Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Blossom South Nursing and Rehabilitation Center,
(CCN: 33-5456),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-1231

Decision No. CR3013

Date: November 27, 2013

DECISION

Here, the Centers for Medicare & Medicaid Services (CMS) moves to terminate the Medicare participation of a long-term care facility that has a long history of chronic noncompliance with program requirements.

Blossom South Nursing and Rehabilitation Center (Petitioner or facility), is a long-term-care facility, located in Rochester, New York, that continues to participate in the Medicare program pursuant to a federal court order. Based on an extended survey/complaint investigation, completed August 8, 2013, CMS determined that the facility was (once again) not in substantial compliance with Medicare program requirements. CMS imposed a remedy: it terminated the facility's Medicare participation. Petitioner appealed.

For the reasons set forth below, I find that the facility had an appalling number of deficiencies that could harm its residents, any one of which puts it out of substantial compliance with program requirements. CMS may therefore impose a penalty – including termination. Federal regulations preclude me from reviewing the penalty imposed.

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. If, as here, a facility "has consistently demonstrated failure to maintain compliance," and its practices have caused harm to residents, it will be designated a "special focus facility," which must be surveyed at least once every six months. Act §1819(f)(8); CMS State Survey Letter, S&C-08-02 (November 2, 2007).

Petitioner became a special focus facility on March 31, 2011. Since then, it has consistently failed to maintain substantial compliance. CMS Ex. 3. Following an extended survey/complaint investigation, completed August 8, 2013, CMS determined that the facility was not in substantial compliance with the following Medicare participation requirements:

- 42 C.F.R. § 483.10(b)(4) (Tag F155 – quality of care: resident rights/right to refuse treatment and formulate advance directive) at scope and severity level D (isolated instance of noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. § 483.15(h)(2) (Tag F253 – quality of life: environment) at scope and severity level E (pattern of noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. § 483.20(k)(3)(i) (Tag F281 – comprehensive care plans/professional standards of quality) at scope and severity level E;

- 42 C.F.R. § 483.25 (Tag F309 – quality of care) at scope and severity level G (isolated instance of actual harm that is not immediate jeopardy);

- 42 C.F.R. § 483.25(d) (Tag F315 – quality of care: urinary incontinence) at scope and severity level D;

- 42 C.F.R. § 483.25(h) (Tag F323 – quality of care: accident prevention) at scope and severity level E;

- 42 C.F.R. § 483.25(m)(2) (Tag F333 – quality of care: medication errors) at scope and severity level F (widespread noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. § 483.35(i) (Tag F371 – dietary services: sanitary conditions) at scope and severity level F;

- 42 C.F.R. § 483.60(b), (d) and (e) (Tag F431 – drug services: service consultation) at scope and severity level D;

- 42 C.F.R. § 483.70(h)(4) (Tag F469 – physical environment: pest control) at scope and severity level E; and

- 42 C.F.R. § 483.75(l)(1) (Tag F514 – administration: clinical records) at scope and severity level D.

CMS Ex. 1.

Pursuant to its authority under the statute and regulations, CMS imposed a remedy: it terminated the facility's program participation. Act §§ 1819(h)(2); 1866(b)(2)(A) (authorizing the Secretary to terminate the provider agreement if she finds substantial noncompliance with program requirements); 42 C.F.R. § 488.412; *see also Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 21 (2000).[1]

Petitioner timely requested a hearing and asked that the hearing **"be expedited.**" P. Hrg. Request (August 20, 2013) (emphasis in original). I granted Petitioner's request.[2]

[1] CMS did not take this action lightly. It had already afforded the facility multiple opportunities to demonstrate that it could achieve and maintain substantial compliance. CMS publically warned that it could terminate a chronically noncompliant facility that did not show significant improvement. CMS Ex. 5 at 3. Ironically, as discussed below, Petitioner now claims that CMS's reluctance to terminate gave the facility greater rights to continue its program participation than the statute and regulations grant to more compliant facilities.

[2] Petitioner now complains that my willingness to grant the facility an expedited hearing denies it due process. Petitioner sought a three-week extension of time in which to file its

I directed the parties to submit pre-hearing exchanges, which included the written declarations of witnesses in lieu of in-person testimony. I noted that any witness the opposing party wished to cross-examine would have to appear at the hearing. Thereafter, CMS counsel waived cross-examination of Petitioner's witnesses, and Petitioner asked that three of CMS's witnesses be produced.

