United States Court of Appeals for the Federal Circuit

05-7130

THE COALITION FOR COMMON SENSE IN GOVERNMENT PROCUREMENT,
(doing business as The Coalition for Government Procurement),

Petitioner,

v.

SECRETARY OF VETERANS AFFAIRS,

Respondent.

Donna Lee Yesner, McKenna Long & Aldridge LLP, of Washington, DC, argued for petitioner. With her on the brief were Joanne L. Zimolzak and Jeniffer M. De Jesus.

Kyle Chadwick, Trial Attorney, Commercial Litigation Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent. With him on the brief were Peter D. Keisler, Assistant Attorney General and David M. Cohen, Director. Of counsel on the brief were Melbourne A. Noel, Jr., Senior Contracts Attorney, Office of General Counsel, United States Department of Veterans Affairs, of Hines, Illinois; John A. Casciotti, Associate Deputy General Counsel, Office of General Counsel, United States Department of Defense, of Washington, DC; and Gerald A. Wesley, Associate General Counsel, Defense Legal Services Agency, United States Department of Defense, of Aurora, Colorado.

Appealed from: United States Department of Veterans Affairs

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DECIDED: September 11, 2006

Before RADER, SCHALL, and LINN, Circuit Judges.

SCHALL, Circuit Judge.

Pursuant to 38 U.S.C. § 502, the Coalition for Common Sense in Government Procurement ("Coalition") petitions for review of the October 14, 2004 letter ("the Dear Manufacturer letter") of the Department of Veterans Affairs ("VA").[1] The Coalition is a multi-industry association representing over 300 companies, including pharmaceutical

[1] Section 502 gives us the authority to directly review the validity of the VA's regulations and the VA's rulemaking process. Paralyzed Veterans of Am. v. Sec'y of Veterans Affairs, 345 F.3d 1334, 1339 (Fed. Cir. 2003).

companies, which provide products and services that are procured by the federal government. The Dear Manufacturer letter requires manufacturers of drugs covered by the health care benefits program of the Department of Defense ("DOD") to refund to DOD the difference between the drugs' wholesale commercial price and their federal ceiling prices.

For the reasons set forth below, we hold that the Dear Manufacturer letter comprises a substantive rule,[2] as defined in 5 U.S.C. § 551(4), and that the VA did not comply with the procedural requirements for substantive rulemaking set forth in the Administrative Procedure Act ("APA"), ch. 324, 60 Stat. 237 (codified as amended at 5 U.S.C. § 551 et seq. (2000)), before issuing the letter. We therefore grant the Coalition's petition for review, set aside the Dear Manufacturer letter, and remand the matter to the VA for compliance with the procedures required by the APA.

BACKGROUND

I.

By way of background, we begin with a discussion of DOD's health care benefits program and the Veterans Health Care Act of 1992 ("VHCA"), Pub. L. 102-585, 106 Stat. 4943 (codified as amended at 10 U.S.C. § 1074 and scattered sections of 38 U.S.C.), which applies to the program and which is administered by the VA.

DOD provides a health care benefits program called TRICARE to active duty service members, retired service members, and their dependents. 60 Fed. Reg. 52078, 52078 (Oct. 5, 1995). TRICARE is administered by the TRICARE Management Activity

[2] Substantive rules are also known as legislative rules. Nat'l Org. of Veterans' Advocates, Inc. v. Sec'y of Veterans Affairs, 260 F.3d 1365, 1374 (Fed. Cir. 2001).

("TMA") within DOD. See PGBA, L.L.C. v. United States, 389 F.3d 1219, 1221 (Fed. Cir. 2004) (summarizing the TRICARE program).

The present action concerns just one aspect of TRICARE, the current TRICARE Pharmacy Benefits Program, which was put in place on May 3, 2004. See 69 Fed. Reg. 17035, 17035 (April 1, 2004) (noting that the final rule would become effective May 3, 2004). Like the pre-May 2004 TRICARE Pharmacy Benefits Program, the current TRICARE Pharmacy Benefits Program covers at least a portion of a beneficiary's cost of prescription drugs when the beneficiary acquires the drugs from one of four sources: a Military Treatment Facility ("MTF"); a network retail pharmacy; a non-network retail pharmacy; or the TRICARE Mail Order Pharmacy ("TMOP").[3] 32 C.F.R. § 199.21(h)(1) (2006). Under 32 C.F.R. § 199.21(i), the amount of cost-sharing between beneficiaries and DOD varies depending on the source of the prescription drugs obtained. Beneficiaries have no co-payment when they obtain drugs from an MTF. Id. § 199.21(i)(2)(i). However, beneficiaries must pay a co-payment when they obtain drugs from a retail pharmacy, id. § 199.21(i)(2)(ii), although the co-payment is smaller when a beneficiary purchases drugs at a network pharmacy rather than at a non-network pharmacy. Compare id. with id. § 199.21(i)(2)(iii). Similar to the pharmacy benefits program, when drugs are purchased through TMOP, beneficiaries pay a co-payment to the TMOP distributor. Id. § 199.21(i)(2)(v).

