In the

United States Court of Appeals

For the Seventh Circuit

No. 09-3485

FAL-MERIDIAN, INC.,

Petitioner,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.,

Respondents.

Petition for Review of an Order of the
Departmental Appeals Board of the
U.S. Department of Health and Human Services.
No. 2265

ARGUED APRIL 12, 2010—DECIDED MAY 6, 2010

Before CUDAHY, POSNER, and EVANS, *Circuit Judges*.

POSNER, *Circuit Judge*. The Meridian nursing home asks us to set aside a final decision by the Department of Health and Human Services that imposed a civil penalty of $7,100 on the nursing home for having violated a regulation under the Medicare and Medicaid provisions of the Social Security Act. 42 U.S.C. §§ 1302, 1395hh. The regulation requires a skilled nursing facility

to "ensure that—(1) the resident environment remains as free of accident hazards as is possible; and (2) each resident receives adequate supervision and assistance devices to prevent accidents." 42 C.F.R. § 483.25(h). The size of the penalty was based on the Department's further determination that Meridian's violation of the regulation was "likely to cause . . . serious injury, harm, impairment, or death to a resident." 42 C.F.R. §§ 488.301, 488.438(a)(1)(i).

It may seem odd that the nursing home would be seeking judicial review of such a tiny penalty, when its lawyer told us that the Department's determinations would not jeopardize the nursing home's license to serve Medicare and Medicaid patients. But the episode (which we're about to narrate) giving rise to those determinations has also incited a tort suit for wrongful death against the nursing home, and the home does not want the finding used to bolster a claim of negligence. Regulatory violations are not negligence per se but they are evidence of negligence. *Beta Steel v. Rust*, 830 N.E.2d 62, 73-74 (Ind. App. 2005); *Zimmerman v. Moore*, 441 N.E.2d 690, 696-97 (Ind. App. 1982). Meridian may also fear that the imposition of a civil penalty for an accidental death may make it harder to attract new residents.

A resident of the nursing home identified only as "B" (the Medicare administration tries to maintain patient anonymity in enforcement actions) was a 60-year-old woman covered by Medicare despite her relative youth. (The likeliest explanation for her coverage is that she had been receiving social security disability benefits for

at least two years, which would entitle her to Medicare benefits. 42 U.S.C. § 426(b). In effect, a finding of total disability accelerates one's entitlement to federal old-age benefits, including Medicare.) B suffered from schizophrenia (perhaps other mental illness or impairments as well) and dysphagia, which means difficulty in swallowing. Her dysphagia was so serious that she could not safely consume *any* food or liquid (including water)—her attempt to do so might result in her inhaling it ("pulmonary aspiration"—the breathing of foreign matter into the trachea or lungs) and as a result strangling. And so a feeding tube, called a "PEG" (percutaneous endoscopic gastrostomy), had been inserted into her stomach through the wall of her abdomen.

Readmitted to the nursing home on February 22, 2008, after the implant of the feeding tube and with a "strict NPO" (*nil per os*—"nothing by mouth") order by the hospital to the nursing home, B was placed in a room with another resident. That resident was required to take all her regular meals, plus snacks, in her bed in the room she shared with B. This placement of B turned out to be a serious error. For she had an irresistible, and possibly insane, compulsion to consume food and drink in the usual way. The conjunction of schizophrenia and dysphagia is not uncommon, and is extremely dangerous. See, e.g., J. Regan, R. Sowman, and I. Walsh, "Prevalence of Dysphagia in Acute & Community Mental Health Settings," 21 *Dysphagia* 95 (2006); T.K.S. Tan, "Dysphagia and Chronic Schizophrenia: A Case Report," 34 *Singapore Med. J.* 356 (1993). Had B been *compos mentis*, she could have eaten and drunk to her heart's content despite the

danger; for a competent person has a right to refuse treatment. *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 278-79 (1990). But her mental illness made her incompetent to make decisions about her health.

Between the date of B's readmission and her death two and a half weeks later, the nursing home's staff repeatedly witnessed her trying to eat and drink, including her roommate's food and drink, and sometimes succeeding. In fact on 18 occasions before B's death, she was observed by the staff to be eating or drinking (mainly the latter); and doubtless there were occasions, maybe many occasions, on which her infractions went unobserved or unrecorded. Yet apparently, as Meridian emphasizes, she had no untoward effects from her episodes of eating and drinking.

