UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BAXTER HEALTHCARE CORPORATION, Plaintiff, v. KERRY N. WEEKS, Acting Administrator, Centers for Medicare & Medicaid Services, *et al.*, Defendants.	:	Civil Action No. 08-2204 (JR)

MEMORANDUM

Baxter Healthcare Corporation is the manufacturer of Advate, a clotting factor that is used to control and prevent bleeding in hemophiliacs. Baxter claims that the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) have violated the Administrative Procedure Act by treating Advate as a "multiple source drug" under 42 U.S.C. § 1395w-3a(c)(6)(C)(ii), a provision of the Medicare statute.

Baxter moved for a preliminary injunction, but after a hearing on the motion, and with the consent of the parties, I ordered that the disposition of the case on the merits would be considered together with the pending motion, and invited the parties to submit supplemental memoranda. Dkt. 12. Judgment will now be entered in favor of the defendants.

Background

Medicare Part B authorizes HHS to reimburse health care providers for drugs they administer to enrolled Medicare beneficiaries. To submit a reimbursement claim, a provider logs onto an automated system and identifies the drug it has administered by the drug's Healthcare Common Procedure Coding System (HCPCS) code. That information is sent to one of several private contractors, who process and pay out the claim with government funds.

As part of its responsibilities overseeing the reimbursement process, CMS maintains a set of national HCPCS codes, which it revises periodically. Declaration of Elizabeth Richter ¶ 5. Each HCPCS code is associated with a short phrase that describes a category of medication -- J0290 for "Ampicillin sodium," for example. See Alpha-Numeric HCPCS, available at http://www.cms.hhs.gov/HCPCSReleaseCodeSets/. To submit a valid reimbursement claim, a provider must select the HCPCS code that most closely describes the drug. Richter Decl. ¶ 9. If no existing code adequately describes the drug, providers can select a "miscellaneous/not otherwise classified" code, which serves as a placeholder while CMS considers whether a new permanent code is needed. Id. ¶ 7.

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), "multiple source drugs" and

"single source drugs or biologicals" are reimbursed at different rates. "Multiple source drugs" are therapeutically equivalent, pharmaceutically equivalent, and bioequivalent to other drugs on the market. 42 U.S.C. § 1395w-3a(c)(6)(C). They typically fall within the same HCPCS code as their equivalents, and their reimbursement rate is the weighted average of the average sale price of all drugs in that HCPCS code plus 6%. Id. § 1395w-3a(b)(1)(A). "Single source drugs and biologicals" are non-multiple source drugs and all biological products. Id. § 1395w-3a(c)(6)(D). They typically have their own HCPCS code, and their reimbursement rate is the lesser of (1) their average sale price, or (2) their wholesale acquisition cost, plus 6%. Id. § 1395w-3a(b)(1)(B).

Advate was the first anti-hemophilic factor to be made without any added human or animal plasma proteins, eliminating the risk of infections caused by viruses like HIV, West Nile Virus, and the human form of Mad Cow disease. Declaration of Deborah K. Williams ¶ 4. The FDA approved Baxter's application for Advate in July 2003, and Baxter began selling the drug on August 20 of that year. Id. ¶ 5; Richter Decl. ¶ 10.

The defendants concede that Advate meets the statutory definition of a biological. See Dkt. 10, at 8. But they contend that they must treat Advate like a multiple source drug because of a grandfather clause in the MMA, which directs the HHS

Secretary to treat single source drugs or biologicals like multiple source drugs if they were "within the same [HCPCS] code [as other drugs] as of October 1, 2003." 42 U.S.C. § 1395w-3a(c)(6)(C)(ii). The defendants assert that, as of October 1, 2003, Advate was within HCPCS code J7192 -- the code for "Factor VII (antihemophilic factor, recombinant) per I.U." -- along with other anti-hemophilic products.

