IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 14-60158

United States Court of Appeals
Fifth Circuit
FILED
March 11, 2015
Lyle W. Cayce
Clerk

PERRY COUNTY NURSING CENTER,

Petitioner

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent

Petition for Review of a Decision of the
Department of Health and Human Services
No A-13-86

Before JOLLY, WIENER, and CLEMENT, Circuit Judges.

PER CURIAM:*

Petitioner Perry County Nursing Center ("Perry") seeks review of a final decision by Respondent, United States Department of Health and Human Services ("DHHS"), upholding an administrative determination that Perry violated specified regulatory requirements pertaining to its participation in the Medicare program. We reject Perry's challenge and dismiss its petition for review.

* Pursuant to 5TH CIR. R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

I. FACTS AND PROCEEDINGS

Perry is a skilled nursing facility ("SNF") located in Richton, Mississippi. It participates in the federal Medicare program, which is administered by the Centers for Medicare and Medicaid Services ("CMS"). CMS relies on the Mississippi State Department of Health ("MSDH") to assist it in determining whether SNFs in the state are in compliance with Medicare regulations. MSDH does this by, *inter alia*, regularly inspecting SNFs and investigating complaints lodged against them through on-site visits called "surveys."[1]

If MSDH finds a violation of Medicare regulations (a "deficiency") during a survey, it reports it to CMS.[2] Deficiencies reported to CMS are called "tags." CMS then determines the scope and severity of the deficiencies and the amount of civil money penalties ("CMPs") to be paid.[3] If an SNF is assessed a CMP, it may appeal to an administrative law judge ("ALJ").[4] The ALJ's decision is reviewed by DHHS's Departmental Appeals Board ("DAB").[5] If the SNF is dissatisfied, it may then seek judicial review of the DAB's decision.[6]

There are two surveys at issue in this case. The first occurred in January 2010, after a Perry staff member stole 2,446 Lortabs, a controlled pain medication. This survey assessed two tags: Tag F224, for failure to develop written policies and procedures to ensure that facility staff do not misappropriate medications, and Tag F425, for lacking appropriate policies to manage the ordering and inventorying of medications. In April 2010, MSDH determined that Perry was back "in substantial compliance."

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[1] *See* 42 U.S.C. § 1395i-3(g)(2), (4).
[2] *See id.* § 1395i-3(h)(1).
[3] *See id.* § 1395i-3(h)(2)(B)(ii); 42 C.F.R. § 488.402.
[4] *See* 42 C.F.R. §§ 431.151(a)(1), 498.5(k).
[5] *See id.* §§ 498.5(k), .80–.83.
[6] *See id.* § 498.5(k).

The second survey occurred in August 2011. It was not a routine survey and appears to have been prompted by concerns over Perry's compliance with Medicare regulations. This survey assessed five tags: (1) Tag F281, for failing to provide prescribed medication to residents; (2) Tag F425, for failing to follow procedures in acquiring, receiving, storing, controlling, and reconciling medications; (3) Tag F520, for the failure of Perry's quality assessment committee to address medication-related deficiencies; (4) Tag F514, for inadequate clinical recordkeeping; and (5) Tag F225, for failing to inform the local police about the Lortab theft. Of these five, the first three—F281, F425, and F520—were determined to create an Immediate Jeopardy to the health and safety of Perry's residents. CMS assessed a CMP of $3,550 per day from April 30, 2011, the day the deficiencies were determined to have begun, to September 6, 2011, the day the immediate jeopardy classification was removed. Perry was then subject to a lower CMP of $150 per day until October 17, 2011, when the facility was found to be in substantial compliance. In total, Perry incurred $467,500 in civil penalties.

Perry requested a hearing with an ALJ, challenging both MSDH's authority to conduct the August 2011 survey and the specific tags cited. The ALJ found that the August 2011 survey was not unlawful and that Perry was not in substantial compliance with Medicare requirements. The ALJ only considered Tags F281 and F425, holding that those two tags "more than justify the penalties imposed." Perry then appealed to the DAB, which affirmed the ALJ's decision.