I convened a telephone hearing on September 25, 2013, from the offices of the Civil Remedies Division in Washington, D.C.[3] Mr. David Rawson appeared from the Offices of General Counsel in New York City on behalf of CMS. Mr. Howard Fensterman, Ms. Betsy Malik, and Mr. Yulian Stern appeared from their offices in Lake Success, New York, on behalf of Petitioner. Thereafter, by letter dated September 27, 2013, Petitioner waived further cross-examination of CMS witnesses and rested its case on the written record.[4]

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prehearing submissions and an indefinite postponement of the hearing. P. Correspondence (September 12, 2013); Tr. 10-12. In a ruling dated September 16, 2013, I denied Petitioner's request to postpone. Ruling (September 16, 2013).

[3] The hearing was initially scheduled for September 25 and 26, 2013. Petitioner objected to those dates. To accommodate Petitioner, I agreed to make myself available any time during the week of September 23 or on September 30, 2013. In accordance with the Civil Remedies Division's standard practice, the hearing was to be conducted by videoconference, to which Petitioner also objected. I overruled the objection and advised that parties that counsel were free to appear in Washington D.C. or at the witnesses' location. Without waiving these overarching objections, Petitioner agreed to the September 30 date. Because one witness was not available on September 30, the parties agreed to take that witness's testimony by telephone on September 25, 2013. At the opening of the September 25 proceedings, however, Petitioner objected, for the first time, to taking the witness's testimony by telephone, arguing that the procedure violated due process. Tr. 13. At that point, it was obviously too late to arrange for videoconferencing. By agreeing to the telephone proceeding in the first place, Petitioner waived its right to object. In any event, as the discussion below establishes, the largely uncontroverted evidence in this case justifies CMS's actions. Petitioner's procedural challenges are therefore largely irrelevant.

[4] We initially designated Rochester, New York, as a hearing location, in order to accommodate the facility's witnesses. However, CMS opted not to cross-examine any of Petitioner's witnesses, so they did not have to appear. Thereafter, CMS asked that its witnesses be allowed to testify from Albany rather than Rochester, New York. Petitioner objected, arguing that it had already arranged to appear in Rochester, and a change of plans could result in additional expenses. Petitioner also preferred to have its clients and their staff nearby to assist with cross-examination. In a ruling dated September 27, 2013, I granted CMS's request to have its witnesses testify from Albany. I declined to compel

I admit into evidence CMS Exhibits (Exs.) 1-24 and P. Exs. A-P and 1-6. Tr. 15, 19, 20-23, 83, 89.

The parties have filed pre-hearing briefs (CMS Br.; P. Br.), post-hearing briefs (CMS Post-hrg. Br.; P. Post-hrg. Br.), and reply briefs (CMS Reply; P. Reply).

II. Issue

The sole issue before me is whether, based on the survey ending August 8, 2013, the facility was in substantial compliance with Medicare program requirements.

Petitioner objects to this articulation of the issue, arguing that due process mandates that it be allowed to address all of the issues presented in CMS's notice letter. Tr. 7-10. I overrule Petitioner's objections for two reasons: 1) the regulations, by which I am bound, dictate the limits of my jurisdiction; and 2) because Petitioner specifically appealed CMS's determination that it was not in substantial compliance, it can hardly claim that it lacked notice of the relevant issue.

III. Discussion

A. The facility was not in substantial compliance with 42 C.F.R. §§ 483.10(b)(4), 483.15(h)(2), 483.20(k)(3)(i), 483.25(d), 483.25(h), 483.60(b), 483.70(h)(4), and 483.75(l)(1), and CMS may terminate its program participation based on any one of those deficiencies alone.[5]

As CMS points out, the surveyors cited eight deficiencies in the areas of professional standards, accident prevention, housekeeping, pest control, resident rights, and drug records. CMS Post-hrg. Br. at 4 (citing CMS Ex. 1). Any one of these deficiencies, by itself, establishes substantial noncompliance. Yet, Petitioner does not address any of these deficiencies in its submissions. The unrebutted evidence thus establishes that the

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CMS or the state agency to expend scarce resources, when acceptable alternatives were available. I ruled that Petitioner could appear from Albany, New York City, Rochester, or Washington, D.C. I also ruled that the state surveyors/witnesses could have their own counsel present in the hearing room. In keeping with my order (entered pursuant to Petitioner's motion during the September 25 proceedings), each party could have a technical expert present, but all other observers would be excluded from the room where the witness was testifying. The entire issue was rendered moot, when Petitioner opted to rely on the written record, without cross-examining any additional witnesses.

