Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Apollo Behavioral Health Hospital, L.L.C.,

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-597

Decision No. CR2908

Date: August 29, 2013

DECISION

Petitioner, Apollo Behavioral Health Hospital, L.L.C., applied for certification in the Medicare program. Initially and on reconsideration, the Centers for Medicare & Medicaid Services (CMS) denied certification, finding that the hospital failed to establish that it met Medicare program requirements. Although it was subsequently certified, Petitioner timely appeals the reconsidered determination, arguing that it is entitled to an earlier effective date. CMS now moves for summary judgment.

For the reasons set forth below, I grant CMS's motion.

Background

A psychiatric hospital is an institution that "is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons." Social Security Act (Act) § 1861(f). It must also meet criteria for general hospitals (section 1861(e)(3)-(9)), maintain clinical records on all its patients,

and meet staffing requirements set by the Secretary. Act § 1861(f)(2), (3), and (4). It may participate in the Medicare program as a provider of services, if it meets this statutory definition and complies with regulatory requirements called conditions of participation. Act §§ 1861(f), 1871; 42 C.F.R. §§ 482.60 *et seq*., 488.3.

A "condition of participation" represents a broad category of services. Each condition is contained in a single regulation, which is divided into subparts called standards. 42 C.F.R. Part 482. Compliance with a condition of participation is determined by the manner and degree to which the provider satisfies the standards within the condition. 42 C.F.R. § 488.26(b). If deficiencies are of such character as to "substantially limit the provider's . . . capacity to furnish adequate care or which adversely affect the health and safety of patients," the provider is not in compliance with conditions of participation. 42 C.F.R. § 488.24(b). CMS may "refuse to enter into an agreement" with a provider that fails to meet even one condition of participation. Act §§ 1866(b)(2)(B), 1861(f); 42 C.F.R. § 488.3(a).

An approved accreditation body, such as The Joint Commission, is authorized, by statute and regulation, to survey and accredit prospective providers and recommend Medicare certification. Institutions accredited by The Joint Commission are generally deemed to meet Medicare conditions of participation. Act § 1865; 42 C.F.R. § 488.5. However, if the Secretary finds that the prospective provider has significant deficiencies, it will be deemed not to meet those conditions. Act § 1865(c).

Here, Petitioner, located in Baton Rouge, Louisiana, applied for Medicare certification as a psychiatric hospital. The Joint Commission conducted a "deeming" survey from August 8 through 10, 2012. Although it found deficiencies, the commission accredited the hospital and recommended certification. CMS Ex. 1. However, after a former patient alleged that the hospital had significant deficiencies, CMS rejected that recommendation and directed the Louisiana Department of Health and Hospitals (State Agency) to conduct a validation survey. CMS Exs. 2, 7. The State Agency surveyed the hospital from September 25 through 27, 2012 and from October 23 through 25, 2012. Based on those survey findings, CMS determined that the hospital did not meet Medicare certification requirements and denied enrollment. CMS Exs. 2, 6, 16. The hospital requested reconsideration. CMS Ex. 49.

In a letter dated January 25, 2013, CMS concluded that, based on findings from the two state surveys, the hospital was not in substantial compliance with program requirements, and affirmed its decision to deny enrollment. The letter invited the hospital to re-apply for certification when it could demonstrate that it fully complied with all requirements for a psychiatric hospital. CMS Ex. 4.

The hospital reapplied. The Joint Commission surveyed again and found deficiencies. CMS Ex. 48. The hospital subsequently submitted evidence to show that it corrected its deficiencies, and The Joint Commission recommended certification effective February 8, 2013. CMS Ex. 3. Based on that recommendation, CMS certified the hospital for enrollment in the Medicare program, effective February 8, 2013. CMS Ex. 5.

Petitioner challenges this effective date, arguing that it should have been certified effective August 20, 2012.

Discussion

Summary Judgment. Summary judgment is appropriate when a case presents no issue of material fact, and its resolution turns on questions of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986); *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 2-3 (2009); *Illinois Knights Templar Home*, DAB No. 2274, at 3-4 (2009), *citing Kingsville Nursing Ctr.*, DAB No. 2234, at 3-4 (2009); *Livingston Care Ctr. v. U.S. Dep't of Health & Human Srvcs.* 388 F.3d 168, 173 (6th Cir. 2004).