[3] MTFs are traditional "brick and mortar" medical facilities operated by the military. Network pharmacies are those commercial pharmacies that have entered agreements with DOD to charge beneficiaries a set price for drugs. Non-network pharmacies are those commercial pharmacies that have not entered such agreements. TMOP allows beneficiaries to order and receive prescriptions by mail from a TRICARE contractor

However, unlike the pre-May 2004 version of the TRICARE Pharmacy Benefits Program, the current program utilizes a Pharmacy Benefits Manager ("PBM"). The PBM is responsible for overseeing the distribution and payment for prescription drugs throughout the retail pharmacy network. When a TRICARE beneficiary purchases covered drugs at a network retail pharmacy, the pharmacy transmits data concerning the beneficiary to the PBM. The PBM then relays this beneficiary information to DOD and requests authorization to pay DOD's portion of the cost-share for the drugs to the network pharmacy. After receiving this information, DOD's Pharmacy Benefits Office checks beneficiary eligibility and potential drug interactions. DOD then authorizes the PBM to approve the transaction, accept the beneficiary's co-pay, and pay the pharmacy the difference between the beneficiary's co-pay and the retail price of the drugs. Most of this information exchange between the network pharmacy and the PBM occurs in "real time" before the beneficiary's prescription is filled. However, DOD's payment to the pharmacy only occurs after a ten-day hold period. Notably, the PBM does not provide these services for non-network retail pharmacies.

II.

The Dear Manufacturer letter concerns the application of the VHCA to the TRICARE Pharmacy Benefits Program. The VHCA was enacted in 1992 to reduce the cost of prescription drugs used in the VA health care benefits programs. As seen, the VHCA is codified at scattered sections of Title 38. The VHCA includes 38 U.S.C. § 8126, which provides in relevant part:

> (a) Each manufacturer of covered drugs shall enter into a master agreement with the Secretary [of the VA] under which—

> (1) beginning January 1, 1993, the manufacturer shall make available for procurement on the Federal Supply Schedule of the General Services Administration each covered drug of the manufacturer;
> (2) with respect to each covered drug of the manufacturer procured by a Federal agency described in subsection (b) on or after January 1, 1993, that is purchased under depot contracting systems or listed on the Federal Supply Schedule, the manufacturer has entered into and has in effect a pharmaceutical pricing agreement with the Secretary . . . under which the price charged during the one-year period beginning on the date on which the agreement takes effect may not exceed 76 percent of the non-Federal average manufacturer price (less the amount of any additional discount required under subsection (c)) during the one-year period ending one month before such date (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period are not available, during such period as the Secretary considers appropriate), except that such price may nominally exceed such amount if found by the Secretary to be in the best interests of the Department or such Federal agencies[.]

Thus, section 8126(a) limits the price that manufacturers of "covered drugs" may charge for drugs "procured by a Federal agency." Section 8126(b)(2) lists DOD as a "Federal agency" to which section 8126(a) applies. Accordingly, section 8126(a) requires that manufacturers charge DOD a percentage of the non-federal average manufacturer price ("non-FAMP") for "covered drugs."[4] This price limit is also called the federal ceiling price ("FCP").

As seen, section 8126 limits "covered drugs" to those obtained through one of two sources: the drugs must be (1) "listed on the Federal Supply Schedule" or (2) "purchased under depot contracting systems." The Federal Supply Schedule ("FSS") of

[4] The non-FAMP is defined as "the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period." 38 U.S.C. § 8126(h)(5) (2000).

the General Services Administration authorizes the VA to award and manage contracts with pharmaceutical companies in order to obtain low prices. See 41 U.S.C. § 259(b)(3) (2000). The statute does not provide a definition of a "depot contracting system." However, section 8126(h)(3) defines the term "depot," as used in "depot contracting system" in section 8126(a), as follows:

> The term "depot" means a centralized commodity management system through which covered drugs procured by an agency of the Federal Government are—
> (A) received, stored, and delivered through—
> (i) a federally owned and operated warehouse system, or
> (ii) a commercial entity operating under contract with such agency; or
> (B) delivered directly from the commercial source to the entity using such covered drugs.

