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UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

OMNI MANOR NURSING HOME, Petitioner, v. TOMMY THOMPSON, Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondents.	)	ON PETITION FOR REVIEW FROM THE FINAL DECISION OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

BEFORE: CLAY, GIBBONS, and GRIFFIN, Circuit Judges.

GRIFFIN, Circuit Judge.

Petitioner Omni Manor Nursing Home ("Omni Manor" or "Omni") appeals the affirmance by the Departmental Appeals Board ("DAB") of a civil monetary penalty ("CMP") imposed by the Secretary of Health and Human Services ("HHS") and Centers for Medicare & Medicaid Services ("CMS") for failure to comply with Medicare/Medicaid regulations. After our review of the record, we conclude that the proper legal standards were employed and that there was substantial evidence to support the decision to impose a civil monetary penalty under 42 C.F.R. § 483.20(k)(3)(i) (2001). Accordingly, we deny the petition for review.

I.

Omni Manor is a long-term care facility in Ohio that participates in the federal Medicare and Medicaid programs under a provider agreement with the Secretary of Health and Human Services. 42 U.S.C. § 1395cc (2001). As a participant in the program, Omni Manor must be in "substantial compliance" with all federal requirements for skilled nursing homes in section 1819 of the Social Security Act, 42 U.S.C. § 1395i-3(a)-(d) and corresponding regulations, 42 C.F.R. §§ 483.1-.75. Facilities that contract with the Secretary of Health and Human Services are periodically inspected by state health agencies to ensure compliance with federal regulations. 42 U.S.C. §§ 1395aa, 1395i-3(g); 42 C.F.R. § 488.20. The Ohio Department of Health ("ODH") is such a facility.

On May 18, 2001, ODH, a contract surveyor of CMS, conducted Omni Manor's annual certification survey. ODH surveyors found Omni Manor out of compliance with twelve federal requirements. The most serious deficiency was cited at the "Immediate Jeopardy" level of scope and severity with regard to a particular deficiency, F-Tag 281.[1] The surveyors found that, while caring for two of the residents, Omni did not meet professional standards of quality with respect to the comprehensive assessment procedures utilized in the administration of cardio-pulmonary resuscitation. Title 42 C.F.R. § 483.20(k)(3)(i) requires "comprehensive care plans" to "[m]eet professional standards of quality." ODH found that "the facility failed to provide the necessary care and services of cardio-pulmonary resuscitation in accordance with the comprehensive assessment and plan of care." The report reflects that several members of the Omni Manor staff were

[1]Each individual deficiency is termed "F-Tag" in ODH's report. The deficiency at issue is numbered F-Tag 281.

interviewed regarding the facility's resuscitation identification procedure. The director of nursing described Omni Manor's procedure governing resuscitation status as follows:

> [For a resident to be on do-not-resuscitate ("DNR") status] [t]here must be a progress note from the physician indicating he has discussed the issue of no cardio-pulmonary resuscitation ("CPR") with the family or resident, and a physician's order must be written for no CPR.

ODH's findings concerned the documentation of two residents' "resuscitation status" following their transfer to Omni Manor after hospitalization. Specifically, the surveyors found that the residents, CL1 and R27,[2] had conflicting information in their medical records regarding their respective resuscitation statuses.

According to the surveyors' report, CL1 was initially admitted to Omni Manor on January 9, 1998. The social service assessment completed upon admission indicated that CL1 had no durable power of attorney, nor any paperwork regarding advanced directives. Consequently, CL1 was considered to be "full code," meaning that he/she would receive cardio-pulmonary resuscitation ("CPR") if needed. The surveyors' review of the records indicated that the resident was sent to the emergency room of a local hospital on March 4, 2001, still at "full code" status. When the resident was transferred back to Omni Manor on March 14, 2001, CL1 had several new diagnoses on the hospital transfer form. The hospital transfer form also listed the resuscitation status of the resident

[2]In compliance with federal privacy regulations, all residents and former residents are referred to exclusively by a number ("Resident *N*" or "R*N*") in all public court documents. "CL" indicates that the surveyors were reviewing the records of a resident who was no longer at the facility, and the record was consequently "closed."

as "DNR" (meaning do-not-resuscitate). The surveyor found that no documentation in CL1's chart indicated that Omni Manor followed up on the discrepancy.

On April 10, 2001, CL1's "skin color went pale and dusky," and the nurse was unable to obtain a blood pressure or a pulse. A later interview with the nurse indicated that when CL1 went non-responsive, she checked the chart to determine CL1's resuscitation status. On the basis of the hospital transfer form dated March 14, 2001, the nurse decided not to initiate CPR, and the EMS squad was never called. The surveyor testified that the record indicated that the facility called the physician for "orders" immediately following CL1's non-responsiveness, and the physician ordered that CL1 be sent to the emergency room. Within fifteen minutes, CL1's condition deteriorated significantly, and CL1's respiration ceased. Another phone call to the physician was made, and a new order was given to release CL1 to the funeral home. The reviewing surveyor found "significant" the fact that a phone call was made while the patient was still alive. The surveyor noted that if CL1's DNR status was clear, the phone call would have been unnecessary. The report concludes that, according to the paperwork on file and the facility's self-defined policy, "[t]his resident should have received CPR when found non-responsive."