The moving party may show the absence of a genuine factual dispute by presenting evidence so one-sided that it must prevail as a matter of law, or by showing that the non-moving party has presented no evidence "sufficient to establish the existence of an element essential to [that party's] case, and on which [that party] will bear the burden of proof at trial." *Livingston Care Ctr.*, 388 F.3d at 173 (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986)). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts, in the form of affidavits and/or admissible discovery material, showing that a dispute exists. *Crestview Parke Care Ctr.*, DAB No. 1836, at 6 (*citing Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986)); s*ee also Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing & Rehab. Ctr.*, DAB No. 1918 (2004). [1]

[1] Petitioner submits eighteen exhibits: four written declarations and 14 documents. Questions arise as to which of these submissions would be admissible. The regulations direct me to examine documentary evidence not submitted at the reconsideration level to determine whether the party has good cause for submitting the evidence for the first time at this level. 42 C.F.R. § 498.56(e)(1). If I find no good cause, I must exclude the evidence from the proceeding and may not consider it in reaching a decision. 42 C.F.R. § 498.56(e)(2)(ii). According to CMS, at the reconsideration level, Petitioner submitted four pages of documentary evidence relating to the deficiencies cited under patient's rights (42 C.F.R. § 482.13) and special staffing (42 C.F.R. § 482.62). CMS Br. at 3; CMS Ex. 50. Petitioner has submitted these documents as P. Ex. 2 at 1-3 and P. Ex. 7 at 2. P. Ex. 2 at 1-3 and P. Ex. 7 at 2 are therefore admissible, and I can consider them in determining whether Petitioner has come forward with admissible evidence showing that

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1. CMS was authorized to perform the validation survey, and I have no authority to review its decision to do so. [2]

As a threshold matter, Petitioner complains that CMS directed a validation survey. Petitioner acknowledges that CMS "has the ultimate authority" to verify a provider's program compliance by ordering a validation survey, but it questions CMS's motives and suggests that CMS exceeded its authority in doing so. P. Br. at 1; *see* Act § 1865(c); 42 C.F.R. § 488.5(c)(2); 488.7(a). In support of its argument, Petitioner cites 42 C.F.R. § 488.7(a), which provides that CMS may require a validation survey "on a representative sample basis" or in response to substantial allegations of noncompliance. According to Petitioner, CMS did not respond to one of these criteria, but ordered the validation surveys for some other, unknown and invalid reason.

First, a provider's hearing rights are established by federal regulations: 42 C.F.R. Part 498. A provider dissatisfied with an initial determination is entitled to further review, but administrative actions that are not initial determinations are not subject to appeal. 42 C.F.R. § 498.3(a); *Florida Health Sciences Ctr., Inc., d/b/a/ Tampa Gen. Hosp.*, DAB No. 2263 at 4 (2009). The regulations specify which actions are "initial determinations" and set forth examples of actions that are not. Directing a validation survey is not an appealable initial determination under 42 C.F.R. § 498.3(b), so I have no authority to review it.[3]

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a material dispute exists. Likewise, Petitioner's written declarations are admissible. *Arkady B. Stern, M.D.*, DAB No. 2329 at 4 n.4 (2010) (observing that "[t]estimonial evidence that is submitted in written form in lieu of live in-person testimony is not 'documentary evidence' within the meaning of 42 C.F.R. § 498.56(e).").

According to CMS, Petitioner also submitted, at the reconsideration level, "about 100 pages of documents related to infection control." CMS Br. at 29. Unfortunately, neither party has identified those 100 pages of documents. Because I base my decision on uncontested facts, I need not review Petitioner's submissions to determine which would be admissible.

[2] My findings of fact/conclusions of law are set forth, in italics and bold, in the discussion captions of this decision.

[3] Nor am I convinced that section 488.7(a) necessarily precludes CMS from directing a validation for some other reason. In any event, the undisputed evidence here establishes that CMS ordered the validation surveys in response to substantial allegations of noncompliance. CMS Exs. 2, 7. Petitioner concedes that a former patient made the allegations but attacks the complainer's motives and veracity. Of course, the purpose of a

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Moreover, Petitioner was denied certification in August, because CMS rejected The Joint Commission's recommendations, not because CMS ordered a validation survey. I have no authority to review CMS's finding that a hospital accredited by The Joint Commission is not in compliance with a condition of participation, because that finding is not an initial determination. 42 C.F.R. § 498.3(d)(9). Having been denied certification because CMS rejected The Joint Commission's recommendation, the hospital's recourse is to demonstrate its substantial compliance based on the validation survey. *See* 42 C.F.R. §§ 489.10, 489.13. If CMS then determines that the prospective provider does not qualify, the prospective provider may appeal (as happened here). 42 C.F.R. § 498.3(b)(1). If I defied the regulations, accepted Petitioner's argument, and denied CMS's authority to direct a validation survey, the hospital would not automatically be certified; rather, it would likely lose all opportunity to challenge the noncompliance finding.