Examination of procurement by MTFs and the TMOP illustrates the features of direct procurement via listing on the FSS and procurement through a "depot contracting system." Under section 8126(a), FCP pricing is available for both MTFs and for the TMOP because they operate either through direct procurement by VA facilities or a prime vendor arrangement in which a merchant middleman distributes drugs to VA facilities. Direct procurement from the FSS expressly falls under section 8126(a). FCP pricing is available for the prime vendor arrangement because the prime vendor arrangement falls under the definition of a "depot contracting system" in section 8126. In contrast to MTFs and the TMOP, prior to May of 2004, DOD could not obtain drugs at low FCP prices for its TRICARE Pharmacy Benefits Program because the program did not utilize either direct procurement from the FSS or a "depot contracting system" as required by section 8126.

On October 10, 2002, a policy group composed of representatives of the various interested components of the VA authored the "White Paper for the Office of the Secretary Tricare and Federal Ceiling Prices" ("the White Paper"). The White Paper described the history of the TRICARE Pharmacy Benefits Program and how DOD had sought from its inception to obtain section 8126 coverage for TRICARE. The White Paper noted, however, that the VA previously had found that the TRICARE Pharmacy Benefits Program did not fall under section 8126. The paper then explained how DOD responded by proposing that the TRICARE Pharmacy Benefits Program be restructured to include a PBM. This proposed restructured TRICARE is referred to in the White Paper as the "new" TRICARE Pharmacy Benefits Program even though it was not implemented as of October of 2002. The White Paper concluded that "covered drugs purchased in the form of DoD beneficiary prescriptions under the retail portion of the new [TRICARE Pharmacy Benefits Program] do qualify for Federal Ceiling Prices because, under the plan submitted to us, such purchases will be a procurement by DoD under a depot contracting system as defined in 38 U.S.C. § 8126(h)(3)." DOD's new TRICARE Pharmacy Benefits Program was eventually implemented on May 3, 2004. See Part I, supra (describing the "new" TRICARE Pharmacy Benefits Program as implemented May 3, 2004). In other words, as of May 3, 2004, the retail pharmacy portion of DOD's TRICARE Pharmacy Benefits Program was deemed to be subject to the price limits of the VHCA.

III.

On October 14, 2004, the VA issued the Dear Manufacturer letter, which is the subject of the present dispute. The letter was authored by the Acting Director of the VA

National Acquisition Center. The Dear Manufacturer letter is addressed to manufacturers of covered drugs and states that 38 U.S.C. § 8126 applies to the TRICARE Pharmacy Benefits Program as it was restructured effective May 3, 2004. The letter explains that the VA had considered in October of 2002 whether DOD's restructured TRICARE Pharmacy Benefits Program met the definition of a "depot contracting system" under section 8126. The Dear Manufacturer letter makes no mention of the White Paper, which was written on October 10, 2002, but states instead that the Secretary of the VA ("Secretary") had determined on October 24, 2002 that the restructured TRICARE Pharmacy Benefits Program would fall under the statute. Based on the Secretary's 2002 determination, the letter reasons that DOD is entitled to the benefits of the lowered FCP prices established under section 8126. The letter states that although TMA was entitled to refunds as of June 1, 2004, no refunds would be demanded until after September 30, 2004. The Dear Manufacturer letter also asserts that the Secretary has the authority to determine whether DOD had established a "depot contracting system" within the meaning of 38 U.S.C. § 8126(a). Because the Secretary exercised that authority by finding that the TRICARE Pharmacy Benefits Program was a "depot contracting system," the letter states that DOD is entitled to FCPs for "covered drugs" distributed through network pharmacies. The letter asserts, "No published notice or rulemaking is required to make effective the policy and requirements already established by statute and written agreements."

In addition to stating that the TRICARE Pharmacy Benefits Program falls under section 8126, the Dear Manufacturer letter provides detailed instructions as to how manufacturers should pay the VA. The letter states:

> Because TMA's retail pharmacy network covered drug purchases will be made initially at commercial prices, TMA will obtain Federal ceiling pricing for these purchases by forwarding detailed purchase data to manufacturers each month and then requesting refunds on a quarterly basis to achieve Federal pricing.

