United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 18-5111 **September Term, 2018**

FILED DECEMBER 7, 2018

LOMA LINDA UNIVERSITY KIDNEY CENTER AND LOMA LINDA UNIVERSITY MEDICAL CENTER,
APPELLANTS

v.

ALEX MICHAEL AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES,
APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 1:15-cv-01721)

Before: PILLARD, *Circuit Judge*, and GINSBURG and SENTELLE, *Senior Circuit Judges*.

J U D G M E N T

The court considered this appeal on the record from the United States District Court for the District of Columbia and the briefs filed by the parties. *See* Fed. R. App. P. 34(a)(2); D.C. Cir. R. 34(j). We accorded the issues full consideration and determined they do not warrant a published opinion. *See* D.C. Cir. R. 36(d). For the reasons stated below, it is hereby

ORDERED and **ADJUDGED** that the judgment of the district court is **AFFIRMED**.

I.

Loma Linda University Kidney Center and Loma Linda University Medical Center (together, the Loma Linda Centers) appeal from a summary judgment rejecting their claim that the Department of Health and Human Services (HHS) owes them exceptional Medicare reimbursement based on what they claim are the unusual circumstances of the dialysis treatments they provide to patients with end-stage renal disease. The Social Security Act, which governs reimbursements for end-stage renal dialysis under the Medicare program, deems a request for exceptional reimbursement approved unless it is disapproved within sixty days. 42 U.S.C. § 1395rr(b)(7). Here, the agency's disapproval letters were dated within the sixty-day period, but the Loma Linda Centers received them later, more than sixty days after their request. HHS treats a disapproval decision as timely if made within sixty days of the request, whereas the Loma Linda

Centers urge us to hold that the statute requires that providers also receive notice of the disapproval within the sixty days. We affirm the district court's grant of judgment in favor of the Secretary.

Under the implementing regulations, HHS's Centers for Medicare and Medicaid Services (CMS) ordinarily reimburses dialysis providers like the Loma Linda Centers at a "composite rate." *See* 42 C.F.R. § 413.180. Reimbursements are processed through insurance companies, called "Medicare administrative contractors" (previously known as "fiscal intermediaries" and referred to here simply as "intermediaries"). 42 U.S.C. § 1395kk-1 note; *see also* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, § 911(b). When "warranted by unusual circumstances," a provider may ask for dialysis reimbursement at more than the composite rate. 42 U.S.C. § 1395rr(b)(7). A provider must request such an exception through an intermediary, which then presents it to CMS for approval. Under the Act, a request "shall be deemed to be approved unless the Secretary disapproves it by not later than 60 working days after the date the application is filed." 42 U.S.C. § 1395rr(b)(7). The implementing rules specify that the sixty-day time period starts when the provider submits its request to the intermediary. *See* 42 C.F.R. § 413.180(g). Neither statute nor rule specifies that CMS must give the provider notice of any disapproval within the sixty days.

On August 28, 2000, the Loma Linda Centers submitted their exception requests to their intermediary, citing "atypical patient mix[es]." *See* J.A. 7, 260; *see also* 42 C.F.R. § 413.180(*l*)(1). The sixtieth working day after that was Friday, November 24, 2000. CMS denied the exception requests by signed letters dated November 15, 2000. J.A. 7, 260. Those letters were sent to the intermediary, which stamped them "received" on November 27, 2000. *Id.* The intermediary then notified the Loma Linda Centers over the next two weeks—one on November 29 and one on December 11. J.A. 15, 266.

The Loma Linda Centers appealed the denials of their exception requests to the Provider Reimbursement Review Board, which ruled in their favor. The Board concluded that the requests should be deemed approved because CMS had not provided notice to the Loma Linda Centers within sixty days. J.A. 51, 288. On review of the Board's ruling, the CMS Administrator reversed. J.A. 53-59. She concluded that CMS did not need to provide notice to the providers or their intermediary within sixty days—it just needed to render its decision by then. J.A. 57-58. The Administrator noted that "[t]he statute does not state that the actual notice of the disapproval must be *received* by the provider within 60 working days after the application is filed." *Id.* Specifically, she reasoned, "the key word in § [1395rr(b)(7)] is 'disapproves,' which is defined in ordinary use as, 'to refuse to approve; reject.'" J.A. 58 (citing Am. Heritage Dictionary (4th ed. 2000)). "[T]he plain language" requires only that CMS make its decision within sixty days. *Id.* CMS therefore concluded that the disapprovals at issue here, dated within the sixty days, were effective. *Id.*

The Loma Linda Centers sought review in district court. On cross-motions for summary judgment, the court held that the statute was ambiguous and that the agency's interpretation was reasonable. J.A. 112-15. The court reasoned that "[t]he key to the Administrator's decision is her conclusion that the term 'disapproves' in 42 U.S.C. § 1395rr(b)(7) does not encompass service of the CMS denial letters." J.A. 112-13. Focusing on "whether the Secretary's interpretation of the Medicare statute is reasonable and warrants deference," the court held: "It is and it does." J.A. 113. The court also denied the Loma Linda Centers' requests for discovery regarding the date on

which the November 15, 2000, letters were actually signed and mailed, because unsupported speculation that the letters were misdated did not overcome the presumption of regularity afforded to public records. J.A. 126-29.