At some point in B's stay the staff revised her care plan to require staff to check on her every 15 minutes. Some of the occasions on which she was seen eating or drinking occurred after the revision. On March 10 her roommate told the staff that she was giving food to her. B was found dead on the bathroom floor the next night. The cause of her death has not been determined. A first death certificate said she had died of "aspiration pneumonia," which is a form of pneumonia for which dysphagia is a risk factor. But the doctor who signed the death certificate later changed his mind and certified that her death had been due to a combination of schizophrenia and chronic obstructive lung disease. She also suffered from bronchitis and congestive heart failure, and had been virtually sleepless since being readmitted to the nursing home. Her death could not have been a surprise.

This is not a wrongful-death case, so uncertainty about the cause of B's death cannot get the nursing home off the hook. The dispositive questions are, first, whether its handling of her physical and mental infirmities was consistent with its duty to keep the home as free as possible from hazards that might cause an accident to a resident (that is subsection (1) of the regulation; subsection (2), though cited by HHS in finding a violation, adds nothing to (1) in this case), and, second, if so, whether the breach of that duty was "likely to cause . . . serious injury, harm, impairment, or death to a resident."

What does "as free of accident hazards as is possible" mean? Taken literally, it would require a nursing home to take precautions regardless of cost, as long as they were at least minimally efficacious. It would have been *physically* possible, as distinct from economically responsible, for Meridian to have reduced to zero the probability of B's eating or drinking, by locking her in the equivalent of a dry cell (even if Meridian would have had to construct one) and not allowing her to leave it without a staff escort. But no one suggests that "possible" is to be taken literally. If it were, and cost were regarded as no obstacle to requiring hazard precautions, this would be unlikely to help the Bs of this world; nursing homes would turn away applicants who can be protected against *all* hazards only at a cost that would far exceed the willingness of the Medicare administration, groaning under its huge deficit, to reimburse the nursing home. (The regulation is not limited to Medicare patients, but most residents of nursing homes are

elderly and thus covered by Medicare.) Although once a person is admitted to a nursing home licensed by Medicare there are restrictions on the home's transferring or discharging the person, 42 U.S.C. § 1395i-3(c)(2)(A), there is (with immaterial exceptions) no requirement that it admit the person in the first place. See 42 U.S.C. § 1395i-3(c)(5); 42 C.F.R. § 483.12(d).

Neither the opinion issued by the Departmental Appeals Board nor the briefs of either party articulates the standard of care imposed by the "as is possible" regulation. We can assume that it's a high standard. The Social Security Act provides that "a skilled nursing facility must provide services to attain or maintain the *highest practicable* physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care." 42 U.S.C. § 1395i-3(b)(2); see also *id.*, § 1396r(b)(2) (emphasis added). The "as is possible" language of the regulation is more or less consistent with "highest practicable" (we hedge with "more or less" because eliminating a particular hazard in a particular way might conflict with maintaining an attractive quality of life—"psychosocial well-being"—as perhaps in our "dry cell" example); in any event Meridian does not challenge the regulation's validity.

The Supreme Court has distinguished "feasibility analysis" from "cost-benefit analysis" in other regulatory settings, e.g., *American Textile Manufacturers Institute, Inc. v. Donovan*, 452 U.S. 490, 508-09 (1981), and the "as is possible" regulation is suggestive of the former. Cf. 29 U.S.C. § 655(b)(5) (OSHA) (feasibility); 33 U.S.C.

§ 1316(a)(1) (Clean Water Act) (achievability); 42 U.S.C. § 7412(d)(2) (Clean Air Act) (same). In "feasibility," or its equivalent "achievability," analysis, the regulatory agency is required to *consider* costs of compliance; but only if they are in some sense prohibitive do they provide a defense. See *American Textile Manufacturers Institute, Inc. v. Donovan*, *supra*, 452 U.S. at 536. In an OSHA case we said that the test was "whether the restrictions would materially reduce a significant workplace risk to human health without *imperiling the existence of, or threatening massive dislocation to, the health care industry*." *American Dental Ass'n v. Martin*, 984 F.2d 823, 825 (7th Cir. 1993) (emphasis added).