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

facility was not in substantial compliance, and CMS was therefore authorized to impose a remedy, including termination.

Petitioner concedes that the statute and regulations authorize CMS to terminate a facility that is not in substantial compliance but argues that, "[w]hile those rules may apply generally[,] they do not apply here." P. Post-hrg. Br. at 10. According to Petitioner's theory, the facility is entitled to continue its program participation, notwithstanding its ongoing substantial noncompliance, because CMS did not impose the penalty of termination until it also determined that the facility's noncompliance was widespread and/or caused actual harm.

CMS Memorandum. In support of its position, Petitioner points to an April 5, 2013 Survey and Certification memorandum issued by CMS. In the memorandum, CMS recognizes that the agency spends a disproportionate amount of its scarce resources monitoring chronically and seriously deficient facilities. The memo describes the steps CMS planned to take in response to a decrease in program funding. For nursing homes, such as Petitioner, "that have exhibited a persistent pattern of poor quality and have been enrolled in the Special Focus Facility initiative" for more than 18 months, but have failed to improve, the state agency would schedule a final "last chance" survey. If that survey did "not reveal appropriate improvement or unless there is a major new development that CMS concludes is very likely to eventuate in timely and enduring improvement in the quality of care or safety[,]" a termination notice might be issued. CMS Ex. 5 at 3. According to Petitioner, this means that CMS can terminate only if the facility receives a scope/severity score above level E.

Petitioner's argument fails for several reasons. First, the memorandum simply does not say what Petitioner claims it says. It emphasizes legitimate agency goals: "to a) speed final resolution (preferably substantial improvement) of the issues with these nursing homes where serious problems have persisted," and b) to continue the Special Focus Facility initiative, consistent with statutory requirements, with a "temporarily" reduced number of facilities. CMS Ex. 5 at 3. The memorandum says nothing about scope and severity levels. I see no contradiction between its contents and CMS's actions here. Indeed, based on the sheer number of deficiencies cited during the August 2013 survey, many of which were repeat deficiencies, CMS could reasonably determine that the facility had not made "appropriate improvement" and was not likely to achieve "timely and enduring" improvements in the quality of its care or safety.

Second, and even more compelling, Petitioner's argument is inconsistent with the statute and regulations. As a matter of law, CMS has broad discretion to select a penalty if a facility is not in substantial compliance, and that discretion is not diminished because the agency is reluctant to terminate any but the "most egregious recidivist institutions." *See Ill. Council*, 529 U.S. at 22. As noted above, the statute and regulations authorize CMS to terminate a facility's program participation whenever that facility is not in substantial

compliance with program requirements. Act §§ 1819(h)(2); 1866(b)(2)(A); 42 C.F.R. § 488.412(a). A facility is not in substantial compliance if its deficiencies pose the potential for causing more than minimal harm. 42 C.F.R. § 488.301. Thus, CMS may terminate a facility's program participation for deficiencies cited at the "D" and "E" levels of scope and severity. *See Beverly Health & Rehab. Servs., Inc., v. Thompson*, 223 F. Supp. 73, 111 (D.D.C. 2002) (holding that the agency's authority to terminate is not limited to immediate jeopardy cases, but "may span all noncompliant facility behavior").

Further, CMS may not allow a chronically deficient facility to continue its program participation indefinitely. If CMS does not approve the facility's plan of correction and timetable, it must terminate. If the facility is not in substantial compliance within six months of the survey, CMS is supposed to terminate. 42 C.F.R. § 488.412(a) and (d).

Finally, Petitioner asks me to rule that CMS was not authorized to terminate its program participation unless its deficiencies were at a scope and severity of Level "F" or higher. To do so, I would have to review CMS's scope and severity findings, which I have no authority to do. The regulations unambiguously limit my jurisdiction. I may review CMS's finding of noncompliance that results in its imposing a remedy. 42 C.F.R. § 498.3(b)(13). I may *not* review CMS's choice of remedy nor the factors it considered in determining the remedy. 42 C.F.R. §§ 488.408(g)(2); 498.3(d)(14). *Beverly Health & Rehab. Servs.*, 223 F. Supp. at 111 (holding that the "determination of what remedy to seek is beyond challenge"). I may not review CMS's scope and severity findings. 42 C.F.R. § 498.3(b)(14).

