Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Epoch Senior Healthcare of Harwich
(CCN: 225525),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-287

Decision No. CR2479

Date: December 20, 2011

DECISION

In this case, I consider a long-term-care facility's obligation to keep itself apprised of changes in professional standards of practice.

Petitioner, Epoch Senior Healthcare of Harwich (Petitioner or facility), is a long-term care facility located in Harwich, Massachusetts, that participates in the Medicare program. The Centers for Medicare and Medicaid Services (CMS) determined that the facility was not in substantial compliance with Medicare program requirements governing infection control (42 C.F.R. § 483.65) because, in testing blood sugar levels, its staff used the same glucoclet pen lancing device for multiple residents. Staff changed the device's blade between uses, but then wiped it with germicide and reused it to extract blood from other residents. The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and CMS had recently warned providers not to reuse these devices, because the practice increases the risk for transmitting blood borne pathogens.

CMS imposed a $4,500 per instance civil money penalty (CMP).

The parties agree that no material facts are in dispute and have filed cross-motions for summary judgment.

For the reasons set forth below, I find that the facility was not in substantial compliance with 42 C.F.R. § 483.65 and that the penalty imposed is reasonable.

I. Background

The Social Security Act (Act) sets forth requirements for nursing facility participation in the Medicare program and authorizes the Secretary of Health and Human Services to promulgate regulations implementing those statutory provisions. Act §1819. The Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare program, a nursing facility must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance. Act § 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every twelve months and more often, if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308.

Here, following its November 18, 2010 recertification survey, CMS determined that the facility was not in substantial compliance with Medicare program requirements, including the regulation governing infection control, 42 C.F.R. § 483.65 (Tag F441), and that the infection-control deficiency posed immediate jeopardy to resident health and safety. CMS Exs. 1, 2. CMS subsequently determined that the facility returned to substantial compliance on January 3, 2011. CMS Ex. 3.

Based solely on its infection control problems, CMS imposed against the facility a per-instance CMP of $4,500. CMS Ex. 2 at 2; CMS Ex. 3.

The parties have filed cross-motions for summary judgment. With its memorandum in support of summary judgment (CMS Br.), CMS submitted 15 exhibits (CMS Exs. 1-15). Petitioner submitted its own motion for summary judgment (P. MSJ), along with a memorandum in support (P. Br.), a separate memorandum opposing CMS's motion (P. Opp. Br.), and six exhibits (P. Exs. 1-6).

II. Issues

Aside from challenging CMS's determination that it was not in substantial compliance, Petitioner does not contest either the amount of the CMP or the immediate jeopardy

finding.[1] Thus, the sole issue before me is whether the facility was in substantial compliance with 42 C.F.R. § 483.65.

Petitioner also raises Constitutional challenges, which I have no authority to review.

III. Discussion

> ***CMS is entitled to summary judgment that the facility was not in substantial compliance with 42 C.F.R. § 483.65, because staff used the same fingerstick device to extract blood from multiple residents, in contravention of the Secretary's rules relating to the health, safety, and well-being of residents, and in contravention of professional standards of practice.***[2]

The parties agree that this case presents no genuine issue of material fact and that its resolution turns on disputes of law. *See* CMS Br. at 1, 8; P. MSJ at 1. Summary judgment is therefore appropriate. *Livingston Care Ctr. v. U.S. Dept. of Health and Human Servs.*, 388 F.3d 168, 173 (6th Cir. 2004) (*citing Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

Program requirements. The Act mandates that every facility participating in the Medicare program establish and maintain an infection control program "designed to provide a safe, sanitary, and comfortable environment" for its residents and designed "to help prevent the development and transmission of disease and infection." Act § 1819(d)(3)(A).The facility must be "designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public."

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[1] In any event, I probably have no authority to review CMS's determination that the deficiency posed immediate jeopardy to resident health and safety. An Administrative Law Judge may review CMS's scope and severity findings (which include a finding of immediate jeopardy) only if a successful challenge would affect the range of the CMP or if CMS has made a finding of substandard quality of care that results in the loss of approval of a facility's nurse aide training program. 42 C.F.R. § 498.3(b)(14); 42 C.F.R. § 498.3(d)(10); *Cedar Lake Nursing Home*, DAB No. 2344 at 9 (2010); *Evergreen Commons*, DAB No. 2175 (2008); *Aase Haugen Homes, Inc.*, DAB No. 2013 (2006). Here, the penalty imposed is a per instance CMP, for which the regulations provide only one range ($1,000 to $10,000), so successfully challenging the level of noncompliance would not affect the range of the CMP. 42 C.F.R. § 488.438(a)(2). Neither party suggests that CMS made a finding that affected approval of the facility's nurse aide training program.