Advate is the most expensive product in HCPCS code J7192. Williams Decl. ¶ 19. Because the government treats Advate like a multiple source drug, and reimburses providers at the same rate for administering Advate as it does for administering any of the other products in group J7192, providers have a financial disincentive to administer Advate to Medicare beneficiaries. Id. Baxter has repeatedly asked CMS to reclassify Advate as a biological, most recently in connection with CMS' February 2007 review of reimbursement rates, but CMS has refused. Id. ¶¶ 11-17. In December 2008, after receiving CMS' denial of its most recent request to reclassify Advate, id., Ex. 8, Baxter filed this suit.

Analysis

There are two issues in dispute: whether Baxter can seek judicial review of its claims at this time, and, if so, whether it can show that the defendants have either misinterpreted or misapplied 42 U.S.C. § 1395w-3a(c)(6)(C)(ii).

Baxter prevails on the first issue, but falls short on the second.

A. Judicial review

1. Standing

The defendants contend that Baxter lacks standing because its interest in improving Advate's competitive position does not fall within the zone of interests protected by 42 U.S.C. § 1395w-3a.

The zone of interests test "is not meant to be especially demanding." Clarke v. Sec. Indus. Ass'n, 479 U.S. 388, 399 (1987). "Congruence of interests, rather than identity of interests, is the benchmark; the zone of interests test serves to exclude only those 'parties whose interests are not consistent with the purposes of the statute in question.'" Amgen Inc. v. Smith, 357 F.3d 103, 109 (D.C. Cir. 2004) (quoting Ethyl Corp. v. EPA, 306 F.3d 1144, 1148 (D.C. Cir. 2002)).

Thus, the relevant question is not whether Baxter's suit is motivated by financial gain, but whether that financial motive is aligned with the interests protected by section 1395w-3a. According to the conference committee report accompanying the MMA, the reimbursement scheme in section 1395w-3a is intended to encourage health care providers to choose between drugs based on their relative efficacy, not their relative reimbursement

rate. H.R. Rep. No. 108-391, at 583-84 (Conf. Rep.) (2003). If, as Baxter claims, Advate is reimbursed at too low a rate, and physicians currently have a financial incentive to administer the other, less advanced clotting factors in HCPCS code J7192, Baxter's interest in this suit is at least "congruent" with those identified by Congress.

Admittedly, if Baxter's challenge were successful, and the reimbursement rate for Advate were to increase, Medicare beneficiaries would have to pay a higher co-payment to obtain Advate. See 42 U.S.C. § 1395l(a)(1)(S). While minimizing costs for Medicare beneficiaries is surely a goal of the Medicare statute, so too is giving beneficiaries access to the most effective and up-to-date products. Currently, health care providers may not even offer beneficiaries the option of using Advate. If Advate's reimbursement rate were to increase, however, and providers had no financial disincentive to administer it, beneficiaries would at least have the choice between paying more for Advate and paying less for one of Advate's competitors -- a preferable outcome.

2. 42 U.S.C. § 1395w-3a(g)(1)

Next, the defendants assert that Baxter's claims are barred by 42 U.S.C. § 1395w-3a(g)(1), which precludes administrative or judicial review of "determinations of payment amounts under this section, including the assignment of National

Drug Codes[1] to billing and payment codes." They argue that Baxter is either challenging the determination of Advate's payment amount, in which case review is barred by the statute's first phrase, or it is challenging Advate's assignment to HCPCS code J7192, in which case review is barred by the statute's second phrase.

Neither argument is quite right. 42 U.S.C. § 1395w-3a(b) describes how HHS must "determine payment amounts." It is a complicated process: for a single source drug or biological, HHS must calculate the average sale price of the product (taking into account certain exempted sales and manufacturers' discounts), the wholesale acquisition cost of the product, and take 106% of the lesser of the two; for a multiple source drug, HHS must calculate the average sale price for all the drugs in that HCPCS code, find the weighted average of those average prices, and take 106% of the outcome. Section 1395w-3a(g)(1) precludes judicial and administrative review of whether HHS made those calculations correctly. But it does not prohibit review of HHS' prior determination that a product is a single source drug or biological, or a multiple source drug. That is the review Baxter seeks here.

