UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs,* –v– ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services, *et al.*, *Defendants.*	**Case No. 18-cv-2084 (RC)**

NOTICE OF ADMINISTRATIVE DECISION

In their Motion for a Preliminary and Permanent Injunction, Plaintiffs stated that on August 10, 2018, Plaintiff Henry Ford Health System submitted a request to Health and Human Services' ("HHS's") Departmental Appeals Board ("the Board") for expedited access to judicial review. ECF No. 2-1 at 14–15. On October 2, 2018, the Board denied Henry Ford's request, noting that Henry Ford could potentially receive unfavorable decisions in its administrative appeals on the grounds that those appeals are precluded by statute. EAJR Ruling No. 4, Docket No. A-18-115 at 5–6 (Oct. 2, 2018) (attached). The Board reasoned that, because of that possibility, Henry Ford had failed to demonstrate that the Agency's reimbursement rule for the 340B Program (the policy that Henry Ford is challenging) was the *only* issue preventing a favorable decision in Henry Ford's administrative appeals. *See id.* at 5.

This decision is notable because it directly undercuts the Government's argument regarding exhaustion. In its Motion to Dismiss, the Government asserted that the Court should not waive further exhaustion of administrative procedures because HHS regulations provide an avenue for appeals that raise a legal issue that agency adjudicators do not have authority to

resolve: expedited access to judicial review. *See* ECF No. 15 at 27 (discussing 42 C.F.R. § 405.990). But Plaintiffs have now received a definitive ruling that the opportunity for expedited judicial review under HHS regulations is *not* available because the Government has asserted that Plaintiffs' claims are barred both by the regulation that Plaintiffs have challenged and by preclusion. *See* EAJR Ruling No. 4 at 5–6.

The decision of the Departmental Appeals Board explicitly acknowledges that "neither the ALJ nor the [Medicare Appeals] Council has the authority to find the 2018 OPPS Rule invalid." *Id.* at 6. The Board's decision thus emphasizes the utter futility of further exhaustion of administrative procedures. The Board forwarded the case to the HHS Office of Medicare Hearings and Appeals ("OMHA"), but OMHA's only option is to "flag those filings and dismiss them promptly" as "non-reviewable determinations," according to HHS's representation to this Court in another lawsuit. *See* ECF No. 2-1 at 18–19 & Ex. U. The Court should waive further exhaustion as utterly futile, as the D.C. Circuit has held is appropriate under far less compelling circumstances. *See Tataranowicz v. Sullivan*, 959 F.2d 268, 274–75 (D.C. Cir. 1992); *see also Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 110–12 (D.D.C. 2015).

Dated: October 9, 2018

Respectfully submitted,

/s/ William B. Schultz

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CERTIFICATE OF SERVICE

I hereby certify that on October 9, 2018, I caused the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

/s/ William B. Schultz
William B. Schultz

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Departmental Appeals Board
Appellate Division, MS-6127
Room G-644, Cohen Building
330 Independence Avenue, SW
Washington, D.C. 20201

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

October 3, 2018

William B. Schultz
Zuckerman Spaeder LLP
1800 M Street NW
Suite 1000
Washington, D.C. 20036

Re: Henry Ford Health System
Internal Control Nos. 21800900583604MIA,
21801000637704MIA, 21801000640004MIA
Board Docket No. A-18-115
EAJR Ruling No. 4
Dated: October 2, 2018

Dear Mr. Schultz:

Enclosed is the Ruling of the Review Entity for Expedited Access to Judicial Review in the cases identified above.

Sincerely yours,

Judith Pichler, Deputy Director
Appellate Division

Enclosures

cc: Director, Medicare Operations Division

Amanda Axeen, Acting Chief Advisor
Charles Koch, Acting Director
Program Evaluation and Policy Division
Office of Programs
Office of Medicare Hearings and Appeals
(EAJR Request included as Enclosure)

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD

Review Entity for Expedited Access to Judicial Review

SUBJECT: Henry Ford Health System DATE: October 2, 2018
Docket No. A-18-115
Internal Control Nos. 21800900583604MIA, 21801000637704MIA, 21801000640004MIA
EAJR Ruling No. 4

RULING REJECTING EXPEDITED ACCESS TO JUDICIAL REVIEW REQUEST

On August 13, 2018, the Departmental Appeals Board received the request (Request) of Henry Ford Health System (Ford, requestor) that the review entity described in 42 C.F.R. § 405.990(a) grant expedited access to judicial review (EAJR) of appeals related to three reimbursement claims for drugs purchased pursuant to section 340B of the Public Health Service Act (the 340B Program).

