiscal intermediary or a carrier under part A or part B of this subchapter, as applicable, respecting whether or not a particular item or service is covered . . . in accordance with section 1395y(a)(1)(A)." *Id*. § 1395ff(f)(2)(B). In other words, Medicare contractors may apply the "reasonable and necessary" standard to specific payments by Medicare contractors through local coverage determinations.

The Act further provides that if a beneficiary requests payment for an inhalation drug for which payment may be made (i.e. that is covered), the amount payable will be equal to the amount provided under section 1395w-3a of the Act. *Id*. § 1395u(o)(1)(G)(ii). Section 1395w-3a, in turn, states that subject to two exceptions, the amount of payment is 106 percent of an amount calculated based on the average sales prices of the inhalation drug. *Id*. § 1395w-3a(b)(1)(A).

The Secretary has provided direction to Medicare contractors through regulations. By regulation, the Secretary has stated, "An LCD [local coverage determination] may provide that a service is not reasonable and necessary for certain diagnoses and/or for certain diagnostic codes. An LCD does not include a determination of which procedure code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service." 42 C.F.R. § 400.202.

B. The Least Costly Alternative Policy and the Local Coverage Determination for DuoNeb

The least costly alternative policy at issue in this case is found in the Secretary's interpretive manuals. The Medicare Benefit Policy Manual states that for durable medical equipment "where there exists a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished, the amount payable is based on the rate for the equipment or alternative treatment which meets the patient's medical needs." Def.'s Ex. 2 at 13-14. The reimbursement is thus based on the payment amount for the least costly alternative. The Medicare Program Integrity Manual extends this concept to non-durable medical equipment, mandating that contractors "shall implement the new Least Costly Alternative (LCA) determinations through an LCD. 'Least Costly Alternative' is a national policy provision that shall be applied by contractors when determining payment for all durable medical equipment (DME). Contractors have the discretion to apply this principle to payment for non-DME services as well." Pl.'s Tab 2 at 13.

Until recently, the inhalation drug DuoNeb was covered under the Act according to the payment formula set out in section 1395w-3a of the Act based on the average sales price of DuoNeb. A.R. 97, 151. In 2006, three Program Safeguard Contractors[1] published draft local coverage determinations proposing revisions to the existing local coverage determinations for nebulizers. *See id.* at 100-21, 126-53, 158-79. Relevant to this case, the draft local coverage determinations stated that the medical necessity of administering albuterol and ipratropium bromide in a combined unit dose had not been established and proposed applying the "least

[1] At that time, Program Safeguard Contractors assisted the Secretary by recommending local coverage determinations for adoption by Medicare contractors.

costly alternative" policy to DuoNeb. *See id.* at 106, 131-32, 163. The Program Safeguard Contractors then initiated a public comment and response period.

In April 2008, the four Medicare contractors in this case issued new local coverage determinations for nebulizers. These determinations stated:

> 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, effective for claims with dates of service on or after November 1, 2008, when one unit of service of code J7620 is billed, if coverage criteria are met, payment 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].

Id. at 488, 514, 540, 566. Therefore, effective November 1, 2008, if a claim is filed for the reimbursement code assigned to DuoNeb, reimbursement will be based on the least costly alternative – the sum of the reimbursement amounts for separate doses of albuterol and ipratropium bromide.

II. ANALYSIS

This case comes before the court on the parties' cross-motions for summary judgment.[2] Plaintiffs contend that the least costly alternative policy is contrary to the plain language of section 1395y(a) of the Act because it unlawfully determines payment rates in a section that only authorizes the Secretary to determine coverage. Defendants rejoin that the broad term "reasonable and necessary," combined with the focus of section 1395y(a) on payment and expenses, does authorize the least costly alternative policy. Defendants further contend that

[2] Summary judgment is an appropriate procedure for resolving a challenge to a federal agency action. The court does not employ the standard of review set forth in Federal Rule of Civil Procedure 56, however. Rather, the standard of review is prescribed by the relevant statute and the Administrative Procedure Act. *Fund for Animals v. Babbitt,* 903 F. Supp. 96, 105 (D.D.C. 1995).

plaintiffs' claims are not subject to this court's jurisdiction because plaintiffs raise factual issues that have not been exhausted in an administrative process, and that Dey lacks standing because it is not a Medicare beneficiary.

Plaintiffs are correct and, for the reasons that will be explained in this opinion, the court's jurisdiction is not dependent upon plaintiffs' exhaustion of any administrative remedy. Defendants, however, are correct that Dey does not have standing under the Act.