Notice letters. In letters dated August 15 and 16, 2013, CMS advised the facility that its Medicare participation would be terminated. CMS Ex. 2. The letters pointed out that Petitioner has been a "special focus facility" since March 2011 and was unable to "graduate" from that program because of its persistent and significant deficiencies.[6] The notice letters tell Petitioner that its provider agreement "will be terminated" and that the action is mandated by sections 1819(h)(2)(c) and 1919(h)(3)(D) of the Act and 42 C.F.R. §§ 488.412 and 488.456. CMS Ex. 2 at 1; CMS Ex. 3 at 1. The notice letters also advise the facility of its appeal rights, citing the regulations governing these procedures, 42 C.F.R. §§ 498.40 – 498.79. CMS Ex. 2 at 2; CMS Ex. 3 at 2-3.

Petitioner was not misled by CMS's notice letters; its hearing request leaves no doubt that it well understood that the issue before me would be whether it was in substantial compliance. It specifically challenged the determination that the facility "was not in substantial compliance with participation requirements as of the date of the survey on

[6] Graduation required two concurrent recertification surveys with no deficiencies or deficiencies at a scope and severity level no greater than "E" and without an intervening survey with deficiencies greater than "E."

August 8, 2013, and that its Medicare Provider agreement will terminate. . . ." P. Hrg. Request at 2. The facility also specifically challenged "**all** of the deficiencies cited," and "**each** and **all** of the findings of fact for each and every F-tag . . . as well as **all** of the conclusions that the findings constituted violations of each Tag number." P. Hrg. Request at 2 (August 20, 2013) (emphasis in original). Thus, Petitioner knew that *all* of the cited deficiencies (except those with the potential for no more than minimal harm) would be in play.

I note, finally, that I am not reviewing how CMS decided to impose this remedy. Nor am I restricted to the facts or evidence available to CMS when it made its decision. Instead, I take a fresh look at the legal and factual bases for the deficiency findings underlying the remedies to determine the facility's substantial compliance. *Britthaven of Chapel Hill*, DAB No. 2284 at 6 (2009). Thus, the fact that CMS took this action only after it found the higher level deficiencies is not relevant.

Deficiencies that show the facility's substantial noncompliance. Deficiencies that pose the "potential for causing more than minimal harm" are not trivial. To the contrary, as the following discussion shows, these purportedly "lower level" deficiencies unquestionably endangered the health and safety of facility residents.

42 C.F.R. § 483.10(b)(4) (Tag F155). Each resident has the right to formulate an advance directive, and the facility must inform him, in writing, of his right to accept or refuse medical treatment, and to formulate an advance directive. If, because of an incapacitating condition or mental disorder, an adult resident is unable to receive necessary information, the facility may, instead, give the information to a family member or appropriate surrogate. According to facility policies, the resident's physician decides whether the resident lacks decision-making authority, then obtains a corroborating opinion from a second physician; both opinions are recorded in the resident's medical record. The physician informs the resident and the resident's agent of the determination, and documents in the resident's medical record that he/she has done so. CMS Ex. 17 at 4; CMS Ex. 20 at 12 (Werth Decl. ¶ 42). Persons with mental retardation or developmental disabilities who lack capacity, as defined by the Surrogates' Court Procedure Act § 1750-B, may complete such an advance directive only if legal counsel is consulted. CMS Ex. 20 at 12-13 (Werth Decl. ¶ 44).

One resident (R9) was severely mentally impaired, with diagnoses of intellectual disability, mental retardation, and schizophrenia. She was followed by the state's Office for People with Developmental Disabilities (OPWDD).[7] The surveyors found no evidence that R9 had the capacity to initiate an advance directive. Yet, she purportedly gave verbal consent for a DNR (do not resuscitate) directive. The DNR form was signed

[7] The New York State OPWDD coordinates services for state residents with developmental disabilities.

by a social worker and a licensed practical nurse (LPN). A nurse practitioner signed the physician signature section, although that signature was not dated. The facility did not even consult the OPWDD to find out if the resident had a guardian. CMS Ex. 1 at 1-4; CMS Ex. 16 at 1, 3; CMS Ex. 20 at 10-12 (Werth Decl. ¶ 35-37).