Yet there is a feature of the "as is possible" regulation that makes us doubt that it creates a feasibility standard as demanding as the one described in *American Dental Ass'n v. Martin*. Medicare pays for the health care of most nursing-home residents. Nursing homes receive a flat per diem reimbursement from Medicare for each day of care that they provide, adjusted for the location of the nursing home and for the resources required to provide adequate care for the different types of resident. See 42 U.S.C. § 1395yy; 42 C.F.R. § 413.335; Medicare Payment Advisory Comm'n, "Medicare Payment Basics: Skilled Nursing Facility Services Payment System" (Oct. 2009), www.medpac.gov/documents/MedPAC_Payment_Basics_09_SNF.pdf (visited Apr. 20, 2010); David A. Bohm, "Striving for Quality Care in America's Nursing Homes: Tracing the History of Nursing Homes and Noting the Effect of Recent Federal Government Initiatives to Ensure Quality Care in the Nursing Home Setting," 4 *DePaul J.*

Health Care L. 317, 357-60 (2001). The per diem limits the precautions that the Medicare administration can realistically require a nursing home to take, for a home will stop admitting residents who require precautions that cost more than the reimbursement that the home can expect to receive. And if we assume that the Medicare administration sets a *reasonable* per diem rate, then in practice the "as is possible" standard will approximate the balancing of magnitude and likelihood of harm against the burden of precautions that is familiar in negligence cases and summarized in the concept of due or reasonable care. E.g., *Mesman v. Crane Pro Services*, 512 F.3d 352, 354 (7th Cir. 2008); *McCarty v. Pheasant Run, Inc.*, 826 F.2d 1554, 1556 (7th Cir. 1987); *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947) (L. Hand, J.). That may explain why the only two cases that we have found that discuss the standard of care imposed by the "as is possible" regulation call it a "reasonableness" standard, *Crestview Parke Care Center v. Thompson*, 373 F.3d 743, 754 (6th Cir. 2004); *Woodstock Care Center v. Thompson*, 363 F.3d 583, 589-90 (6th Cir. 2003), although the cases do not mention the reimbursement angle.

One more preliminary question remains to be addressed, and that is the standard of judicial review of the Departmental Appeals Board's "as is possible" and "likely to cause . . . serious . . . harm" determinations. Normally we would simply assume that the Board's judgments are entitled to the usual deference that courts give administrative decisions. *Woodstock Care Center v. Thompson*, *supra*, 363 F.3d at 589; see also *Thomas*

Jefferson University v. Shalala, 512 U.S. 504, 512 (1994); *Clancy v. Office of Foreign Assets Control*, 559 F.3d 595, 605-06 (7th Cir. 2009); *Singh v. Mukasey*, 536 F.3d 149, 154 (2d Cir. 2008). But our opinion in *Bettner v. Administrative Review Board*, 539 F.3d 613, 620-21 (7th Cir. 2008), treated as an open question whether an administrative decision should be reviewed without any deference paid the administrator when the decision was based on a grant of summary judgment; and this is the position urged by Meridian. But we reject it (answering the question left open in *Bettner*), consistent with decisions of other circuits concerning judicial review of administrative decisions made without an evidentiary hearing. *Gibson v. SEC*, 561 F.3d 548, 552-53 (6th Cir. 2009); *Martex Farms, S.E. v. EPA*, 559 F.3d 29, 32 (1st Cir. 2009); *Hasan v. U.S. Dep't of Labor*, 545 F.3d 248, 250-51 (3d Cir. 2008); *Cogeneration Ass'n v. FERC*, 525 F.3d 1279, 1282-83 (D.C. Cir. 2008).

All it means for a decision to be based on a grant of summary judgment is that there are no issues that would benefit from being resolved in an evidentiary hearing. That does not extinguish the role of judgment, based on the knowledge and experience of the administrative agency, based on uncontested facts, and based on facts that do not require determination in trial-type proceedings governed by rules of evidence ("legislative" rather than "adjudicative" facts). The absence of an evidentiary hearing does not alter the standard of judicial review of administrative decisions, set forth in the Administrative Procedure Act, which permits courts to set aside such decisions only (so far

as might bear on this case) if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "unsupported by substantial evidence." 5 U.S.C. § 706. It is true that our review of a district court's decision granting summary judgment is plenary. But that is because the only question presented by an appeal from a judgment based on such a grant is whether the winning party was entitled to judgment as a matter of law, and judicial review of pure legal rulings is plenary—it has to be in order to maintain uniformity of law throughout the appellate court's jurisdiction. *Mucha v. King*, 792 F.2d 602, 605-06 (7th Cir. 1986). Agencies are given more decisional latitude by legislatures than trial courts are—discretion for example to interpret regulations and often the agency's organic statute as well.