A. The Court Has Jurisdiction Over Plaintiffs' Claim, but Plaintiff Dey Does Not Have Standing to Sue.

Before reaching the merits of the case, the court first must determine whether it has jurisdiction over the claim and whether the parties have standing to sue.

1. Jurisdiction

Defendants contend that the court lacks jurisdiction over plaintiffs' claims because their claims do not fall within the limited exception in the Act to the requirement that plaintiffs exhaust administrative remedies before bringing an action in court. The limited exception, defendants argue, is for beneficiaries who challenge a local coverage determination on purely legal grounds and put no material facts into dispute. Defendants assert that plaintiffs have put material facts into dispute by questioning whether DuoNeb is therapeutically equivalent to separate doses of albuterol and ipratropium bromide and contending that defendants have failed to consider the effects on the market of their local coverage determinations. Plaintiffs rejoin that these factual disputes are irrelevant to the sole issue of law to be determined in this case. Plaintiffs are correct.

The Act generally requires plaintiffs to exhaust administrative remedies before bringing a challenge in court, however the Act carves out a limited exception. Section 1395ff(f)(3) provides that in a challenge to a local coverage determination where "there are no material issues of fact in dispute, and the only issue of law is . . . that a regulation, determination, or ruling by the Secretary is invalid, the moving party may seek review by a court of competent jurisdiction without . . . exhausting . . . administrative remedies." 42 U.S.C. § 1395ff(f)(3).

While plaintiffs do raise factual issues in their briefing, including whether DuoNeb is therapeutically equivalent to separate doses of its components, these factual issues are not material to plaintiffs' primary challenge: whether the Act grants the Secretary the authority to implement the least costly alternative policy under section 1395y(a) of the Act. This question is purely legal, regarding the interpretation of the authority granted in the Act, and any factual matters raised by plaintiffs are immaterial to its resolution. It is this narrow question to which the court's inquiry is limited.

2. Standing

Defendants argue that Dey does not have standing to sue because the Act limits standing to challenge local coverage determinations to beneficiaries, and Dey is not a beneficiary. Plaintiffs rejoin that Dey has prudential standing because it has suffered a legal wrong due to the local coverage determinations and it falls within the zone of interests protected by the Act. Defendants are correct.

The Act limits standing to challenge local coverage determinations to beneficiaries: "An action under this subsection seeking review of a . . . local coverage determination may be initiated only by individuals . . . enrolled under part B . . . who are in need of the items or services that are the subject of the coverage determination." 42 U.S.C. § 1395ff(f)(5); *see Bailey*

v. Mut. of Omaha Ins. Co., 534 F. Supp. 2d 43, 46 n.2 (D.D.C. 2008). This explicit direction by Congress supersedes any judicial determination of whether a party falls within the zone of interests test. *See Block v. Cmty. Nutrition Inst.,* 467 U.S. 340, 349 (1984) (holding that specific Congressional language overrides the presumption favoring judicial review).

Because Dey, as a drug manufacturer, is not "in need of the items or services that are the subject of the coverage determination," Dey is denied standing by the Act. *See* 42 U.S.C. § 1395ff(f)(5). Plaintiffs' arguments that Dey falls within the zone of interests test are inapposite. Dey is therefore dismissed from this case.

B. The Plain Language of the Medicare Act Precludes the Secretary's Authority to Implement the Least Costly Alternative Policy.

Hays contends that the language of the Act unambiguously bars the Secretary from implementing the least costly alternative policy under section 1395y(a) because it runs contrary to the clear language of section 1395w-3a setting payment amounts for covered inhalation drugs. Defendants rejoin that the "reasonable and necessary" language of section 1395y(a) is ambiguous, conferring great discretion on the Secretary, and that the least costly alternative policy is a permissible construction of section 1395y(a) because that provision explicitly addresses payment and expenses. Further, defendants argue, section 1395y(a) operates "notwithstanding any other provision." Analyzing the parties' arguments under the *Chevron* standard, the court holds that the least costly alternative policy is not authorized by the Act.

1. The Chevron *Standard*

Under the Administrative Procedure Act, a court must set aside agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;" "contrary to constitutional right, power, privilege, or immunity;" or "in excess of statutory . . . authority . . .

or short of statutory right." 5 U.S.C. § 706(2).[3] The Supreme Court in *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984) set forth the applicable methodology for reviewing whether an agency's interpretation of a statute it administers is in accordance with law. Under *Chevron*, the court first must determine whether Congress has "directly spoken to the precise question at issue." *Id*. at 842 ("If the intent of Congress is clear, that is the end of the matter . . . ."). If Congress has not directly spoken, then the court must defer to a "permissible" construction of the statute by the agency. *Id*. at 843. In Medicare cases, the court must give additional deference to the Secretary's interpretation of the Act because of the "tremendous complexity" of the Medicare program. *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994); *see Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994).