II. ANALYSIS

A. Standard of Review

We review the decision of the DAB according to the standards provided in the Administrative Procedure Act ("APA") and the Medicare statute. The

APA "permits the setting aside of agency actions, findings, and conclusions that are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law' or 'unsupported by substantial evidence.'"[7] Under this standard, "there is a presumption that the agency's decision is valid, and the plaintiff has the burden to overcome that presumption by showing that the decision was erroneous."[8] Moreover, under the Medicare statute, the agency's factual findings, "if supported by substantial evidence on the record considered as a whole, shall be conclusive."[9] Finally, we "give substantial deference to an agency's interpretation of its own regulations," to which we assign "controlling weight unless it is plainly erroneous or inconsistent with the regulation."[10]

B. Tags F281 and F425

Perry challenges its citations and penalties under Tags F281 and F425, the only two tags considered by the ALJ and DAB. Tag F281 arises from Perry's alleged noncompliance with 42 C.F.R. § 483.20(k)(3)(i), which requires SNFs to "[m]eet professional standards of quality." Tag F425 cites Perry for violating 42 C.F.R. § 483.60(a) and (b), which require SNFs to provide effective pharmaceutical services "including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals"[11] and to "employ or obtain the services of a licensed pharmacist" to maintain accurate drug receipt and dispensation records.[12] The DAB upheld the ALJ's determination that Perry was noncompliant with both regulations.

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[7] *Cedar Lake Nursing Home v. U.S. Dep't of Health & Human Servs.*, 619 F.3d 453, 456 (5th Cir. 2010) (quoting 5 U.S.C. § 706(2)(A)–(E) (2010)).

[8] *Tex. Clinical Labs, Inc. v. Sebelius*, 612 F.3d 771, 775 (5th Cir. 2010).

[9] 42 U.S.C. § 1320a-7a(e).

[10] *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (quoting *Udall v. Tallman*, 380 U.S. 1, 16–17 (1965)) (internal quotation marks omitted); *see also Auer v. Robbins*, 519 U.S. 452, 461–62 (1997).

[11] 42 C.F.R. § 483.60(a).

[12] *Id.* § 483.60(b).

1. Tag F281

The substance of Perry's challenge to Tag F281 is that, when the deficiency cited pertains to medication, 42 C.F.R. § 483.20(k)(3)(i)'s "professional standards of quality" requirement must be interpreted in accordance with 42 C.F.R. § 483.25(m), which defines the medication error rates that SNFs must not exceed. Under 42 C.F.R. § 483.25(m), an SNF "must ensure that—(1) [i]t is free of medication error rates of five percent or greater; and (2) [r]esidents are free of any significant medication errors." Perry contends that, when medication is at issue, these two requirements form the *exclusive* basis for interpreting 42 C.F.R. § 483.20(k)(3)(i)'s requirement that SNFs "[m]eet professional standards of quality." In other words, if Perry's medication dispensation performance was compliant with 42 C.F.R. § 483.25(m)—Perry contends that it was[13]—it could not have been noncompliant with 42 C.F.R. § 483.20(k)(3)(i).

Because CMS interprets 42 C.F.R. § 483.20(k)(3)(i) as defining a standard of performance independent of 42 C.F.R. § 483.25(m),[14] Perry must show that CMS's interpretation is plainly erroneous or inconsistent with the regulation. First, Perry relies on DHHS's commentary when promulgating 42 C.F.R. § 483.25(m), in which the agency noted that the regulation "left a facility free to create and manage its own [drug distribution] system *in any way it sees fit* as long as it does not make 'significant' medication errors and has an overall

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[13] We doubt that Perry was compliant with 42 C.F.R. § 483.25(m). The DAB found that at least one resident experienced a significant medication error when Perry staff failed to provide a prescribed painkiller. As the regulation requires SNFs to operate "free of *any* significant medication errors," *id.* § 483.25(m)(2) (emphasis added), the DAB's determination that Perry violated 42 C.F.R. § 483.20(k)(3)(i) *even if* the standards of 42 C.F.R. § 483.25(m) were applied was not erroneous.