[1] A "National Drug Code" is an 11-digit number that is used to identify a drug's vendor, properties, and package size. See http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm.

Similarly, Baxter is not challenging HHS' decision to assign Advate to HCPCS code J7192; it is only challenging HHS' determination that Advate was "within" J7192 before October 1, 2003, the cutoff date in the MMA's grandfather clause. Baxter would be content if the defendants left Advate in group J7192, as long as they were required to treat it as a biological, rather than as a multiple source drug.[2] See Dkt. 13, at 11.

3. 42 U.S.C. § 1395ii

Through its incorporation of 42 U.S.C. § 405(h), 42 U.S.C. § 1395ii precludes any "action against the United States, the [HHS Secretary], or any officer or employee thereof . . . under [28 U.S.C. §] 1331 . . . to recover on any claim arising under" the Medicare Act. Section 1395ii is inapplicable, however, when a plaintiff could not otherwise obtain

[2] Baxter claims that it is entitled to judicial review even if review were barred by section 1395w-3a(g)(1) because the defendants' actions were *ultra vires*, and "[j]udicial review is favored when an agency is charged with acting beyond its authority," Dart v. United States, 848 F.2d 217, 221 (D.C. Cir. 1988). See Dkt. 3, at 15 n.9. That argument stretches the definition of *ultra vires* action too far. An agency only acts *ultra vires* when it exceeds a clear and mandatory limit on its regulatory jurisdiction. See, e.g., Mitchell v. Christopher, 996 F.2d 375, 378 (D.C. Cir. 1993) (a valid *ultra vires* claim must challenge "the very composition or 'constitution' of an agency."). There is no question that HHS has the authority under the Medicare statute to determine whether a product is a single source drug, a biological, or a multiple source drug. Whether HHS made the correct determination about Advate is a routine "dispute over statutory interpretation" that does not rise to the level of an *ultra vires* claim. Dart, 848 F.2d at 231.

administrative review of its claims. See Action Alliance of Senior Citizens v. Leavitt, 483 F.3d 852, 859 (D.C. Cir. 2007).

The defendants admit that Baxter itself could not access HHS' administrative review process. See January 8, 2009 Hearing Tr., at 33. But, citing Am. Chiropractic Ass'n, Inc. v. Leavitt, 431 F.3d 812 (D.C. Cir. 2005), they contend that section 1395ii still bars Baxter's claims because Baxter could find a doctor or a hospital to present its claims for HHS adjudication.

Leavitt does not require such an expansive reading of section 1395ii. In that case, a national association of chiropractors challenged an HHS determination that authorized reimbursement for chiropractors, medical doctors, and osteopaths who performed a certain spinal procedure. The association claimed that the statute only authorized chiropractors to receive reimbursement. The Court of Appeals acknowledged that the association itself could not seek administrative review of its claims. But because an association "speaks only on behalf of its member[s]," and any of the association's members could obtain administrative review of its claims, section 1395ii was still applicable. Id. at 817 (citation omitted).[3] Baxter is not suing

[3] The other case defendants cite in support, Nat'l Athletic Trainers Ass'n v. U.S. Dep't of Health & Human Services, 455 F.3d 500 (5th Cir. 2006), also involves a national association suing on behalf of its members, and the court employs the same logic to bar the association's claims.

on behalf of anyone who could seek administrative review of its claims, and Leavitt does not require Baxter to recruit a physician or hospital to act as its proxy in an administrative process. Because section 1395ii "does not apply . . . [when it] would mean no review at all," it is inapplicable here. Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 19 (2000).