[2] I make this one finding of fact/conclusion of law.

Act § 1819(d)(3)(B). The statute also says that facilities must provide services "in compliance with . . . accepted professional standards and principles which apply to professionals providing services" and "must meet such other requirements relating to the health, safety, and well-being of residents . . . as the Secretary [of Health and Human Services] may find necessary." Act § 1819(d)(4).

The infection control regulation echoes the statutory requirements for an infection control program. 42 C.F.R. § 483.65.[3] In its preamble, the regulation's drafters confirmed that, under the rule, a facility "must ensure" that its personnel follow aseptic and isolation techniques "in accordance with acceptable professional practice." 52 *Fed. Reg.* 38,589 (Oct. 16, 1987).[4] *Accord* 42 C.F.R. § 483.20(k)(3) (requiring that services "meet professional standards of quality").

The facility's practice. The facts of this case are not in dispute. Twenty-one facility residents were diabetics who needed regular blood glucose testing to determine their needs for insulin. CMS Ex. 1 at 10-11.

To test the blood, the facility used a device called a glucocet 2 automatic lancing device. CMS Ex. 13 at 11-14; P. Ex. 1; P. Ex. 5 at 3-4 (Wadlow Decl. ¶ 9). The device looks like a pen to which a lancet or blade is attached. The user presses a release button at the end of the pen, which causes the lancet to puncture the resident's skin (usually at the side of a finger) so that a small amount of blood can be obtained and tested. CMS Ex. 13 at 11-12. At the time of the survey, the facility had in place a policy/procedure that instructed staff

[3] The regulation provides, in pertinent part:

> The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.
>
> (a) *Infection control program.* The facility must establish an infection control program under which it—
>
> (1) Investigates, controls, and prevents infections in the facility;
>
> (2) Decides what procedures, such as isolation, should be applied to an individual resident; and
>
> (3) Maintains a record of incidents and corrective actions related to infections.

[4] The regulation has been modified over the years, but this basic requirement has not changed: the facility must follow professional standards of practice in providing a safe and sanitary environment. *See, e.g.*, 54 *Fed. Reg.* 5345-46 (Feb. 2, 1989); 56 *Fed. Reg.* 48,860-61 (Sept. 26, 1991).

to clean the pen with a germicidal wipe after each use. CMS Ex. 13 at 7; P. Ex. 5 at 4-5 (Wadlow Decl. ¶ 12).[5] The parties agree that facility staff changed the blade after each use, but they used the same device to test the blood of multiple residents, wiping it off with a germicide between uses. CMS Ex. 14 at 2 (Grady Decl. ¶ 3); P. Ex. 5 at 4 (Wadlow Decl. ¶ 11).

The Secretary's warnings. Such reuse of the glucocet device may once have been an acceptable practice. However, on August 26, 2010 (approximately 12 weeks prior to the survey), both the CDC and the FDA issued warnings that "use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens," primarily the hepatitis B virus. Both issuances noted that the problem is especially pronounced in long-term care facilities and concluded that "[f]ingerstick devices should **NEVER** be used for more than one person." CMS Ex. 8 at 1-2. Instead, facilities should use auto-disabling, **single-use** fingerstick devices, also referred to as "safety lancets." CMS Ex. 7 at 4-5; CMS Ex. 8 at 1-2 (emphasis in the originals).[6]

The following day, August 27, 2010, CMS posted to its website and sent to the directors of the state agencies revisions to the State Operations Manual (SOM). CMS Ex. 6. The revisions addressed infection control standards in nursing homes (§ 483.65 – Tag F441) and were effective "immediately." Pursuant to these revisions, CMS adopted, as an interpretive rule, the CDC and FDA warnings:

> Fingerstick devices must never be used for more than one resident. Although the package instructions for some fingerstick devices may indicate or imply the potential for multiple patient use, surveyors and health care workers must adhere to this CMS guidance regarding the avoidance of multiple patient use of fingerstick devices, consistent with recent statements of the CDC and the FDA.

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[5] Presumably, staff also disposed of the used blade, although, surprisingly, its written procedure does not instruct them to do so. CMS Ex. 13 at 7.