The letter contains instructions for calculating refunds as well as FCPs under the new system. To this effect, the letter references a website for information about transmitting data and collecting refunds. Further, the VA attached six pages of sample calculations to aid manufacturers in calculating FCPs.

The effect of the Dear Manufacturer letter is to require that manufacturers calculate and pay refunds for covered drugs purchased at network pharmacies. Manufacturers are also required to adjust their sales data for the purposes of calculating non-FAMPs. Although the Dear Manufacturer letter states that TMA would begin demanding refunds as of September 30, 2004, the VA has agreed to stay enforcement pending judicial review. However, in its agreement to stay enforcement, the VA explicitly states that it does not purport to speak on behalf of DOD. As noted, the Coalition has petitioned us for review of the Dear Manufacturer letter.

DISCUSSION

I.

As noted above, the Coalition cites 38 U.S.C. § 502 as the basis for our jurisdiction to review the Dear Manufacturer letter. Section 502 provides in relevant part as follows:

> An action of the Secretary to which section 552(a)(1) or 553 of title 5 (or both) refers (other than an action relating to the adoption or revision of the schedule of ratings for disabilities adopted under section 1155 of this title) is subject to judicial review. Such review shall be in accordance with

> chapter 7 of title 5 and may be sought only in the United States Court of Appeals for the Federal Circuit.

Thus, section 502 gives us exclusive jurisdiction over "[a]n action of the Secretary [of Veterans Affairs] to which section 552(a)(1) or 553 of title 5 (or both) refers . . . ." 38 U.S.C. § 502 (2000).

Sections § 552(a)(1) and 553 are part of the APA. Both section 552(a)(1) and section 553 govern procedures for agency rulemaking. Section 552(a)(1) provides in relevant part as follows:

> (a) Each agency shall make available to the public information as follows:
> (1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public—
>
> * * *
>
> (D) substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and
> (E) each amendment, revision, or repeal of the foregoing.

Section 553 sets forth guidance as to when notice and comment procedures are required and specific procedures for conducting notice and comment rule making. Section 553 provides in relevant part as follows:

> (b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—
> (1) a statement of the time, place, and nature of public rule making proceedings;
> (2) reference to the legal authority under which the rule is proposed; and
> (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

> Except when notice or hearing is required by statute, this subsection does not apply—
> (A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or
> (B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.
> (c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.
> (d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—
> (1) a substantive rule which grants or recognizes an exemption or relieves a restriction;
> (2) interpretative rules and statements of policy; or
> (3) as otherwise provided by the agency for good cause found and published with the rule.
> (e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

Both sections 552(a)(1) and 553 require that specific procedures be followed with regard to substantive rules. In contrast, neither section 552(a)(1) nor section 553 refers to "orders." Because section 502 only gives us jurisdiction to review agency actions to which sections 552(a)(1) or 553 refer, we therefore lack jurisdiction to review orders under section 502. In contrast, we have jurisdiction to review rules because both sections 552(a)(1) and 553 refer to an agency rule. This jurisdiction extends to both substantive rules, to which both sections 552(a)(1) and 553 apply, e.g., LeFevre v. Sec'y, Dep't of Veterans Affairs, 66 F.3d 1191, 1196-98 (Fed. Cir. 1995) (evaluating the merits of a challenge to a substantive rule), and interpretative rules, to which section

552(a)(1) applies, e.g., Nat'l Org. of Veterans Advocates, 260 F.3d at 1376-77 (exercising jurisdiction to evaluate the merits of a challenge to an interpretative rule).

Section 551 provides definitions of agency substantive "rules" and "orders" as used in the APA. Section 551(4) states that a "rule" means

> the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing[.]

An "order" is defined in section 551(6) as

> the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing[.]

In those cases where we have jurisdiction under section 502, we review the merits of a petition for review under 5 U.S.C. § 502 according to the APA. Disabled Am. Veterans v. Gober, 234 F.3d 682, 690 (Fed. Cir. 2000). Under the APA, we "decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning and applicability of the terms of an agency action." 5 U.S.C. § 706 (2000). We will uphold an agency rule unless it is

> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
> (B) contrary to constitutional right, power, privilege, or immunity;
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
> (D) without observance of procedure required by law . . . .

Id.

II.