42 C.F.R. § 405.990 provides that a party to a Qualified Independent Contractor (QIC) reconsideration determination may obtain EAJR in place of a hearing before an ALJ if a review entity certifies that the ALJ does not have the authority to decide a question of law or regulation relevant to the matters in dispute and that there are no other issues of material law or fact in dispute. The review entity is defined as up to three reviewers who are ALJs or Members of the Departmental Appeals Board. 42 C.F.R. § 405.990(a)(1). The review entity in this case consists of the two undersigned Members of the Departmental Appeals Board.

For the reasons explained below, we deny the request for EAJR.

Background

The 340B Program, administered by the Health Resources and Services Administration (HRSA) within the Department of Health and Human Services (HHS), allows participating hospitals and other health care providers to purchase certain covered outpatient drugs at discounted prices from manufacturers. Reimbursement rates for drugs dispensed to hospital outpatients under Medicare, including for those originally purchased under the 340B program, are promulgated through regulations under the Hospital Outpatient Prospective Payment System (OPPS). Section 1833(t)(14)(A)(iii) of

the Social Security Act (Act) requires the Secretary of HHS to set the reimbursement rate for a covered drug to be equal to the average acquisition cost of the drug for that year, taking into account hospital acquisition cost survey data. If hospital acquisition cost data are not available, the law requires that reimbursement be equal to reimbursement rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary for purposes of section 1833(t)(14). On November 13, 2017, the Centers for Medicare & Medicaid Services (CMS) issued a OPPS final rule in which the Secretary adjusted, *inter alia*, the calendar year (CY) 2018 reimbursement rate for separately payable, nonpass-through drugs acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. *See* 82 Fed. Reg. 52,356, 52,493 (Nov. 13, 2017), revised by 82 Fed. Reg. 59,216 (Dec. 14, 2017) (2018 OPPS Rule). The 2018 reimbursement rate for such drugs acquired outside the 340B Program remained at ASP plus 6 percent. *Id.*

Ford participated in a lawsuit "challenging the 2018 OPPS Rule as a violation of the statutory requirements for calculating reimbursement rates for drugs covered by the 340B program under [section 1833(t)(14)(A)(iii) of the Act]." Request at 2 (citing *Am. Hosp. Ass'n v. Hargan*, No. 1:17-cv-02447 (D.D.C. filed Nov. 13, 2017)). The plaintiffs argued that "the 2018 OPPS Rule impermissibly exceeded CMS's authority to 'adjust' the reimbursement rate each year and that it was inconsistent with section 340B of the Public Health Service Act and the Administrative Procedure Act." *Id.* The Court found that the plaintiffs did not have standing until they presented claims for reimbursement to CMS. *Id.* (citing *Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45 (D.D.C. 2017), *aff'd sub nom., Am. Hosp. Ass'n. v. Azar*, No. 18-5004, 2018 WL 3431746 (D.C. Cir. July 17, 2018)).

After the 2018 OPPS Rule went into effect on January 1, 2018, Ford submitted three claims for reimbursement of drugs purchased under the 340B Program. Requestor Exhibit (R. Ex.) 1, at 1; R. Ex. 2, at 1; R. Ex. 3, at 1. On January 25 and 30, 2018, WPS Government Health Administrators (WPS), a Medicare Administrative Contractor, issued an initial determination notice for each claim that granted reimbursement according to the rate as adjusted by the 2018 OPPS Rule. R. Ex. 1, at 2; R. Ex. 2, at 2; R. Ex. 3, at 2. Ford requested redetermination from WPS for all three claims on February 8, 2018. R. Ex. 1, at 4; R. Ex. 2, at 4; R. Ex. 3, at 4. In its requests for redetermination, Ford argued that:

> The new rate violates . . . [section 1833(t)(14)(A)(iii)(II) of the Act], the authority to pay for this drug, because it: (1) is not an "adjustment" to the statutory default rate (ASP+6%), (2) is based on acquisition cost, when reliable data on acquisition cost is concededly unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B program.

R. Ex. 1, at 4; R. Ex. 2, at 4; R. Ex. 3, at 4. On March 6, 2018, WPS issued unfavorable redetermination decisions for all three claims, stating that "the services in question have already been paid" and that "there does not appear to be any errors impacting the payment amount, which is the maximum payment amount allowed by Medicare for this service." R. Ex. 1, at 5; R. Ex. 2, at 5; R. Ex. 3, at 5.