According to the report, R27 was also transferred to Omni Manor from a hospital. The hospital transfer orders were located in the "miscellaneous" section of his/her record. The hospital transfer form was dated March 29, 2001, and indicated that R27 was DNR. The physician's admission notes also indicated that R27 and R27's family had requested that R27 be designated as DNR status due to a terminal illness. Nevertheless, the surveyors found no standing physician's order stating that the resident was DNR. When the surveyors asked two nurses working in that unit

to determine the resuscitation status of R27, both nurses flipped to the physician's order section and indicated that R27 would receive CPR. Based on this evidence, the Secretary found that Omni Manor had not taken sufficient steps to ensure that R27's wishes regarding resuscitation status were clear in the medical record and therefore apparent to the staff.

As a result of these two situations, ODH concluded that Omni Manor was not in substantial compliance with 42 C.F.R. § 483.20(k)(3)(i). Omni was found in substantial compliance on a revisit survey on May 22, 2001. Omni disputed the findings of non-compliance and filed a request for hearing in accordance with 42 C.F.R. § 488.408(g). An administrative law judge ("ALJ") conducted a two-day hearing during which nine witnesses testified. The ALJ subsequently affirmed CMS's decision to impose a $5,750 CMP, addressing six of the twelve assessed deficiencies and upholding five. Omni Manor appealed that decision to a three-member panel of the DAB pursuant to 42 C.F.R. § 498.80. The DAB fully affirmed the ALJ's decision in a written opinion. Omni Manor has specifically limited this appeal to only one of the deficiencies; namely, whether substantial evidence existed to find that the facility did not meet professional standards of quality with respect to the comprehensive assessment procedures utilized in the administration of cardio-pulmonary resuscitation.[3]

Jurisdiction for the review of CMPs is established by 42 U.S.C. § 1320a-7a(e), which provides that "[a]ny person adversely affected by a determination of the Secretary under this section

[3]Omni has not appealed the Secretary's decision that the four other deficiencies were supported by substantial evidence or contested the reasonableness of the CMP that was assessed for those deficiencies.

may obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides."

II.

"Judicial review of decisions under 42 U.S.C. § 1320a-7a(e) is limited to determining whether the findings are supported by substantial evidence and whether the proper legal standards were employed." *MeadowWood Nursing Home v. United States Dep't of Health & Human Servs.*, 364 F.3d 786, 788 (6th Cir. 2004). The standard is highly deferential. *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583, 588 (6th Cir. 2003). When the Secretary's interpretation of regulations is reviewed, "courts may overturn the Secretary's decision only if it is 'arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law.'" *St. Francis Health Care Ctr. v. Shalala*, 205 F.3d 937, 943 (6th Cir. 2000) (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994), quoting 5 U.S.C. § 706(2)(A)). Finally, courts must "give substantial deference to an agency's interpretation of its own regulations." *Thomas Jefferson Univ.*, 512 U.S. at 512. Courts must defer to reasonable regulatory interpretations. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 94-95 (1995)*; Woodstock*, 363 F.3d at 588*; St Francis*, 205 F.3d at 944. "The findings of the Secretary with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive." 42 U.S.C. § 1320a-7a. "'Substantial evidence is defined as such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. In our review, we do not consider the case *de novo*, nor resolve conflicts in the evidence, nor decide questions of credibility.'" *MeadowWood*, 364 F.3d at 788 (quoting *Myers v. Sec'y of Health & Human Servs.*, 893 F.2d 840, 842 (6th Cir. 1990) (internal citations omitted)).

Therefore, the Court must determine (1) whether the correct legal standard was applied and, if so, (2) whether the findings were supported by substantial evidence.

III.

Omni Manor asserts that it was at all times in substantial compliance with the participation requirements of 42 C.F.R. § 483.20(k)(3)(i) by providing the appropriate "professional standards of quality." Omni Manor therefore contests both the Secretary's interpretation of the appropriate "professional standards of quality" and the evidence that supports the Secretary's decision. Omni Manor argues that the Secretary's required "professional standards of quality" with respect to the documentation of the residents' resuscitation status created a new "substantive" requirement under the existing regulations. We disagree.

Title 42 U.S.C. § 1395hh(a)(2) provides:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

If a rule or requirement is "substantive," it is subject to the Administrative Procedures Act's ("APA") "notice and comment" requirements, 5 U.S.C. § 553 (2005), though a merely "interpretive" rule or regulation is not, 5 U.S.C. § 553(b); *see Your Home Visiting Nurse Servs., Inc. v. Sec'y of Health & Human Servs.*, 132 F.3d 1135, 1139 (6th Cir. 1997).