[14] CMS explains that its guidance documents clearly differentiate between "errors in the techniques of medication administration," which should be cited under 42 C.F.R. § 483.20(k)(3), and "actual medication errors," which should be cited under 42 C.F.R. § 483.25(m). CMS, STATE OPERATIONS MANUAL app. PP, at 155 (2015).

medication error rate of less than five percent."[15] Perry reads this statement as granting SNFs virtual carte blanche in managing medications, limited only by the two listed criteria in 42 C.F.R. § 483.25(m). This interpretation would, however, render superfluous *any* regulation affecting SNFs' drug distribution mechanisms. If we were to agree with Perry, the medication-error regulation would not only preempt 42 C.F.R. § 483.20(k)(3)(i) but also, for example, 42 C.F.R. § 483.60, which establishes specific pharmaceutical procedures for SNFs to follow.[16] Perry points to nothing to indicate that DHHS intended 42 C.F.R. § 483.25(m) to have such an expansive reach.

Second, Perry asserts that a "plain reading" of the regulations supports its interpretation. We find no basis for this assertion. There is nothing in 42 C.F.R. pt. 483 to suggest that 42 C.F.R. § 483.25 contains the exclusive definition of "professional standards of quality" as applied to SNFs' drug distribution. 42 C.F.R. § 483.25(m) makes no reference to 42 C.F.R. § 483.20(k)(3)(i) or to "professional standards of quality."

Third, Perry relies on *Caretel Inns of Brighton*, a 2012 decision in which an ALJ, in choosing a standard to apply when assessing compliance with 42 C.F.R. § 483.20(k)(3)(i), held that "the regulation at 42 C.F.R. § 483.25(m)(2) establishes the standard of quality, *supplanting any lesser standard*."[17] Critically, the ALJ chose 42 C.F.R. § 483.25(m)(2) over a *less* stringent standard, reasoning that "[t]he application of any lesser standard from another source would constitute a failure to follow the Secretary's regulations."[18] Thus,

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[15] Medicare and Medicaid; Requirements for Long Term Care Facilities, 56 Fed. Reg. 48,826, 48,853 (Sept. 26, 1991) (emphasis added).

[16] *See, e.g.*, 42 C.F.R. § 483.60(c) (requiring every resident's drug regimen to be "reviewed at least once a month by a licensed pharmacist"); *id.* § 483.60(d) (detailing drug labeling requirements); *id.* § 483.60(e) (setting drug storage requirements).

[17] DAB No. CR2643, 2012 WL 5389866, at *11 (U.S. Dep't of Health & Human Servs. Oct. 12, 2012) (emphasis added).

[18] *Id.*

Caretel does not support Perry's approach; it indicates, at most, that 42 C.F.R. § 483.25(m) establishes a floor for 42 C.F.R. § 483.20(k)(3)(i), not a ceiling.

Finally, Perry suggests that a specific regulation, such as 42 C.F.R. § 483.25(m), trumps a general regulation, such as 42 C.F.R. § 483.20(k)(3)(i). This canon of construction, however, applies only when two regulations are inconsistent and cannot be reconciled.[19] CMS's interpretation does not present such a conflict.

In conclusion, Perry has not met its burden of showing that CMS's interpretation of 42 C.F.R. § 483.20(k)(3)(i) was plainly erroneous or inconsistent with the regulation. Furthermore, Perry does not challenge the DAB's specific findings that it failed to meet professional standards of quality with respect to the distribution of medication.[20] Accordingly, we affirm the DAB's determination that Tag F281 was properly imposed.

2. Tag F425

Perry's challenge to Tag F425 is similar. It asserts that 42 C.F.R. § 483.60(a) and (b), like 42 C.F.R. § 483.20(k)(3)(i), address "medication errors" and thus are governed by the standard defined in 42 C.F.R. § 483.25(m). We find this contention likewise unconvincing. 42 C.F.R. § 483.60(a) and (b) require an SNF to have pharmaceutical procedures in place and a pharmacist to oversee those procedures. A facility could easily be found in compliance with the requirements of this section but not in compliance with the requirements of 42 C.F.R. § 483.25(m), or vice versa. Furthermore, these two regulations

[19] *See United States v. Mackay*, 757 F.3d 195, 199 (5th Cir. 2014).