Ford sought reconsideration of its claims with Maximus Federal Services (Maximus), a QIC. R. Ex. 1, at 7; R. Ex. 2, at 7; R. Ex. 3, at 7. Maximus issued favorable reconsideration determinations finding that Ford had been "underpaid." R. Ex. 1, at 11-14; R. Ex. 2, at 11-14; R. Ex. 3, at 9-13. Maximus subsequently informed Ford by letter that it was reopening each of its appeals and that new reconsideration determinations would be issued under new Medicare appeal numbers. R. Ex. 1, at 15; R. Ex. 2, at 16; R. Ex. 3, at 15. On July 11, 2018, Maximus issued a letter informing Ford that it would not be issuing new reconsideration determinations, and that the new Medicare appeal numbers had been deleted from its system. R. Ex. 1, at 18; R. Ex. 2, at 19; R. Ex. 3, at 18. Ford asserts that it requested review in filings before an administrative law judge (ALJ) of the Office of Medicare Hearings and Appeals (OMHA).[1] R. Ex. 1, at 19-22; R. Ex. 2, at 20-23; R. Ex. 3, at 19-22.

Legal Standards for EAJR

42 C.F.R. § 405.990(b) provides, in relevant part, that a party may request EAJR in place of an ALJ hearing if the following conditions are met:

- A Qualified Independent Contractor (QIC) has made a reconsideration determination, and the party has filed a request for an ALJ hearing in accordance with § 405.1002 and the ALJ has not issued a final action;
- The requestor is a party, as defined in § 405.990(e);
- The amount in controversy meets the requirements of § 405.1006(b) or (c);
- If there is more than one party to the reconsideration, each party concurs, in writing, with the request for EAJR; and
- There are no material issues of fact in dispute.

[1] The regulation at 42 CFR § 405.990(b)(1) provides that a party may request EAJR if (1) a QIC has made a reconsideration determination, and the requestor has a pending request for an ALJ hearing in accordance with 42 C.F.R. § 405.1002, or a pending request for Council review in accordance with § 405.1102; or (2) the appeal has been escalated from the QIC to OMHA for an ALJ hearing. Here, Maximus issued three reconsideration determinations on Ford's claims, but subsequently informed Ford that it would not be issuing new reconsideration determinations, and had deleted the new Medicare appeal numbers from its system. We need not make a finding in this Ruling whether Ford satisfies the requirements for EAJR found in section 405.990(b)(1) insomuch as our conclusion rests on Ford failing to satisfy the requirements found in sections 405.990(c)(2) and 405.990(g)(3)-(4) because the validity of the disputed provisions is not the only issue precluding a decision favorable to the requestor.

The regulation further provides that the request for EAJR must:

- Allege that there are no material issues of fact in dispute and identify the facts that the requestor considers material and that are not disputed; and
- Assert that the only factor precluding a decision favorable to the requestor is a statutory provision that is unconstitutional, a provision of a regulation or national coverage determination, or a CMS Ruling that the requestor considers invalid.

The request must also specify any statutory provision that the requestor considers unconstitutional or the provisions of any regulation or national coverage determination that the requestor considers invalid. 42 C.F.R. § 405.990(c)(1) and (c)(2).

If the QIC reconsideration is based on facts that the requestor is disputing, the requestor must state why it considers those facts immaterial. 42 C.F.R. § 405.990(c)(4). Moreover, if the QIC reconsideration is based on a provision of law, regulation, national coverage determination, or CMS Ruling in addition to the provision the requestor considers unconstitutional or invalid, the request for EAJR must include "a statement as to why further administrative review of how [the additional] provision applies to the facts is not necessary." 42 C.F.R. § 405.990(c)(5).

EAJR Request

Ford alleges that the only material dispute on appeal is the proper reimbursement amount for its three claims. Request at 4. Ford asserts that the only factor precluding favorable decisions is "that the provisions of the 2018 OPPS Rule setting reimbursement rates for drugs subject to the 340B Program are invalid." *Id.* (citing 82 Fed. Reg. 52,356, 52,493-52,511, 52,622-625 (Nov. 13, 2017)). Specifically, Ford reiterates its argument that the provisions "exceed CMS's authority to 'adjust' reimbursement rates for drugs subject to the 340B Program under . . . [section 1833(t)(14)(A)(iii)(II) of the Act] and are inconsistent with the statute establishing the 340B Program." *Id.* at 4-5. Ford further alleges that neither the ALJ nor the Medicare Appeals Council (Council) have the authority to rule on this issue because it involves the validity of a regulation, and "[a]ll laws and regulations pertaining to the Medicare and Medicaid programs… are binding on ALJs… and the Council." *Id.* at 5 (citing 42 C.F.R. § 405.1063(a)). Finally, Ford asserts that the amount in controversy exceeds the $1,600 threshold for judicial review. *Id.* (citing 82 Fed. Reg. 45, 592 (Sep. 29, 2017)).