In determining whether Congress has directly spoken to the issue under the first step of the *Chevron* analysis, the court begins with the statutory language. *Chevron*, 467 U.S. at 842. If the statute's text is plain and unambiguous, "the sole function of the courts is to enforce it according to its terms." *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989) (internal citations omitted). The plainness or ambiguity of statutory language "is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). If analysis of the statutory language and its context does not yield a plain meaning, the court may look to the statute's overall purpose and its legislative history to discern Congress's intent. *See*

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[3] Section 1395ff(b) specifies 42 U.S.C. § 405(g) as "the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act." *Heckler v. Ringer*, 466 U.S. 602, 615 (1984); *see* 42 U.S.C. § 1395ff(b). The court reviews the Secretary's actions pursuant to section 405(g) where applicable; "where no provision of § 405(g) is on point, we apply the judicial review provisions of the APA." *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 78 (2d Cir. 2006).

id. at 341 (interpreting an ambiguous statutory term in light of the statute's overall purpose); *Chevron*, 467 U.S. at 845-54 (discussing at length the legislative history of the relevant statute after finding the statute's text an inadequate guide as to the meaning of the provision interpreted by the challenged regulations).

2. Application of the Chevron *Standard*

The dispute in this case turns on the construction of the phrase, "no payment may be made . . . for any expenses incurred for items and services . . . which . . . are not reasonable and necessary" in section 1395y(a) of the Act. Section 1395y(a) provides:

> (a) Items or services specifically excluded – Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services –
> (1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

42 U.S.C. § 1395y(a)(1)(A). Whether this provision authorizes the Secretary's least costly alternative policy, and in particular the construction of "reasonable and necessary," is at the heart of the dispute in this case.

At step one of the *Chevron* analysis, the question before the court is whether, after looking at the language, context and legislative history of section 1395y(a), Congressional intent with respect to the language is clear. Based on an analysis of these sources of meaning, the court holds that Congressional intent is clear and section 1395y(a) does not authorize the Secretary to set a payment rate for an item or service that differs from the statutory formula in section 1395w-3a.

a. Text

Hays argues that "reasonable and necessary" modifies "items and services." Based on this reading, Hays contends that the Secretary must deny all coverage for an item or service that is not reasonable and necessary. Once the Secretary determines that an item or service is reasonable and necessary and therefore not barred by section 1395y(a), however, Hays contends that this section does not provide authorization to determine the payment rate for that item or service. Instead, Hays argues, the Act provides a very specific formula for reimbursement in section 1395w-3a. According to Hays, the Act leaves no gaps – once a coverage decision is made under 1395y(a), the Secretary must go directly to the reimbursement formula in section 1395w-3a to determine the amount of payment. The least costly alternative policy, which does not bar payment for an item or service, but instead determines the rate of payment for a covered item at the level of its least costly alternative, is therefore not authorized by section 1395y(a). Hays supports this reading of the Act with language from the Secretary's regulations governing the local coverage determination program: "An LCD does not include a determination . . . with respect to the amount of payment to be made for the service." 42 C.F.R. § 400.202.

Defendants rejoin that the term "reasonable and necessary" modifies "expenses." On this reading, the Secretary is authorized to find that certain expenses related to a covered item or service are not reasonable and necessary and determine that no payment will be made for those expenses. Citing *Heckler* and *Good Samaritan Hospital v. Shalala*, 508 U.S. 402 (1993), defendants emphasize that "reasonable and necessary" is a broad term, leaving great discretion to the Secretary. They further argue that section 1395y(a) does not contain any presumption of coverage or dictate that all items and services that are reasonable and necessary must be reimbursed for the full amount claimed. Defendants dispute the distinction Hays draws between

coverage and reimbursement decisions. With respect to Hays' argument that the amount of payment for a covered item is set by section 1395w-3a, defendants rejoin that section 1395w-3a still sets the amount of reimbursement; the Secretary merely decides that a particular item or service will be reimbursed at the amount specified by 1395w-3a for its least costly alternative. Finally, defendants argue that Hays' interpretation of section 1395y(a) treats the statutory language "expenses incurred for" as mere surplusage.[4]

Whether "reasonable and necessary" modifies "items or services" or "expenses" matters because defendants argue that their authority to set payment rates under section 1395y(a) derives from Congress's directive barring payments of unreasonable and unnecessary *expenses*. The most natural reading of section 1395y(a), however, is that "reasonable and necessary" modifies "items and services" and not "expenses" and so defendants construction does not stand and the Act does not authorize them to set payment rates through section 1395y(a).