4. Final agency action

Under the APA, Baxter may only seek review of "final agency action." 5 U.S.C. § 704. "Final agency action" must meet two criteria: "First, the action must mark the consummation of the agency's decisionmaking process -- it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." Bennett v. Spear, 520 U.S. 154, 177-78 (1997).

CMS' December 4, 2008 letter to Baxter satisfies these requirements. The letter rejects Baxter's request to reclassify three of its products, including Advate. See Dkt. 3, Ex. 8. CMS offers several paragraphs of analysis in support of its decision, and its legal conclusion is unequivocal: it " will continue to treat Advate . . . as [a] multiple source drug[] for payment purposes under [Medicare] Part B." Id.

Though the defendants cite three cases in which the court found that a letter from an agency was not final action, each is distinguishable: the CMS letter was not "purely advisory," Bennett, 520 U.S. at 178, or a "preliminary determination," Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n, 324 F.3d 726, 731 (D.C. Cir. 2003), or "purely informational in nature," Indep. Equip. Dealer Ass'n v. EPA, 372 F.3d 420, 427 (D.C. Cir. 2004). CMS stated its legal position firmly and finally, and Baxter has the right under the APA to challenge that position.

B. Merits

To prevail, Baxter must show that the defendants have either misinterpreted the MMA's grandfather clause, or applied the clause in an arbitrary or capricious manner.

Under the familiar Chevron approach, to assess the validity of the defendants' interpretation of the MMA:

> [I] ask first whether "the intent of Congress is clear" as to "the precise question at issue." If, "by employing traditional tools of statutory construction," [I] determine that Congress' intent is clear, "that is the end of the matter." But "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." If the agency's reading fills a gap or defines a term in a reasonable way in light of the Legislature's design . . . that reading [has] controlling weight, even if it is not the

> answer "the court would have reached if the question initially had arisen in a judicial proceeding."

Regions Hosp. v. Shalala, 522 U.S. 448, 457 (1998) (quoting Chevron U.S.A. Inc. v. NRDC, 467 U.S. 837, 842-43 (1984)).

The statutory language at issue here is ambiguous. In its entirety, the MMA's grandfather clause states, "[w]ith respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs." 42 U.S.C. § 1395w-3a(c)(6)(C)(ii). Baxter argues that the clause is clear, and covers only those single source drugs or biologicals that the HHS Secretary (through CMS) placed in an HCPCS code before the cutoff date. See Dkt. 13, at 5. But the relevant phrase is "single source drugs or biologicals that are within the same [HCPCS] code," not single source drugs or biologicals that are "placed" or "assigned" or "grouped" within the same HCPCS code. 42 U.S.C. § 1395w-3a(c)(6)(C)(ii) (emphasis added). Reading "placed" or "assigned" or "grouped" into the grandfather clause would not only inject words into the provision, but also depart from the structure of the Medicare Part B statute, which does not operate through the "assignment" of drugs and biological products to HCPCS codes. Instead, the process is decentralized: health care providers submit

reimbursement claims using the HCPCS codes that they believe most closely describe the drugs they administered. Richter Decl. ¶ 9. CMS occasionally issues guidance statements to resolve questions from the public or from private contractors about the appropriate code for a specific product, and it convenes an annual workgroup to consider requests to modify the HCPCS code list. Id. ¶ 5. But, in most cases, CMS does not issue a definitive statement that a particular drug should be billed under one HCPCS code or another. In the context of that somewhat organic assignment process, the grandfather clause's requirement that a drug fall "within the same HCPCS code" is unclear.