[6] In issuing the warnings against reusing the fingerstick devices, the CDC cites authoritative scientific studies: 1) CDC, *Transmission of hepatitis B virus among persons undergoing blood glucose monitoring in long-term-care facilities – Mississippi, North Carolina and Los Angeles, California, 2003-2004*. MMWR 2005; 54:220-23; 2) Patel AS, White-Comstock MB, Woolard D, Perz JF. *Infection Control Practices in Assisted Living Facilities: A Response to Hepatitis B Virus Infection Outbreaks*. ICHE 2009; 30(3):209-14; and 3) Thompson ND, Perz JF. *Eliminating the Blood: Ongoing Outbreaks of Hepatitis B Virus Infection and the Need for Innovative Glucose Monitoring Technologies*. J. DIABETES SCI. TECH. 2009; 3(2):283-88. CMS Ex. 7 at 2, 4-5.

CMS Ex. 6 at 2, 3. The revised rule also provided that reuse of fingerstick devices for more than one resident "should be treated as immediate jeopardy." CMS Ex. 6 at 3.

In transmittals to the state agency directors, dated September 24, 2010 and October 1, 2010, CMS included, as an example of a deficient practice that is immediate jeopardy, the facility's reuse of fingerstick devices for more than one resident, explaining that the practice exposes facility residents to bloodborne infections. P. Ex. 3 at 2; CMS Ex. 5 at 3, 20.

On November 24, 2010, the Massachusetts state agency issued a Circular Letter to the state's long-term care administrators "to highlight" CMS's notice "that multiple patient use of fingerstick devices is considered an immediate jeopardy situation if found to be the practice in a skilled nursing/nursing facility." CMS Ex. 11.

Petitioner's arguments. Petitioner concedes that, at the time of the November survey, its practice was to reuse fingerstick devices. Nevertheless, Petitioner points out that the infection control regulation (42 C.F.R. § 483.65) does not explicitly preclude that practice and argues that CMS has imposed a substantive new rule without providing an opportunity for notice-and-comment. P. Br. at 8-9. In Petitioner's view, the rule is therefore invalid and unenforceable. Petitioner also argues that its reuse of the fingerstick device was "a valid infection control technique." P. Br. at 21. Finally, Petitioner complains that neither CMS, the state agency, nor any other authority sent the facility advance notice of the practice change, so the facility should not be held accountable for violating the rule. P. Opp. Br. at 3-4.

Substantive v. interpretive rule. As a threshold matter, I reject, as legally unsound and practically unworkable, Petitioner's suggestion that a facility need not meet any standard of practice that is not specified in a regulation, and its corollary, that each individual "standard of care" must be considered a substantive rule, promulgated as a notice-and-comment regulation. P. Br. at 8-9. In *Omni Manor Nursing Home*, DAB No. 1920 (2004), *aff'd*, 151 F. App'x 427 (6th Cir. 2005), the facility claimed that it was not subject to the provisions of the State Operations Manual (SOM) that address when to resuscitate a resident in distress. The facility argued that under section 1871(a)(2) of the Act -- which says that the Secretary must promulgate substantive rules by regulation -- the Secretary must promulgate by notice-and-comment any "standard of practice" that she seeks to enforce. The Departmental Appeals Board (Board) explicitly rejected this position and held that requiring standards of practice to be specified in a regulation "would undercut Congressional intent to ensure quality of care in nursing facilities, since professional standards may change over time." *Omni Manor,* DAB No. 1920 at 11.

Professional standards of practice. Nor do I agree that the facility's reuse of the fingerstick device is a valid infection control technique that comports with accepted standards of practice. *See* P. Br. at 19-21. Both the CDC and the FDA are agencies

within the Department of Health and Human Services. The SOM emphasizes that "all infection prevention and control practices [must] reflect current [CDC] guidelines." CMS Ex. 5 at 10.

The CDC is charged with preventing and controlling disease and promoting environmental health and health education in the United States. Among other responsibilities, it identifies and defines preventable health problems and maintains active surveillance of diseases through epidemiologic and laboratory investigations and data collection, analysis, and distribution. It serves as the lead agency within the Public Health Service in developing and implementing operational programs relating to environmental health problems and conducts operational research aimed at developing and testing effective disease prevention, control, and health promotion programs. The CDC is responsible for controlling the introduction and spread of infectious diseases. *See* www.cdc.gov/maso/pdf/cdcmiss.pdf; *see also* 42 U.S.C. § 241.

The FDA is responsible for protecting the public health by assuring the safety, efficacy and security of, among other items, medical devices. In this regard, the FDA provides accurate, science-based information to the public on the safe use of these products. 21 U.S.C. § 393(b).

Thus, by law, the CDC and the FDA define and disseminate "acceptable standards of practice" in matters related to preventing the spread of disease and the safe use of medical devices. I do not second guess the guidance these agencies provide.