We turn at last to the specifics of this case. The implantation of the PEG tube (the feeding tube), and the hospital's NPO ("nothing by mouth") directive to the nursing home, signaled that the risk to B of serious harm from consuming food or drink was high. It's true that she turned out to be able to eat and drink intermittently during the 18 days between her return to the nursing home and the last day of her life, without incident. It's the nature of a risk, compared to a certainty, that one can have a run of luck. Her luck may or may not have run out on March 11—remember that we don't know the cause of her death. But risk there was, and it could have been reduced in a number of ways. B could have been placed in a double room (no single rooms were available) with a roommate who did not eat

in her room. The bathroom sink would still have been a problem, but remember that the "as is possible" standard does not require the adoption of every physically possible precaution that can be imagined. The government's lawyer told us that just replacing B's roommate with a resident who did not eat in the room might have satisfied the regulation (we do not treat that as a concession, however). *That* precaution would have been virtually costless, since of the nursing home's 39 residents 20 were assigned to eat in the dining room rather than in their own room; B's roommate could have been required to change places with one of those 20.

Alternatively, B could have been placed in a double room without a roommate and with a lock on the sink, requiring her to notify staff if she wanted to wash her hands or face. This would have been a much more costly measure and we do not say it is required. It might be the kind of measure that would exceed the Medicare per diem and so would not be reimbursed; and we are not told whether any rooms became vacant during her brief stay. But it is enough, to require us to uphold the Department's decision, that Meridian failed to take a precaution (the change in roommates) that, though perhaps not fully efficacious, would have had a nontrival effect in reducing the risk of a harm otherwise quite likely to occur; and it would have been very cheap. It might have been completely effective, moreover, if conjoined with another inexpensive precaution—namely, effective supervision of B's forays outside her room. Many of her forbidden snatchings of food and drink were from the plates of other residents in the

dining room, where she could have been watched; and then the only source of danger would have been the bathroom sink. And that was a limited danger. Dysphagia is especially serious when the sufferer is a rapid swallower, as B was, and it is difficult to swallow rapidly the water that flows from a tap in the sink. You either have to put your face in the sink and turn your head sideways, and often you'll still just get a trickle, or cup your hands in order to collect the water—and then watch most of it trickle between your fingers.

When the staff did catch B trying to eat or drink, it told her to desist ("reminded her of her dietary restrictions" and "encouraged" her to abide by them). But these "verbal cues" (such as "eating may cause death"), addressed to a madwoman, attempting to "redirect her when she was observed attempting to consume food and fluids," were ineffective and known by the staff to be so. For upon her return to the nursing home B had gotten out of the wheelchair in which she had arrived, strode to the kitchen, and asked the cook for food. A nurse told the cook, and B, that B was NPO. B yelled, "Go to hell bitch. I remember you and you are wrong." One hour later B was caught drinking from the water fountain and a nurse asked her to stop and again reminded her of the danger that forbade her to have food or water in her mouth and B yelled "You are a fucking liar and fuck the doctor too." She then locked herself in a bathroom and when she emerged it was apparent that she had been drinking out of the sink. A nurse asked her not to lock herself in the bathroom. B laughed.

It is true, as Meridian points out, that B was not *so* mentally impaired as to be unable to *understand* the meaning of the staff's admonitions to her. An affidavit from one of the nurses states that "B chose to remain non-compliant with her restrictions despite being advised of the risks." But she could not *comply*, because of her mental illness (schizophrenia inadequately controlled by medication—for she had delusions during her stay at the nursing home), which doubtless both exacerbated and was exacerbated by her sleeplessness.

Meridian complains that the case should not have been decided on summary judgment; that there should have been an evidentiary hearing. (This is different from its argument that an administrative decision made without benefit of an evidentiary hearing should be reviewed as if the administrative agency adjudicator were a district judge.) Meridian would be right if the nursing home had tendered evidence that, if believed, would show that it had done everything possible (within the meaning of the regulation) to minimize the risk of an accident to B. But it could not show that. It could not show that because it had and has no evidence to rebut the argument that placing B in a room with a noneater, and controlling her out-of-room activities more effectively, would at reasonable cost have significantly reduced the danger of strangulation.

The petition for review is

DENIED.

5-6-10