Analysis

We deny Ford's request for EAJR because it does not meet the requirements of 42 C.F.R. § 405.990. A request for EAJR must show that the only issue precluding a decision favorable to the requestor is the constitutionality of a statute or the validity of a regulation, national coverage determination, or CMS Ruling. 42 C.F.R. §§ 405.990(c)(2), 405.990(g)(3)-(4). Ford asserts that the provisions in the 2018 OPPS Rule adjusting the rate used to determine reimbursement amounts for drugs purchased under the 340B Program for CY 2018 are inconsistent with section 1833(t)(14)(A)(iii) of the Act and section 340B of the Public Health Service Act. Ford claims that the alleged invalidity of these provisions is the sole issue that precludes a decision in its favor. However, we find that Ford's appeals present the additional issue of whether an ALJ has jurisdiction to hear appeals that challenge the reimbursement rate for drugs purchased under the 340B program or whether the appeals are excluded by section 1833(t)(12) of the Act and 42 C.F.R. § 405.926(c). Jurisdiction is a potentially dispositive issue and is within an ALJ's authority to determine on appeal. Thus, we conclude Ford has not satisfied the conditions for EAJR because the challenged provisions in the 2018 OPPS Rule are not the sole issue that precludes a decision in Ford's favor.

The applicable authority is at best ambiguous as to whether Ford's appeals may be heard pursuant to procedures set forth in 42 C.F.R. Part 405. The regulations provide a list of determinations that are considered "initial determinations" and thus may be appealed under Part 405. The list includes determinations that involve "[i]ssues having a present or potential effect on the amount of benefits to be paid under Part A or Part B of Medicare, including a determination as to whether there was an underpayment of benefits paid under Part A or Part B, and if so, the amount thereof." 42 C.F.R. § 405.924(b)(11). Ford's appeals seemingly fall within the parameters of section 405.924(b)(11) in that the initial determinations issued by WPS contained determinations regarding the amount of benefits to be paid under Medicare Part B. The regulations, however, also provide a list of actions that are not "initial determinations," and thus may not be appealed under Part 405. The list of actions that are not initial determinations include "[a]ny issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B…." *Id.* § 405.926(c). Moreover, the statute authorizing the Secretary to adjust the rates paid under the OPPS precludes all administrative and judicial review of "the development of the [OPPS] classification system," including adjustments and fee schedule amounts for particular drugs. Act § 1833(t)(12)(A), (E); *see also Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004) (holding that there is no judicial review for *prospective* payments made through the OPPS system pursuant to Act § 1833(t)(12)(A)). Thus, an ALJ must determine whether an appeal that uses an initial determination of

reimbursement for drugs purchased under the 340B Program as a vehicle to challenge the validity of the regulation that sets the rate for reimbursement of those drugs may be heard under Part 405, or whether it is excluded by section 1833(t)(12) of the Act and 42 C.F.R. § 405.926(c).

Our conclusion should not be read to infer that all requests for EAJR are precluded on the grounds that an ALJ may find that it lacks jurisdiction to hear the appeal. Rather, our conclusion rests on the principle that EAJR is inappropriate in situations where, as here, the issue of jurisdiction is a potentially dispositive issue that remains in dispute. By Ford's own admission, CMS instructed Maximus to reopen its reconsideration determinations and dismiss its appeals because "in CMS's view, there are no administrative appeal rights for disputes about reimbursement under the 340B Program . . . ." Request at 4 n.3. Thus, the issue of jurisdiction has clearly been placed in dispute and remains in dispute. We agree with Ford that neither the ALJ nor the Council has the authority to find the 2018 OPPS Rule invalid. However, an unfavorable ruling on the preliminary question of jurisdiction would potentially result in a final disposition of the appeals without reaching the validity of the regulation. Therefore, we conclude that the issue of the regulation's validity is not the "only factor precluding a decision favorable to the requestor" as required by the EAJR regulations. We therefore must reject the request.

Conclusion

Given the above, we find that Ford has not demonstrated that the only factor precluding a decision favorable to the requestor is the constitutionality of a statute or the validity of a regulation, national coverage determination, or CMS Ruling. Accordingly, pursuant to 42 C.F.R. § 405.990(i), we deny Ford's request for expedited access to judicial review. We therefore forward the case to OMHA for consideration.

Constance B. Tobias

Constance B. Tobias, Chair
Departmental Appeals Board

Leslie A. Sussan, Member
Departmental Appeals Board

DEPARTMENT OF HEALTH & HUMAN SERVICES

DEPARTMENTAL APPEALS BOARD

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Washington, D.C. 20201
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