Unfortunately, the case law governing the demarcation between "substantive" rules and "interpretive" rules is not always clear. The Supreme Court has specified that APA rulemaking

provisions do apply when an agency adopts a "new position inconsistent with any of the [agency's] existing regulations." *Guernsey*, 514 U.S. at 100. Put differently, "[a]n interpretative rule simply states what the administrative agency thinks the statute means, and only 'reminds' affected parties of existing duties . . . . On the other hand, if by its action, the agency intends to create new law, rights or duties, the rule is properly considered to be a legislative rule." *Friedrich v. Sec'y of Health & Human Servs.*, 894 F.2d 829, 834 (6th Cir. 1990) (internal citation and quotation marks omitted); *Ohio Dep't of Human Servs. v. United States Dep't of Health & Human Servs.*, 862 F.2d 1228, 1234 (6th Cir. 1988); *Gen. Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc).

In *Friedrich*, a plaintiff filed suit challenging the Secretary's determination that Medicare did not cover "chelation therapy" for treatment of atherosclerosis. 894 F.2d at 835. The plaintiff claimed that this per se exclusion of coverage amounted to a substantive change in the program and was a departure from prior Medicare policy. *Id.* Prior policy was to cover FDA-approved drugs prescribed by a physician if the carrier determined the use to be "reasonable and necessary." *Id.* Although the district court found the Secretary's per se exclusion of the drug was a substantive decision, we disagreed. *Id.* at 837. This Court held that the coverage determination "creates no new law. Rather, it interprets the statutory language 'reasonable and necessary' as applied to a particular medical service or method of treatment." *Id.*; *see also Warder v. Shalala*, 149 F.3d 73 (1st Cir. 1998) (holding Heath Care and Financing Administration's classification of specific equipment as "durable medical equipment" rather than "braces" was an "interpretative" not "substantive" decision); *Crestview Parke Care Ctr.*, 373 F.3d 743, 750 (6th Cir. 2004) (upholding HHS's interpretative rule allowing ALJs to grant summary judgment without an in-person hearing).

Here, the CMS's determination was not inconsistent with prior regulations. *See Shalala*, 514 U.S. at 87-88. It did not "create new law, rights or duties." *See Friedrich*, 894 F.2d at 834. The ALJ found that the Secretary's determination interpreted the professional standard of quality to require the facility to "determine a resident's resuscitation status promptly upon admission and readmission and [] have a system in place to clearly communicate the status of the resident to all staff." It did not mandate a specific method that must be implemented to accomplish this objective. Accordingly, we conclude that the CMS determination is interpretative, not substantive.

Omni Manor's other arguments also lack merit. The Secretary's interpretation of the federal regulation and Ohio state law is not inconsistent. Nursing facilities may both inform their patients about state laws governing advanced directives *and* document and clearly communicate the resident's resuscitation status to all staff members. The ALJ's use of the professional journal article and witness testimony was permissible because the rules of evidence do not strictly apply to administrative hearings. 5 U.S.C. § 556(d); *see also Cline v. Sec'y of Health, Educ. & Welfare*, 444 F.2d 289, 291 (6th Cir. 1971). Furthermore, the DAB found no basis for Omni's assertion that the journal article was not entered into evidence at the administrative hearing. Accordingly, we conclude that the Secretary's interpretation and the ALJ's examination was not "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law." *Thomas Jefferson Univ.*, 512 U.S. at 512 (quoting 5 U.S.C. § 706(2)(A)).

IV.

Finally, following our review of the record, we also conclude that substantial evidence supports the Secretary's imposition of a CMP. The record contains substantial evidence that the

medical files of CL1 and R27 did not clearly communicate the respective resuscitation status of the residents to all members of the staff. In this regard, the ALJ found that:

> [w]ith regard to facility documentation, what I am looking at is whether, at the time of the survey, the surveyors and the facility staff were able to show compliance with the participation requirements [the communication of the resident's resuscitation status]. The inability to find such documents is the gravamen of the citation at issue.

In CL1's case, the evidence showed an apparent contradiction between the hospital transfer order and Omni's medical record. In R27's case, the resident had requested DNR status, but Omni had failed to document the resident's wishes in a way that the entire nursing staff could recognize. These findings were supported by the testimony of the surveyors and the actual medical records on the day of the survey. The ALJ found all of the CMS witnesses credible. Thus, significantly, "[t]he findings of the Secretary with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive." 42 U.S.C. § 1320a-7a. As "we do not consider the case *de novo*, nor resolve conflicts in the evidence, nor decide questions of credibility," *MeadowWood*, 364 F.3d at 788 (internal citation and quotation marks omitted), we are satisfied that substantial evidence existed.

For these reasons, we deny the petition for review.