The facility's Director of Social Work agreed that the advance directive should have been discussed with OPWDD to see if a guardianship had been established for R9. She also told Surveyor Linda Werth that a psychiatrist had visited the resident but had not determined her capacity. In any event, residents without capacity should be considered Full Code until a health care proxy decides otherwise. CMS Ex. 20 at 11 (Werth Decl. ¶ 38).

The facility's failure to assess the resident's capacity to make an informed decision, its failure to consult the state office overseeing the resident's welfare, and its disregard for its own policies violated the resident's rights and put it out of substantial compliance with 42 C.F.R. § 483.10(b)(4).

42 C.F.R. § 483.15(h)(2) (Tag F253). The facility must provide housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior.

Throughout the facility and throughout the days of the survey, the surveyors saw evidence of deficient housekeeping and maintenance. On the first day of the survey, Surveyor Luz Ortiz saw a puddle of liquid in a resident room, with the resident walking from one unit to another, her pants soaked from groin to floor. Surveyor Ortiz detected "a strong urine odor." Surveyor Holly Miller observed a toilet bowl full of feces, the seat soiled with a 5 centimeter by 1 centimeter smear of brown matter, and a foul odor emanating. The following morning, surveyors saw a resident standing in a puddle, a strong urine odor permeating the room. Although two nurse aides entered the room, neither checked the resident to see if incontinence care was needed. On another day, the surveyors observed soiled briefs lying on the floor and feces on the wall of a resident room. The housekeeper, who was in the room, told the surveyors that she did not know whether the nurse aides were supposed to clean it up. She left to get her supervisor. In another room, the surveyors reported a strong urine odor and a stripped mattress with visible spots. On yet another day, they smelled a strong urine odor emanating from a resident room and found the resident sitting in the room, eating breakfast. CMS Ex. 1 at 6-7; CMS Ex. 18 at 9 (Ortiz Decl. ¶ 35); CMS Ex. 19 at 12 (Miller Decl. at 12 ¶ 42); *see* discussion of deficiencies cited under 42 C.F.R. § 483.25(d), below.

Surveyor Miller observed gouges on the wall and railings that had been painted over, and the floor near the elevator by the main entrance was sticky and dirty from a dried liquid spill. CMS Ex. 1 at 8; CMS Ex. 19 at 12 (Miller Decl. ¶ 43).

Stainless steel sinks in two patient rooms lacked cover plates for the sink valves and drain pipes below the sink, which left exposed openings around the piping where it entered the wall. A light lens above one of the sinks was missing. In one of the resident rooms, the footboard on one of the beds was crumbling and the plastic was loose. The nightlight grill was unscrewed and the grill was sideways. In another room, the baseboard heater cover was falling off. CMS Ex. 1 at 8; *see* discussion of deficiencies under 42 C.F.R. § 483.70(h)(4), below (showing the importance of eliminating places where insects and other pests can harbor).

Significantly, housekeeping and maintenance deficiencies were longstanding, having been cited in surveys completed on **March 19, 2013**, **September 14, 2012**, **March 9, 2012**, **September 21, 2011**, and **February 26, 2010**. Surveyors repeatedly cited strong urine odors, dirty floors, gouges on the walls and railing, and equipment in disrepair. CMS Ex. 1 at 6-9.

Thus, the uncontroverted evidence establishes that, for years, the facility was either unable or unwilling to maintain a "sanitary, orderly, and comfortable interior," and was not in substantial compliance with 42 C.F.R. § 483.15(h)(2). Not only were the conditions described gross and disgusting, they also created an unsanitary environment, putting residents at risk of infection. *See* CMS Ex. 18 at 10 (Ortiz Decl. ¶ 36); CMS Ex. 19 at 12 (Miller Decl. ¶ 44).

42 C.F.R. § 483.20(k)(3)(i) (Tag F281). Services provided or arranged by the facility must meet professional standards of quality.

The surveyors found three residents for whom the facility had not provided services that met professional standards of quality. One resident (R89) was administered the narcotic, morphine, in the absence of a physician order.[8] Petitioner concedes that this was a deficiency under section 483.20(k)(3)(i). P. Reply at 2.

A second resident's (R127's) physician had prescribed a vaginal yeast suppository every day for three days to treat a yeast infection. The nurse taking the verbal order did not write down the specific name of the medication. Although the physician's order was dated July 17, 2013, as of July 19, the ordered medication had not been delivered to the facility. On July 22, the surveyors observed vaginal cream applicators on a medication cart, which, according to the nurse, were for R127. But the instructions for the medication said to administer for seven days, not three. When the surveyor asked for clarification, the director of nursing told her that a medication error had been made. The physician's order should have been clarified before the medication was administered. If the appropriate medication were not available, the physician should have been notified and the order changed.