[20] The DAB upheld the ALJ's determination that the medication deficiencies cited by CMS constituted violations of professional standards of quality. This conclusion is supported by substantial evidence.

have different purposes, as 42 C.F.R. § 483.25(m) is plainly result-oriented,[21] whereas 42 C.F.R. § 483.60(a) and (b) focus on process. The issues that CMS found justified Tag F425 were primarily documentation errors, hinging on Perry's failure to follow procedures, and not incidents of residents receiving incorrect medications. Accordingly, we affirm the DAB's determination that Tag F425 was properly imposed.[22]

C. Tag F520

Perry also seeks to set aside Tag F520, which is based on an alleged violation of 42 C.F.R. § 483.75(o)(1)'s requirement that an SNF maintain a quality assessment and assurance committee. The ALJ did not consider this tag because she found that Tags F281 and F425 "more than justify the penalties imposed." The DAB concluded that this decision was within the ALJ's discretion. Perry does not challenge the ALJ's determination that Tags F281 and F425 alone justify the CMPs imposed, but rather contends that it has the right to appeal all deficiencies cited because any deficiencies not successfully appealed remain in its public record. It further contends that the imposition of Tag F520 is not supported by substantial evidence.

Although Perry raises a reasonable concern, it cites no persuasive legal authority for its position. DHHS has long interpreted its regulations to require ALJs to review only those findings that are material to the outcome of a case.[23] Perry has failed to show that this approach is plainly erroneous or inconsistent with the regulation. The DAB's decision to pretermit a review of Tag F520 was

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[21] *See* Medicare and Medicaid; Requirements for Long Term Care Facilities, 56 Fed. Reg. 48,826, 48,853 (Sept. 26, 1991) (discussing DHHS's decision to set an "outcome-oriented standard" for medication errors, rather than a process-oriented one).

[22] As with Tag F281, Perry does not challenge the DAB's factual finding that it violated pharmaceutical procedures. We find the DAB's determination to be supported by substantial evidence.

[23] *See Alexandria Place*, DAB No. 2245, 2009 WL 1455338, at *17 n.9 (U.S. Dep't of Health & Human Servs. Apr. 30, 2009) (collecting cases).

not arbitrary or capricious, and we decline to consider Perry's substantive challenge to it.[24]

D. Legality of August 2011 Survey

Finally, Perry asserts that all of the tags should be set aside because CMS violated its own regulations in conducting the August 2011 survey. CMS may only reopen "initial or reconsidered determination[s] within 12 months after the date of notice of the initial determination."[25] According to Perry, the August 2011 survey constituted an illegal reopening of the April 2010 determination that Perry was back in substantial compliance with Medicare regulations after the Lortab-theft incident. In support of this characterization, Perry notes that several MSDH documents concerning the August 2011 survey refer back to the January 2010 investigation. Specifically, the form containing the August 2011 survey results states that the prior complaint investigation had been "re-opened," and MSDH sent Perry several letters to that effect, as well.

To the extent that Perry challenges the August 2011 tags as illegal reopenings of the April 2010 determination of substantial compliance, we are not convinced. None of the five deficiencies identified in August 2011 relate back to the April 2010 findings, and MSDH's conclusion that Perry had successfully resolved the two tags cited in the January 2010 survey remains untouched. Furthermore, the CMPs at issue were imposed for a period of noncompliance starting on April 30, 2011. The actions that resulted in Tags F281, F425, F520, and F514 either occurred after this date or were ongoing as of it.

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[24] *See Senior Rehab. & Skilled Nursing Ctr. v. Health & Human Servs.*, 405 F. App'x 820, 825 (5th Cir. 2010) (per curiam) (unpublished) (citing *Claiborne-Hughes Health Ctr. v. Sebelius*, 609 F.3d 839, 847 (6th Cir. 2010)).

[25] 42 C.F.R. § 498.30.

The only tag cited in August 2011 that even arguably implicates the April 2010 determination is Tag F225, which found a deficiency based on Perry's failure to report the Lortab theft to the police. First, we note that the CMPs imposed on Perry may be justified without Tag F225.[26] Second, Perry does not dispute that, as of April 30, 2011, it still had not reported the loss of Lortabs to the police. Third, and finally, we agree with CMS that Tag F225 is a new deficiency, not a reopening of an old one. Broadly, Tag F225 is related to Tag F224 from the January 2010 survey, as both penalize actions related to the same loss of Lortabs. That these two tags concern the same period of time and underlying facts is, however, not persuasive because they address different conduct. Penalizing Perry for failing to report the loss of narcotics is not a revision of the previous penalty for losing them. As Tag F225 does not revise, or even revaluate, Tag F224, there is no reopening. We thus conclude that Tag F225, like the other tags cited in August 2011, concerns deficiencies not relevant to the April 2010 substantial-compliance determination.