The Coalition argues that we have jurisdiction to review the Dear Manufacturer letter under section 502 because it comprises a substantive rule to which sections 552(a)(1) and 553 refer. The Coalition asserts that the letter is a rule because it does more than clarify the manufacturers' existing obligations. Instead, the Coalition contends, the letter reverses agency policy in that it (i) changes the VA's position as to whether the TRICARE Pharmacy Benefits Program is covered by the VHCA and (ii) requires that manufacturers pay refunds. It therefore is substantive. The Coalition argues that the VA recognized the Dear Manufacturer letter represents a reversal of policy because it makes statements concerning the policy ramifications for affected industries. The Coalition also contends that the agency action affected "individual rights and obligations" by requiring affirmative actions from all manufacturers and is therefore a substantive rule. Thus, the Coalition argues, the Dear Manufacturer is more than a mere interpretative rule.

With respect to the content of the Dear Manufacturer letter, the Coalition contends that the letter must be set aside on two grounds. First, the Coalition argues that the letter is substantively invalid because it relies on erroneous constructions of "procure," "covered drug," and "depot" as used in section 8126. Second, the Coalition contends that the letter is procedurally defective because the government did not comply with sections 552(a)(1) and 553 before issuing the letter, and therefore it must be set aside.

The government characterizes the Dear Manufacturer letter as an order, which is not referred to in 5 U.S.C. §§ 552(a)(1) or 553 and is therefore not reviewable under 38

U.S.C. § 502. In support of this characterization, the government points out that, in its opening brief, the Coalition frequently characterizes the Dear Manufacturer letter as an order. The government also argues that the Dear Manufacturer letter does not actually represent a decision to require refunds: In actuality, the Secretary decided in October of 2002 to require the refunds. The Dear Manufacturer letter merely implements that decision or provides public notice of that decision.[5]

In the alternative, the government argues that even if the Dear Manufacturer letter is a rule rather than an order, it is an interpretative rule for which no notice and comment procedures are required. The letter is interpretative, the government urges, because it merely interprets the VHCA. The government argues that the fact that the letter is "binding" does not make it a substantive rule because interpretative rules are binding interpretations of federal statutes. Thus, the government asserts that the binding nature of a rule does not make it substantive. Even if the Dear Manufacturer letter is a substantive rule, the government contends, we lack jurisdiction under section 502 because the statute only gives the Federal Circuit the authority to review the VA's actions and not DOD's actions, which are at issue in the present case. According to the government, this is because DOD is seeking refunds under the Dear Manufacturer letter and, if notice and comment procedures were necessary, it would have been DOD's responsibility to promulgate regulations in the Code of Federal Regulations.

In the event that the case is not dismissed for lack of jurisdiction, the government defends the Dear Manufacturer letter as being substantively valid. Thus, the

[5] The government does not contend that the Dear Manufacturer letter reflects an enforcement decision unreviewable under Heckler v. Chaney, 470 U.S. 821 (1985).

government defends the letter's interpretation of the terms "procure," "covered drug," and "depot" in section 8126.

III.

We first address whether the Coalition's claim for pre-enforcement review of the Dear Manufacturer letter is ripe for judicial review. It is appropriate for us to consider ripeness even though it is not raised by the parties because ripeness is a jurisdictional consideration that the court may address sua sponte. Nat'l Park Hospitality Ass'n v. Dep't of the Interior, 538 U.S. 803, 808 (2003) ("The ripeness doctrine is 'drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction,' but, even in a case raising only prudential concerns, the question of ripeness may be considered on a court's own motion." (quoting Reno v. Catholic Soc. Servs., 509 U.S. 43, 58 (1993))).

Ripeness involves a two-part inquiry. First, we must determine whether the issue is fit for judicial review. Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967); Nat'l Org. of Veterans' Advocates, Inc. v. Sec'y of Veterans Affairs, 330 F.3d 1345, 1346 (Fed. Cir. 2003). Second, we must consider whether withholding judicial review would work hardship on the parties. Abbott Labs., 387 U.S. at 149.