The Administrator had expressly accepted for review both the notice issue and the merits but had only resolved the first issue, so the court remanded to the agency. J.A. 116-17. After the Board affirmed CMS's denial of the Loma Linda Centers' exception requests on their merits, the providers again sought judicial review of their sixty-day notice claim. The district court adhered to its initial ruling, unpersuaded by the Loma Linda Centers' contention that our intervening decision in *Gundersen Lutheran Medical Center, Inc. v. Sebelius*, 666 F.3d 1335 (D.C. Cir. 2011), required reversal. J.A. 234-36. The court granted summary judgment in favor of HHS. J.A. 244-45. This appeal followed.

II.

The relevant provisions of the governing statute make no mention of the time within which HHS must notify a provider that the agency has denied its request for an exception to the ordinary kidney-dialysis reimbursement rate. Rather, the statute specifies only that "[e]ach application for such an exception shall be deemed to be approved unless the Secretary disapproves it by not later than 60 working days after the date the application is filed." 42 U.S.C. § 1395rr(b)(7). We sustain the Secretary's conclusion that the statute does not require that notice be received by the provider within the sixty-day period. As the Secretary observed, the plain meaning of "disapprove" is simply "reject"—it does not mean both reject and notify. J.A. 58. Other sections of the Act include express deadlines for mailing or receipt of notice. The provision governing individuals' benefits claims, for example, specifies not only the time for decision, but that notice must be "mailed to the individual filing the claim before the conclusion of [the] 45-day period." 42 U.S.C. § 1395ff(a)(2)(A). Similarly, a decision by the Board "shall be final unless the Secretary . . . reverses, affirms, or modifies" it "within 60 days after the provider of services is notified of the Board's decision." 42 U.S.C. § 1395*oo*(f)(1). Such specification elsewhere in the statute suggests that the absence of any such requirement here is deliberate. That conclusion is consistent with the legislative history, which reveals that the provision at issue was enacted in response to complaints that the agency took too long to make its determinations. *See* H.R. Rep. No. 99-727, at 76 (1986).

The agency's position comports with our decision in *Gundersen*, which rejected a similar claim that a failure of notification within the statutory sixty days required HHS to grant its application. We do not, however, read *Gundersen* to support the Loma Linda Centers' argument that a decision must be communicated outside the agency within the sixty-day period to satisfy the statute's timely-determination requirement. In *Gundersen*, we acknowledged that "'disapproves' is a meaningless concept unless disapproval is communicated in some fashion." 666 F.3d at 1336. We did not require that the decision necessarily be shared outside the agency for it to be timely under Section 1395rr(b)(7). Rather, we thought "there would have to be some evidence that a disapproval decision was rendered in an official way, at a certain time," presumably "in writing"; a disapproval only "in the mind of the decision maker" or "uttered only within" CMS would not suffice. *Id*. at 1336-37. We specifically rejected the provider's contention that "notification [to the provider] within 60 days was . . . necessary for the [agency's] disapproval to be effective." *Id*.

at 1335. Ultimately, because the intermediary there received written disapproval within the sixty days, we held that the decision "was clearly memorialized." *Id.* at 1337.

According to the Loma Linda Centers, a decision cannot be said to have been made until it is final, and a decision is not final until it is communicated to someone else. *See* Appellants' Br. 13-14. They analogize to cases discussing when an agency decision is final and reviewable. *Id.* But, as the government points out, effectiveness and finality are legally distinct. Appellee's Br. 17 (citing *Western Union Tel. Co. v. FCC*, 733 F.2d 375, 377 (D.C. Cir. 1985)). Here, we conclude that the decisions were effective when they were authoritatively memorialized in writing, nine days before the deadline, even though it is not apparent on this record whether the intermediaries or anyone else outside the agency had them in hand until later.

The Loma Linda Centers suggest another reason why even the dates of the determination letters may not suffice as evidence that HHS met the statutory deadline: If the letters were not in fact authoritatively signed until nine or more days after they were dated, the requisite determination would still be late. Appellants' Br. 18 n.3. The Loma Linda Centers provide no basis for such speculation. As the district court held, the presumption of regularity typically afforded public records supports the agency's conclusion that CMS memorialized its decision in writing on the date of the letter. *See Riggs Nat'l Corp. & Subsidiaries v. Comm'r of Internal Revenue*, 295 F.3d 16, 20 (D.C. Cir. 2002).

We recognize that the statute's time frame for an adverse determination without a corresponding deadline for notification to the provider of the disapproval, combined with the rule giving applicants 180 days from "the date of the decision" to appeal, 42 C.F.R. § 413.194(c), leaves open the potential for an odd result. The agency could, in theory, make its decision promptly yet drag its heels in notifying the provider, thereby diminishing the provider's time to appeal. We noted this concern in *Gundersen*, and observed that, "if, for some hypothetical reason, [CMS'] decision was not available to the applicant in a timely manner, the relevant question would be how to interpret the appeal regulation—not the statute." 666 F.3d at 1337. That issue is not before us here, as the Loma Linda Centers have not raised it and the facts do not support it, but we agree with the suggestion in *Gundersen* that, should it arise, it would put in issue the time the agency affords for a provider to appeal, as distinct from the meaning of the statutory reference to disapproval. In the meantime, a provider presumably can ensure that its right to appeal is not jeopardized by calling the intermediary or HHS once the sixty days expires to determine whether the Secretary disapproved its request. *See id.* at 1337.

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The Clerk is directed to withhold issuance of the mandate until seven days after resolution of any timely petition for rehearing or rehearing *en banc*. *See* Fed. R. App. P. 41(b); D.C. Cir. R. 41(b).

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY:
/s/
Ken Meadows
Deputy Clerk