The Act bars payment for expenses incurred for items and 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." 42 U.S.C. § 1395y(a)(1)(A). A natural reading of the language links "reasonable and necessary for diagnosis or treatment" to the items or services that diagnose or treat. This is the way courts have read this clause. *See, e.g.*, *Heckler*, 466 U.S. at 617 (referring to the Secretary's decision under section 1395y(a) as "whether a particular medical *service* is 'reasonable and necessary'") (emphasis added); *U.S. Seniors Ass'n, Inc. v.*

[4] The parties also dispute whether the Secretary can take costs into account when determining whether an item or service is reasonable and necessary. Because Hays challenges whether the Secretary has the authority to dictate the payment rate, not whether the Secretary may take cost into account in determining whether an item or service is reasonable and necessary, this question is not necessary to the determination of this case and the court does not address it.

Shalala, 182 F.3d 965, 967 (D.C. Cir. 1999) ("If a *service* is deemed not to have been reasonable and necessary, Medicare will not make a payment. . . .") (emphasis added); *Power Mobility Coal. v. Leavitt*, 404 F. Supp. 2d 190, 194 (D.D.C. 2005) ("All Medicare coverage is limited to *services* that are medically 'reasonable and necessary' for the diagnosis or treatment of illness.") (emphasis added). Moreover, section 1395ff(f)(2)(B), defining a local coverage determination, mandates a determination of whether or not a particular *item* or *service* is covered, and not whether a particular expense is covered. 42 U.S.C. § 1395ff(f)(2)(B) ("'local coverage determination' means a determination . . . respecting whether or not a particular item or service is covered . . . in accordance with section 1395y(a)(1)(A)").

This natural reading is further supported by the rule of statutory construction whereby "[o]rdinarily, qualifying phrases are to be applied to the words or phrases immediately preceding and are not to be construed as extending to others more remote." *United States v. Pritchett*, 470 F.2d 455, 459 (D.C. Cir. 1972). While this rule will give way where the context indicates otherwise, *United States v. Barnes*, 295 F.3d 1354, 1360 (D.C. Cir. 2002), as discussed below, the context in this case provides further support for construing "reasonable and necessary" to modify its immediate antecedent "items or services."[5]

[5] Defendants contend that the reading of the Act endorsed by the court today renders the term "expenses" mere surplusage. It does not. The use of "expenses incurred" may be understood to refer to the general scheme of the Act whereby beneficiaries and participating entities are reimbursed by Medicare for expenses incurred. *See* 42 U.S.C. § 1395*l*(a) ("there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part . . . ."); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 205 (1988) ("Under the Medicare program, health care providers are reimbursed by the Government for expenses incurred in providing medical services to Medicare beneficiaries.").

b. Context

Hays contends that the context of section 1395y(a) within the Act demonstrates Congress's intent that decisions about payment rates may not be made under that section. Hays argues that the Act sets out a comprehensive scheme whereby coverage determinations are made under section 1395y(a) and reimbursement decisions are made under separate provisions, in this case section 1395w-3a, and argues that defendants' reading would render section 1395w-3a subordinate to section 1395y(a). Defendants rejoin that a fundamental prerequisite of section 1395w-3a is a finding that an item or service is "reasonable and necessary" under section 1395y(a) and that, under the least costly alternative policy, section 1395w-3a would still set the payment amount based on the average sales price of the least costly alternative. Hays' arguments are well taken.

Section 1395y(a) bars payment for any expense incurred for items and services which are not reasonable and necessary under the entire Act. The Act then provides for the amount of payment for particular classes of items and services in numerous sections. In the case of the inhalation drugs at issue in this case, the section that prescribes payment is section 1395w-3a which specifies a reimbursement rate of 106 percent of the average sales price. 42 U.S.C. § 1395w-3a(b)(1)(A). In many other cases, reimbursement is set at the "reasonable cost" of the item or service. *See, e.g.*, 42 U.S.C. § 1395f(b) ("The amount paid to any provider of services . . . with respect to services for which payment may be made under this part shall . . . be . . . the lesser of (A) the reasonable cost of such services . . . or (B) the customary charges with respect to such services."); *see generally* 42 U.S.C. § 1395x(v) (defining "reasonable costs" as "the cost actually incurred, excluding therefrom any part of the incurred cost found to be unnecessary in the efficient delivery of needed health services").