2. The hospital was not a Medicare-certified provider until February 2013, so the procedures for terminating a Medicare-certified provider, found at 42 C.F.R. § 488.28, do not apply here.

Next, Petitioner maintains that CMS improperly terminated its provider agreement without providing proper notice and affording it the opportunity to correct its deficiencies, as required by 42 C.F.R. § 488.28. That regulation allows a *certified* provider with standard-level deficiencies to continue its program participation, if certain criteria are met. The provider would then be given "a reasonable time" to achieve compliance.

But the regulation applies to Medicare-certified providers only, not to prospective providers. And, contrary to Petitioner's claim, it was not a Medicare-certified provider when CMS denied its enrollment. I accept, for purposes of summary judgment, that: CMS initially planned to certify the hospital based on The Joint Commission's recommendation; that it assigned the hospital a provider number; and that it had the acceptance notice prepared. This does not mean that Petitioner was certified. The certification process is described in 42 C.F.R. § 489.11. Under that regulation, once CMS has determined that a prospective provider meets the requirements for Medicare participation, it sends the prospective provider written notice of that determination and two copies of the provider agreement. Assuming that the prospective provider wishes to participate, it must return both copies, signed by an authorized official, together with a written statement as to the institution's financial solvency. If CMS then accepts the

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validation survey is to verify such allegations. Petitioner's attacks are simply irrelevant to the question of whether the validation survey was authorized under section 488.7(a).

agreement, it returns one copy to the provider with written notice indicating the dates on which it was signed by the provider's representative and accepted by CMS and specifying its effective date. Petitioner was nowhere near completing this process when CMS ordered the validation surveys, so it was not certified and not entitled to the opportunity to correct called for in section 488.28.

3. CMS is entitled to summary disposition because the parties agree that the hospital did not meet all program requirements at the time of the September and October surveys, and I have no authority to review CMS's refusal to consider the hospital's corrective action plan.

Finally, the parties agree that, at the time of the September and October surveys, the hospital had deficiencies. CMS maintains that it could not be certified, because it had three condition-level deficiencies: infection control (42 C.F.R. § 482.42), patient's rights (42 C.F.R. § 482.13), and special staffing requirements for psychiatric hospitals (42 C.F.R. § 482.62). Petitioner argues that its deficiencies were "standard level deficiencies that do not qualify as condition level deficiencies." P. Br. at 3.

Certainly, a hospital cannot be certified if it has condition-level deficiencies. 42 C.F.R. § 488.3(a). Here, however, because Petitioner concedes that it had deficiencies at the times of the surveys, I need not decide whether Petitioner met all conditions. If the prospective provider meets all applicable conditions but has lower-level deficiencies, its effective date for participation can be no earlier than the date CMS or the state agency "receives an acceptable plan of correction for the lower-level deficiencies." 42 C.F.R. § 489.13(c)(2)(ii); *Comm. Hosp. of Long Beach*, DAB No. 1938 (2004). CMS's refusal to accept Petitioner's plan of correction is not an initial determination and thus is not reviewable in this forum. 42 C.F.R. § 498.3(a); *see Conchita Jackson, M.D.*, DAB No. 2495 (2013).

Among those uncontested deficiencies[4] are the following:

Infection control (42 C.F.R. § 482.42). The hospital must provide a sanitary environment to avoid the sources and transmission of infections and communicable diseases. It must have in place an active program to prevent, control, and investigate infections and communicable diseases. 42 C.F.R. § 482.42. To this end, it must designate an infection

[4] Although CMS cites many other problems, I rely only on those facts that Petitioner concedes. I do not include facts that Petitioner challenges, even where it has not come forward with admissible evidence to establish that a factual dispute exists.

control officer, who develops and implements policies. The infection control officer must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases and must maintain a log of incidents. 42 C.F.R. § 482.42(a)(1) and (2).