Turning first to the question of fitness, we find that the issues presented by the parties deal largely with legal issues of statutory construction, which we have previously held fit for pre-enforcement judicial review. See Nat'l Org. of Veterans' Advocates, 330 F.3d at 1347. Second, we find that hardship would be incurred by both parties if we were to forego judicial review. The VA has agreed to stay enforcement of the Dear Manufacturer letter pending judicial review. The government is losing out on hundreds

of millions of dollars in refunds from manufacturers annually as a result of the stay. If the parties end the stay, the manufacturers represented by the Coalition will be forced to pay millions. Further, we have recognized that pre-enforcement review under 38 U.S.C. § 502 is ripe under Abbott Laboratories. Id. at 1347. Therefore, we find that the Coalition's petition for review of the Dear Manufacturer letter is ripe for review.

IV.

We next address the proper characterization of the Dear Manufacturer letter. There are three possible ways to view the Dear Manufacturer letter: (1) as an order, as defined in section 551(6); (2) as a substantive rule, as defined in section 551(4); or (3) as an interpretative rule. Our characterization of whether the Dear Manufacturer letter is an order or a rule will determine whether we have jurisdiction under section 502. That is because section 502 gives us jurisdiction over those categories of agency actions to which either section 552(a)(1) or section 553 refers. Thus, we have jurisdiction under section 502 to review substantive and interpretative rules, but not orders. The determination of whether the letter is a substantive rule or an interpretative rule will determine whether the agency was required to comply with the publication requirement of section 552(a)(1) and the notice and comment procedures of section 553.

We begin with the government's argument that the Dear Manufacturer letter is an order. As seen, section 551(6) defines an "order" as "the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing[.]" Notably, "adjudication" is defined under the APA as "agency process for the formulation of an order." 5 U.S.C. § 551(7) (2000). Thus, an order is issued as part of an adjudicatory

process. See Nat'l Labor Relations Bd. v. Sears, Roebuck & Co., 421 U.S. 132, 158-59 (1975) (noting that an order is part of "adjudication" under the APA). In contrast to an order, the Dear Manufacturer letter was not written as part of an adjudicative process, such as an enforcement proceeding against a particular manufacturer. Instead, the letter prospectively requires action on behalf of all drug manufacturers. See Goodman v. Fed Commc'ns Comm'n, 182 F.3d 987, 995 (D.C. Cir. 1999) ("Although bearing some superficial resemblance to a rule, the Implementation Order addressed a proposal made on behalf of certain licensees only for a temporary, remedial waiver of the agency's build out rules—not for their general, prospective amendment."). The fact that the Coalition sometimes refers to the letter as an order does not alter the nature of the Dear Manufacturer letter. We thus conclude that the Dear Manufacturer letter is not an order.

We next examine whether the Dear Manufacturer letter is a substantive rule, as the Coalition argues, or an interpretative rule, as the government urges. In determining whether an agency action is a substantive rule, we begin by looking to 5 U.S.C. § 551(4). E.g., Paralyzed Veterans of Am. v. Sec'y of Veterans Affairs, 308 F.3d 1262, 1264 (Fed. Cir. 2002). As seen, section 551(4) states that "rule" means

> the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing[.]

The definition of a substantive rule is "broad" and includes action that is "'legislative in nature, is primarily concerned with policy considerations for the future rather than the

evaluation of past conduct, and looks not to the evidentiary facts but to policy-making conclusions to be drawn from the facts.'" Paralyzed Veterans, 308 F.3d at 1264-65 (quoting Lefevre, 66 F.3d at 1196). Substantive rules thus "effect a change in existing law or policy or . . . affect individual rights and obligations." Paralyzed Veterans of Am. v. West, 138 F.3d 1434, 1436 (Fed. Cir. 1998); see Lefevre, 66 F.3d at 1198 (finding that the Secretary's decision not to create a presumption of service-connection for particular diseases was a substantive rule in part because the decision had "an immediate and practical impact" on veterans claiming benefits). The change in existing law affected by a substantive rule is binding not only within the agency, but is also binding on tribunals outside the agency. Splane v. West, 216 F.3d 1058, 1064 (Fed. Cir. 2000). Thus, a substantive rule has the "force and effect of law." Id. Accordingly, we have characterized substantive rules as "'gap filling' or an exercise of [an agency's] rulemaking power." Id. at 1063. In contrast to a substantive rule, an interpretative rule "'simply indicates an agency's reading of a statute or a rule. It does not intend to create new rights or duties, but only reminds affected parties of existing duties.'" Id. at 1063 (quoting Paralyzed Veterans of Am., 138 F.3d at 1436).