Defendants' reading of the provision as barring *expenses* that are not reasonable and necessary would give the Secretary enormous discretion under section 1395y(a) to determine the payment amount for every item and service covered under the Act without reference to the payment provisions of the Act. This flies in the face of the detailed statutory provisions, including section 1395w-3a, which set up explicit formulas for how much a beneficiary or provider will be paid for particular items and services. If the Secretary has 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).[6]

There is no indication that Congress intended to confer such broad authority through section 1395y(a); in fact the explicit language of section 1395w-3a and other reimbursement provisions indicates the contrary. Section 1395w-3a(b) states that the reimbursement rate for a covered multiple source drug, such as DuoNeb, is "106 percent of the amount determined under paragraph (6)." 42 U.S.C. § 1395w-3a(b)(1)(A). Paragraph six, in turn, sets out a calculation of the average sales price using volume-weighted average sales prices, and subsection (c)(3) sets out the requirement that the calculation of the average sales price must include all discounts or other price concessions made by the manufacturer. *Id*. § 1395w-3a(b)(6) & (c)(3). The section further creates two exceptions when the Secretary need not use this reimbursement methodology. *Id*. §

[6] While in this case defendants insist that the least costly alternative policy does not set the payment amount, which would still be set by section 1395w-3a based on the average sales price of albuterol and ipratropium bromide separately, it does set the payment rate and nothing in their reading of the statutory language as barring expenses that are not reasonable and necessary would limit their authority to set payment amounts under section 1395y(a).

1395w-3a(d) & (e). This provision, dictating payment amounts for covered items and services, is extraordinarily detailed. It does not make sense to conclude that Congress, having minutely detailed the reimbursement rates for covered items and services, intended that the Secretary could ignore these formulas whenever she determined that the *expense* of an item or service was not reasonable or necessary. *See Roselli v. Noel*, 414 F. Supp. 417, 424 (D.R.I. 1976) ("The comprehensiveness of this explicit statutory scheme belies the . . . assertion that it gives rise to an implicit delegation of virtually unlimited authority . . . .").

Moreover, in the case of payment rates for items or services that are set in the Act at "reasonable cost," reading section 1395y(a) to bar the Secretary from payment of expenses that are not reasonable and necessary would be entirely duplicative. If the Secretary may not allow payment for an unreasonable or unnecessary expense under section 1395y(a), then the Act's direction that "reasonable costs" will be the costs actually incurred, excluding any part of the incurred cost found to be unnecessary in the efficient delivery of needed health service, would be duplicative and unnecessary. Any "incurred cost found to be unnecessary in the efficient delivery of needed health services," 42 U.S.C. § 1395x(v), would be barred under section 1395y(a). "Because the court's duty is to give meaning to each word of a statute, the court cannot properly treat one authorization . . . as duplicative of another authorization . . . .". *Fin. Planning Ass'n v. S.E.C.*, 482 F.3d 481, 492 (D.C. Cir. 2007).

c. Legislative History

Hays contends that the legislative history makes clear that "reasonable and necessary" refers to a medical decision as to whether or not an item or service contributes meaningfully to treatment. Defendants rejoin that the limited legislative history hardly supports Hays' position that cost may not be considered in coverage determinations. The question of whether the

Secretary may consider costs under the "reasonable and necessary" standard is irrelevant to this case. However, the legislative history does provide support for Hays' construction of the statutory text.

The limited available legislative history supports reading the Act such that "reasonable and necessary" modifies "items and services." In its report, the Senate stated, "the bill would bar payment for health items or services that are not reasonable and necessary for the treatment of illness and injury . . . ." S. Rep. No. 89-404, 1965 *U.S. Code Cong. and Adm. News* 1943, 1989. This language drops "expenses" altogether providing further support for the proposition that Congress intended "reasonable and necessary" to modify "items or services." Defendants argument that nothing in this section 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 and 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.

III. CONCLUSION

For the foregoing reasons, Hays' motion for summary judgment is granted with respect to the claim that the Secretary lacks authority under 42 U.S.C. § 1395y(a) to apply the least costly alternative policy to DuoNeb; defendants' motion for summary judgment is denied; and plaintiff Dey is dismissed from this case. An appropriate order accompanies this memorandum opinion.

Henry H. Kennedy, Jr.
United States District Judge