To the extent that Perry challenges the August 2011 survey itself as procedurally deficient under 42 C.F.R. § 498.30, and the tags imposed as tainted by this defect, we likewise find this contention wholly unconvincing. CMS interprets 42 C.F.R. § 498.30 as limiting only the agency's ability to reopen *determinations*—that is, determinations that an SNF is in substantial compliance or noncompliance with the Medicare regulations.[27] In CMS's view, a survey, whether routine or instigated by a specific complaint, is not a determination, and CMS's decision to survey Perry in August 2011 is not governed by 42 C.F.R. § 498.30.

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[26] *Cf. Senior Rehab.*, 405 F. App'x at 825 (noting that only those findings material to the outcome of a case must be reviewed).

[27] *See* 42 C.F.R. § 498.30.

We defer to CMS's interpretation of its own regulations, as it is neither plainly erroneous nor inconsistent with the regulation.[28] The plain language of 42 C.F.R. § 498.30, as well as a structural reading of 42 C.F.R. pt. 498 as a whole, supports CMS's approach. There is nothing in 42 C.F.R. § 498.30 about surveys. Moreover, 42 C.F.R. § 498.3(a)(1) notes that this set of regulations concerns the "procedures for reviewing initial determinations that CMS makes," while 42 C.F.R. § 498.3(b) lists the decisions that constitute initial determinations by CMS. Nothing in that list suggests that a survey or complaint investigation is an initial determination, or that 42 C.F.R. § 498.30 governs CMS's decision to reopen such a survey or investigation.[29] Perry's complaint relies, essentially, on the fact that the word "reopen" appears in a regulation and the word "re-opened" appears in some of the documents produced by the August 2011 survey. To give credence to this coincidence would be to exalt form over substance.

We also note that MSDH and CMS possess broad authority to survey SNFs. According to the Medicare statute and implementing regulations, each SNF must be inspected at least once every fifteen months (a "standard survey"), and any SNFs found to have provided a substandard quality of care must be reinspected (an "extended survey").[30] Furthermore, MSDH and CMS may specially investigate an SNF if the facility receives complaints; experiences "a change of ownership, management, or director of nursing"; or presents "other indicators of specific concern" (an "abbreviated standard survey").[31] Any SNF found to have provided a substandard quality of care

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[28] *See Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994).

[29] The list of initial determinations includes, for example, determinations of "[w]hether a prospective provider qualifies as a provider," *id.* § 498.3(b)(1), and "[w]hether to deny or revoke a provider or supplier's Medicare enrollment," *id.* § 498.3(b)(17).

[30] 42 U.S.C. § 1395i-3(g)(2)(A)(iii)(I), (B)(i).

[31] 42 C.F.R. § 488.301; *see also id.* § 488.308(e).

during an abbreviated standard survey is also subject to reinspection (a "partial extended survey").[32] MSDH and CMS's documentation are consistent in referring to the August 2011 survey as a "partially extended survey" or a "partially extended complaint survey." At oral argument, counsel for CMS explained that the survey was triggered—and, it turns out, justifiably—by Perry's history of violations and by serious concerns over its continued noncompliance with Medicare regulations.[33] In light of CMS's broad authority to survey SNFs participating in the Medicare program, we cannot conclude that the August 2011 survey was an impermissible exercise of this authority.

III. CONCLUSION

The findings and conclusions of the DAB with regard to Perry's violations of 42 C.F.R. §§ 483.20(k)(3)(i) and 483.60(a)–(b) are not arbitrary or capricious, are in accordance with the law, and are supported by substantial evidence. Perry's challenges to the legality of the August 2011 survey and the DAB's decision not to review tags unnecessary to the outcome of this case are without merit. Accordingly, we DISMISS this petition for review.

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[32] *Id.* § 488.301.

[33] *See* CMS, *supra* note 14, § 7205.2 ("Facilities with poor histories of compliance may be surveyed more frequently to ensure that residents are receiving quality care in a safe environment."); *id.* ("The State may conduct surveys as frequently as necessary to determine if a facility complies with the participation requirements as well as to determine if the facility has corrected any previously cited deficiencies. There is no required minimum time which must elapse between surveys.").