We conclude that the Dear Manufacturer letter is substantive in nature because it changes existing law and affects individual obligations. The letter changes existing law and affects individual obligations because it creates a new refund system. Under the new system, manufacturers are required to pay refunds totaling $100 to $200 million annually to TMA for covered drugs purchased at network pharmacies. They also are required to change their sales data for the purpose of calculating non-FAMPs. The Dear Manufacturer letter itself contemplates that it is changing existing law when it

states that the VA "has agreed not to demand refunds . . . until after September 30, 2004." Thus, the refund system described in the letter has "general or particular applicability and future effect." See 5 U.S.C. § 551(4). We conclude that the VA intended its refund system to be binding not only on itself, but also on tribunals interpreting whether or not a manufacturer has complied with the letter. The letter references a DOD website for further details concerning its refund system. Among other things, the website contains a manual entitled "Process and Procedures for Manufacturer Refunds." The manual contemplates disputes between the agency and manufacturers, which would likely be resolved by the courts. Thus, it is clear that the letter was intended to have binding effect outside the agency. Based on the foregoing, we find that the Dear Manufacturer letter is a substantive rule to the extent that it establishes a refund system for imposing FCPs on manufacturers.

We reject the government's argument that the Dear Manufacturer letter is merely an interpretative rule. Contrary to the government's arguments, we find that the Dear Manufacturer letter did more than just interpret the VHCA. The establishment of a refund system comprises a form of gap filling that is substantive in nature rather than a mere interpretation of a statutory term. We also reject the government's argument that the letter merely implements the policy set forth in the White Paper. The White Paper merely proposed an interpretation of section 8126; it did not set forth a refund system and mandate compliance. In contrast, the Dear Manufacturer letter establishes a refund system and requires that manufacturers comply. Further, an agency's characterization of its actions as interpretative is not dispositive. See Splane, 216 F.3d at 1063. Thus,

we find that the VA's contention that the letter is interpretative does not alter our conclusion that the Dear Manufacturer letter comprises a substantive rule.

V.

We next determine whether the Dear Manufacturer letter is reviewable under section 502. As required for jurisdiction under section 502, we hold that sections 552(a)(1) and 553 apply to the Dear Manufacturer letter because it is a substantive rule and not an order or an interpretative rule. Contrary to the government's argument that the Coalition is seeking review of DOD's actions, the Dear Manufacturer letter was authored by the Acting Executive Director of the VA National Acquisition Center and is therefore "[a]n action of the Secretary" under section 502. We conclude that we have jurisdiction to review the Dear Manufacturer under 38 U.S.C. § 502.

VI.

Finally, we address the Coalition's arguments that the Dear Manufacturer letter must be set aside because it is a substantive rule and the agency did not comply with the procedures set forth in sections 552(a)(1) and 553 before issuing the letter. This issue requires little discussion.

Under 5 U.S.C. § 706(2)(D), we must set aside an agency action that is made "without observance of procedure required by law." As seen, section 553 requires that an agency comply with notice and comment procedures before issuing a substantive rule. An agency's failure to comply with notice and comment procedures is grounds to set aside an agency rule. See Nat'l Org. of Veterans' Advocates, 260 F.3d at 1375 ("Failure to allow notice and comment, where required, is grounds for invalidating the rule."). Having found that the Dear Manufacturer letter is a substantive rule, the sole

question is whether the agency complied with section 553. It is undisputed that notice and comment procedures of section 553 were not followed before the issuance of the Dear Manufacturer letter. Therefore, we set aside the Dear Manufacturer letter because it is procedurally defective under 5 U.S.C. § 553 and remand the matter to the agency for compliance with the APA's procedural requirements, including both 5 U.S.C. §§ 552(a)(1) and 553.[6]

CONCLUSION

For the foregoing reasons, we hold that the Dear Manufacturer letter comprises a substantive rule that was enacted without compliance with the procedures required by the APA. We therefore set aside the letter as procedurally defective and remand the matter to the VA for compliance with the procedures required by the APA.

COSTS

Each party shall bear its own costs.

REMANDED

[6] Section 552(a)(1) creates procedural requirements applicable to substantive rules. Although the government should comply with these procedures on remand, we do not base our finding that the Dear Manufacturer letter is procedurally defective on these grounds.

In addition to its argument that the Dear Manufacturer letter is procedurally defective, the Coalition contends that the interpretation of the VHCA in the letter is unlawful under section 706 because it is "arbitrary, capricious, an abuse of discretion, or otherwise contrary to law." However, we find that it is unnecessary for us to reach this argument given our conclusion that the letter is procedurally defective.