CMS alleges, and Petitioner does not dispute, that facility policy dictated that the infection control officer survey the hospital monthly, focusing on environmental issues related to infection control. His/her observations were to be recorded on a worksheet, copies routed to the appropriate department heads, and presented monthly to the hospital's performance improvement committee. CMS Ex. 8. Among the specific areas surveyed, the infection control officer was supposed to look at hand washing facilities (liquid soap dispensers, counter space, paper towel dispensers, trash receptacles, presence of alcohol rub) and to observe employees to see if they demonstrated good hygiene and were free of outward signs of infection. CMS Ex. 8 at 4-5. Petitioner concedes that its infection control officer failed to conduct a hand hygiene survey in September 2012. P. Br. at 4; CMS Ex. 49 at 3.

Petitioner maintains that one such lapse should not put the condition out. Of course, the lapse takes on greater significance considering that the policy went into effect in June, which means that facility staff failed to meet its obligation one out of four times.

The lapse becomes even more significant, because the surveyors found that facility staff did not demonstrate good hand hygiene in significant ways, which are detailed in the statement of deficiencies. CMS Ex. 6 at 19-20. During the September survey, they observed unhygienic practices by more than one staff member. They saw two mental health technicians wipe drool from a patient, while performing other duties, without taking adequate precautions. CMS Ex. 6 at 19-20. When the surveyors questioned one of the employees, he admitted that he had not "perform[ed] hand hygiene after wiping the drool" or handling dirty food containers and plates. He denied knowing that his pen and clipboard were dirty and that he should have practiced hand hygiene. CMS Ex. 6 at 21-22.

The surveyors also observed the hospital phlebotomist (medical professional who draws blood) standing in the hallway next to the nurses station. She held a laboratory tray containing needles, vials, gloves, biohazard counter, white cup, alcohol preps, guaze, and tape. She entered a patient's room without first performing hand hygiene. She pulled gloves out of the tray and put them on. She drew the patient's blood, and, after she withdrew the needle, the surveyors observed "three squirts of blood" on the patient's forearm. She disposed of the needle, labeled the vial of blood, removed her gloves and put them in a cup on the tray. She then opened the door, left the room, and walked to the

nurses station, without performing hand hygiene. She handed a copy of the lab slip to a hospital employee and left, without performing hand hygiene. When surveyors later questioned her, she said that she could not perform hand hygiene, because one of the sinks in a patient room did not work. CMS Ex. 6 at 22-23.

Petitioner does not challenge the surveyors' observations, nor deny that they constitute infection-control deficiencies, but it characterizes them as "a few isolated incidents [that] should not rise to the level of a condition level deficiency." P. Br. at 6; *see also* P. Ex. 13 at 2 (Gopalam Decl. ¶ 9); P. Ex. 14 at 2 (Katta Decl. ¶ 4); CMS Ex. 49 at 3. Whether they rose to condition-level (which I find highly likely), such deficiencies are significant enough to warrant CMS's insisting that they be corrected before the hospital could be certified.

Patient's rights (42 C.F.R. § 482.13). The hospital must protect and promote each patient's rights. 42 C.F.R. § 482.13. Among other rights, the patient has a right to participate in the development and implementation of his/her care plan. 42 C.F.R. § 482.13(b)(1). The patient also has the right to make informed decisions regarding his or her care, which includes being informed of health status, being involved in care planning and treatment, and being able to request or refuse treatment. 42 C.F.R. § 482.13(b)(2).

Patient #7 was a 26-year-old woman admitted to the facility under a "physician emergency certificate" on August 7, 2012, with diagnoses of schizophrenia and borderline intellectual functioning. Facility staff identified her problems as aggression, impulse control, and anxious mood. CMS Ex. 36 at 7, 12. Her treatment plan offered staff little guidance for responding to aggressive and violent behavior. To address "disrupted behavior," it says "medication as prescribed to control anxiety" and "redirect as needed." CMS Ex. 36 at 9.

At 8:00 a.m. on August 11, Patient #7 was sitting quietly in the day room. By 8:35, however, she was in her room "screaming and crying," because staff would not allow her to change beds. She began punching the walls and threatened to break a window. She pulled the mattress off her bed and punched and broke the window. CMS Ex. 36 at 2-3. Staff administered Ativan and Haldol, but, at 8:50 that morning, she was in the day room, screaming and threatening staff. She threw chairs, and said that she would "rather go to jail than to sleep in that bed." CMS Ex. 36 at 2. So staff called the sheriff's office. CMS Ex. 36 at 2.