Petitioner also asserts that no resident suffered actual harm as a result of its practice, which, for purpose of summary judgment, I accept as true but find not material. P. Opp. Br. at 5 (*citing* P. Ex. 5 at 3 (Wadlow Decl. ¶ 7)). A facility is not in substantial compliance if its deficiencies pose a greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301. Engaging in a practice that exposes residents to bloodborne pathogens, including hepatitis B, presents the potential for more than minimal harm, and thus puts the facility out of substantial compliance with the regulation governing infection control (42 C.F.R. § 483.65).

Notice. Petitioner complains that neither CMS, the state agency, nor any other authority sent the facility a notice of the practice change. P. Ex. 5 at 3, 5-6 (Wadlow Decl. ¶ 7, 14-17). The facility first learned about the ban on reusing fingerstick devices when told so by one of the surveyors on the second day of the survey. CMS Ex. 5 at 5-6 (Wadlow Decl. ¶¶ 14, 15). It received the state agency's circular letter after the time of the survey. P. Ex. 5 at 6-7 (Wadlow Decl. ¶ 17).

Petitioner recognizes that professional standards "evolve over time" but argues that a Medicare-certified facility has no obligation to remain current. P. Br. at 12 (asserting "providers are not under any obligation to constantly search CMS' website to monitor

changes in Appendix PP [to the SOM], which is directed at surveyors. Such a burden is no where set forth and would be unreasonable if it were."); P. Br. at 13-15 (arguing the state and federal agencies must advise providers of changes in professional standards, and, until the facility receives individual notice of a change, it is not bound to follow them); P. Br. at 18 (asserting "[u]ntil recommendations from agencies such as the CDC and FDA are incorporated into conditions of participation and actually communicated in writing to providers, providers cannot be expected to update their practices and policies to reflect same"); P. Opp. Br. at 8 (arguing the facility cannot be accountable unless and until the state agency sends it "actual . . . written notice" of a new standard).[7]

I reject the suggestion that a healthcare provider of any sort has no obligation to keep up to date on practice standards. As CMS points out, the facility must designate a medical director who is responsible for implementing resident care policies and coordinating medical care. 42 C.F.R. § 483.75(i). The SOM explains that this makes the medical director responsible for developing, implementing, and evaluating resident care policies and procedures "that reflect current standards of practice." He/she must therefore know about current standards of practice. SOM, Appendix PP, Tag 501 at 624-625.[8]

Moreover, facilities have ample notice that they must comply with evolving standards of practice because the statute and regulations explicitly say so. Implicit in the statutory requirement is the requirement that a participating facility keep itself apprised of changing standards. *Accord Life Care Ctr. of Tullahoma*, DAB No. 2304 at 47 (2010), *aff'd*, No. 10-3465, 2011 WL 6275916 (6th Cir. 2011); *Wade Pediatriacs*, DAB No. 2153 at 23 (2008) (*citing* 467 U.S. 51 at 61 n.10) (suggesting that a party should exercise "reasonable diligence" to acquire program knowledge and that "it would be negligence to remain ignorant by not using those means"). The CDC, the FDA and CMS maintain easily-accessible websites on which they publish this information, so any provider can and must keep apprised of changes in standards. Indeed, as Petitioner concedes, its nurse consultant knew about the change and implemented it in a sister facility, which belies the suggestion that the information was not readily available. P. Opp. Br. at 4, 14; P. Ex. 5 at 7 (Wadlow Decl. ¶ 19); CMS Ex. 13 at 1.

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[7] In this regard, Petitioner also complains that facilities surveyed after receiving the November 24 circular letter would have made the change prior to the date of their surveys and thus would not have been found out of compliance. P. Br. at 22. In fact, CMS could legitimately cite any facility for noncompliance from at least the date CMS published the SOM change (if not the date CDC and FDA issued their warnings) until the date the facility corrected its practice.

[8] CMS could therefore have cited a deficiency under section 483.75(i). That it did not do so does not relieve the facility of its obligation to comply with section 483.65.

Finally, I reject Petitioner's suggestion that CMS retroactively applied the rule change. P. Br. at 13-15. On August 26, the CDC and the FDA issued their warnings. CMS Exs. 7, 8. CMS posted its revision to the SOM on August 27, advising that the change was effective "immediately." CMS Ex. 6. More than two months *after* the rule change, CMS cited the facility for not complying.

IV. Conclusion

For these reasons, I deny Petitioner's motion for summary judgment and grant CMS's motion. The undisputed facts establish that the facility was not in substantial compliance with 42 C.F.R. § 483.65 because it continued to reuse fingerstick devices after the CDC and the FDA warned providers that the practice increased the risk for transmitting blood borne pathogens.

/s/
Carolyn Cozad Hughes
Administrative Law Judge