Moving to step two of the Chevron analysis then, the defendants need only show that their interpretation of the grandfather clause is permissible. In its December 4, 2008 letter rejecting Baxter's request for reclassification, CMS explained that in considering whether a drug fell within the scope of the grandfather clause, it looked at: (1) "the [FDA] approval," to determine whether the product at issue was a drug or a biological product; (2) "therapeutic equivalents as determined by the FDA," to determine, if the product was a drug, whether it was a single source drug or a multiple source drug; (3) "the date of first sale in the United States," to determine whether it predated the cutoff date for the grandfather clause; and (4) whether an existing HCPCS code "sufficiently described"

the drug. Williams Decl., Ex. 8. Because Advate was sold before October 1, 2003, because HCPCS code J7192 sufficiently described Advate's characteristics, and because code J7192 contained other clotting factors, CMS categorized Advate as a multiple source drug. Id.

Baxter argues that Advate does not meet the defendants' interpretation of the grandfather clause. It notes that, before the October 1, 2003 cutoff date, there was confusion among contractors over whether HCPCS code J7192 "sufficiently described" Advate. Compare Williams Decl., Ex. 1 (suggesting that the code for "miscellaneous/not otherwise classified" drugs, J7199, was the appropriate code for Advate), with id., Ex. 2 (arguing that J7192 was sufficient). The confusion was so widespread that on August 27, 2004, CMS had to issue a "one-time notification" to all contractors that "the payment limit that should be used for Advate is the same payment limit that is currently assigned to [HCPCS code] J7192." Id., Ex. 3. In Baxter's view, given the confusion in the marketplace and the fact that CMS did not declare its view until 2004, CMS cannot claim that, as of October 1, 2003, it had determined that code J7192 sufficiently described Advate.

Baxter's argument is flawed in two respects. First, CMS need not have determined before October 1, 2003 that Advate was within code J7192; the grandfather clause only requires CMS

to determine whether, as of October 1, 2003, there was an existing HCPCS code that sufficiently described Advate. That determination can occur at any point, and CMS can rethink its decision, as Baxter hoped it would do upon receiving Baxter's repeated requests for reclassification. Second, the confusion among contractors and providers over the appropriate code for Advate is irrelevant. While CMS is not *required* to assign drugs to specific HCPCS codes, and often lets providers and contractors figure out the appropriate codes by themselves, it still retains the ultimate authority to determine whether a product is sufficiently described by an existing HCPCS code and to assign that product to a particular code. See 42 U.S.C. § 1395w-3a(g)(1) (prohibiting judicial or administrative review of the HHS Secretary's "assignment of National Drug Codes to billing and payment codes"). As long as there is a basis for CMS' determination that Advate was "sufficiently described" by code J7192 -- and there is -- its conclusion that Advate is within the scope of the grandfather clause is valid.[4]

[4] Baxter also contends that CMS applied its interpretation of the grandfather clause in an arbitrary and capricious manner when it agreed to reclassify certain drugs (Synvisc, Octagam, Gammagard, Flebogamma, and Gamunex) as single source drugs or biologicals, but refused to reclassify Advate. Each of those determinations was consistent with the defendants' stated interpretation of the grandfather clause, however: the five named products were either first sold after October 1, 2003, or did not share an HCPCS code with another product. See Richter Decl. ¶¶ 30-32.

Baxter has cause to feel treated unfairly. In 2003, it was the first to introduce a clotting factor free of animal or human proteins, only to have its product reimbursed at less than its average sale price under the Medicare statute. Meanwhile, five years later, its competitor, Wyeth, introduced a nearly identical clotting factor, which is reimbursed at its average sale price because its entrance to the market postdated the cutoff date in the MMA's grandfather clause. See Richter Decl. ¶¶ 26-28. But Baxter's quarrel is with Congress. Unless and until Congress modifies the language of the grandfather clause, or eliminates it entirely, I am bound to apply the law as written. When I do so, and accord the defendants the deference their interpretation is due, I cannot find that they acted improperly.

Conclusion

Although Baxter is entitled to judicial review of its APA claims, it fails to show that the defendants' interpretation of the MMA is impermissible, or that the defendants have acted arbitrarily or capriciously in their application of the MMA. Accordingly, the accompanying order will enter judgment in favor of the defendants.

JAMES ROBERTSON
United States District Judge