Deputies came and took the patient away. CMS Ex. 36 at 2. The patient record includes no physician order authorizing the transfer. Moreover, sending to jail a mentally-ill patient in an acute psychotic state is hardly an appropriate intervention, particularly for a psychiatric hospital whose staff are supposed to be trained to handle such events. Fortunately, the deputies seemed to have recognized this, because they did not take

Patient #7 to jail; they took her to another psychiatric hospital. About 20 minutes later, a nurse from Earl K. Long Medical Center called the hospital to say that the deputies delivered Patient #7 there, but that she had no records. The RN taking the call told her "I did not send any records being that I was not transferring [the patient] to any facility. [A]s far as I understood, deputies were taking her to jail." CMS Ex. 36 at 1. Later that night, the deputies returned the patient to the hospital, in handcuffs, but "calm and pleasant." CMS Ex. 36 at 1.

Hospital administration subsequently determined that the "nurse involved in this incident was not performing up to the standards of the hospital" and her employment was terminated. P. Ex. 4 at 32.

Patient #1 was admitted to the hospital, also under a "physician emergency certificate," on October 16, 2012. She suffered from paranoid schizophrenia and displayed violent and aggressive behaviors. CMS Ex. 30 at 8, 9, 13. Even though her psychiatric evaluation includes among her problems "severe psychosis, violent and aggressive behaviors," her treatment plan offers no instructions to staff for responding to acute behavioral episodes. CMS Ex. 30 at 16-18. An "updated" plan reports no improvement, but offers no new interventions. CMS Ex. 30 at 19; CMS Ex. 43 at 2 (Goodfellow Decl. ¶ 6); *see* CMS Ex. 45 at 3, 4 (Bergmann Decl. ¶¶ 8, 10).

On the morning of October 18, Patient #1 became "very psychotic" and attempted to attack staff and other patients. CMS Ex. 30 at 3. Staff administered Haldol and Ativan. CMS Ex. 30 at 2. Throughout the morning, the patient's psychotic behavior continued, and staff again administered Haldol and Ativan. At about 1:00 p.m. they apparently administered Thorazine. CMS Ex. 30 at 2. On the "daily nurse flow sheet," the registered nurse (RN) on duty documented the patient's behaviors and other symptoms, but, for reasons Petitioner does not explain, left blank the section designating "interventions provided," writing only "n/a" ("not applicable"). CMS Ex. 30 at 7.

At 8:35 a.m. on October 19, Patient #1's psychiatrist prescribed Thorazine "stat" (immediately) to control her behaviors. CMS Ex. 30 at 12. Apparently, the hospital had no Thorazine in stock. CMS Ex. 42 at 2 (Gonyea Decl. ¶ 6). They did not administer the medication as ordered, but called the police, who escorted Patient #1, in hand cuffs, to Earl K. Long Medical Center. CMS Ex. 30 at 1, 24, 25. Again, the patient record includes no physician order authorizing the transfer. CMS Ex. 30 at 12. Confused about the purpose of the transfer (from one psychiatric hospital to another), staff from Earl K. Long called Apollo to inquire. The RN taking the call said that the patient had no medical issue, but was "beating up" everyone, and it would be easier for Earl K. Long to find her a new placement. After what appears to have been an unpleasant exchange, the Apollo nurse hung up the phone while the Earl K. Long nurse was speaking. CMS Ex. 30 at 20.

Petitioner concedes all of these facts, but denies that it is hospital policy to call police when a patient becomes violent. Petitioner points out that staff called police "only twice." Petitioner then seems to disregard one of the episodes and argues that "this unfortunate episode" should not rise to the condition level. P. Br. at 7; P. Ex. 13 at 2 (Gopalam Decl. ¶ 10) (admitting that he does not challenge the "law enforcement incident with a patient," but, characterizing it as "an isolated situation.").

Petitioner does not point to any provision in either patient's care plan describing appropriate responses to aggressive patient behavior. CMS asserts these care plan interventions were not there, and Petitioner has not come forward with evidence establishing that a dispute exists on this issue.

Based on these undisputed facts, the facility had significant deficiencies under 42 C.F.R. § 482.13, that warranted CMS's insisting that they be corrected before the facility could be certified.

Because I find these and the infection control deficiencies sufficient to justify CMS's actions, I need not consider the deficiencies cited under 42 C.F.R. § 482.62 (special staffing).

Conclusion

CMS is entitled to summary judgment because the parties agree – and undisputed evidence establishes – that the hospital had deficiencies at the times of the validation surveys. As a matter of law, CMS was authorized to order validation surveys, and I have no authority to review its decision to do so; the hospital was not certified at the time of the validation surveys, so was not entitled to a reasonable opportunity to correct its deficiencies.

/s/
Carolyn Cozad Hughes
Administrative Law Judge