[8] This incident was also cited under 42 C.F.R. § 483.25(d). *See* discussion, below.

The third resident (R155) had a suprapubic catheter. The physician order for the catheter said to encourage the use of a leg strap. The surveyor observed that the catheter tubing was curled up, and the resident told her that he curled it because otherwise it pulled. He said that it was not secured to his leg at any time. The nurse aide told the surveyor that the resident did not have a leg strap for the catheter that morning. The nurse manager said that she was not aware of the problem and would investigate.[9]

Professional standards of quality, and, thus, 42 C.F.R. § 483.20(k)(3)(i), dictate that staff follow physician orders. Its failure to do so with these three residents puts it out of substantial compliance with the regulation.

Again, this was a repeat deficiency, having been cited in surveys ending **March 19, 2013** and **January 19, 2013**. CMS Ex. 1 at 9-13.

42 C.F.R. § 483.25(d) (Tag F315). Under the statute and the quality-of-care regulation, each resident must receive, and the facility must provide, the necessary care and services to allow a resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. Act § 1819(b); 42 C.F.R. § 483.25. To this end, the regulation requires (among other provisions) that, based on the resident's comprehensive assessment, the facility must ensure that 1) a resident who enters the facility without an indwelling catheter is not catheterized unless his/her medical condition demonstrates that catheterization is necessary; and 2) a resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

R155, discussed above, was catheterized because he suffered from urinary retention. His physician's instructions to encourage use of a leg strap were documented in his Medication Administration Record (MAR), with a start date of July 13, 2013. According to the sign-off on the MAR, the order was "completed" from July 13 through 23, 2013. But, as noted above, the resident had no leg strap. The registered nurse who, with the surveyor, observed the resident, agreed that the catheter tube should have been secured to the resident's leg. According to facility policy, catheter tubing should be strapped to the resident's inner thigh, using a leg strap. Further, the resident's nurse aide care guide mentioned that he had a catheter but included no guidelines for catheter care. CMS Ex. 1 at 17-19.

Another resident (R45) was diagnosed with psychotic disorder and Alzheimer's dementia. Her cognitive skills were moderately impaired, and she required supervision.

[9] This incident was also cited under 42 C.F.R. § 483.25(d) (Tag F309), and I discuss it in more detail, below.

She was occasionally incontinent of urine, but was not on a toileting program. According to her care plan, she was noncompliant with daily care and hygiene needs and would not change clothes when incontinent. The plan called for an assessment of her toileting needs. The surveyors observed R45 with urine running down her leg and into her sneakers. She walked from one unit to another and went into her room, where she removed her sneakers, changed her slacks, and put the wet sneakers back on. The surveyors also saw a pool of urine on top of the uncovered mattress on her bed.[10]

The nurse aide told the surveyor that the two residents occupying the room urinated a lot, so their care plans called for leaving sheets off their beds. When the surveyor pointed out the pool of urine on the mattress, the nurse aide said that she was not assigned to R45. A housekeeper subsequently entered the room and cleaned the mattress.

The surveyors reported that, the following day, "a urine odor was present in the room," and R45 was standing in a "large amount" of urine. The surveyor stayed with her until a nurse aide entered the room. When shown the resident's wet sneakers, the aide denied that she was wet and left the room. The surveyor reported that the following day, the room smelled strongly of urine while the resident sat there, eating her breakfast.

When questioned, the nurse manager told the surveyor that the resident was not cognitively capable of doing her own care and should have been given incontinence care. She also said that the nurse aides were supposed to check the resident every two hours. CMS Ex. 1 at 19-20.

These deeply disturbing observations evidence facility staff's disregard of their responsibilities to restore to R45 as much normal bladder function as possible. I do not consider leaving sheets off her mattress to be an adequate response to a resident's incontinence. Staff's failure to afford R45 appropriate incontinence care, along with its failure to secure R155's catheter tubing as ordered, put the facility out of substantial compliance with 42 C.F.R. § 483.25(d).

42 C.F.R. § 483.25(h) (Tag F323). The quality-of-care regulation also mandates that the facility "ensure" that each resident's environment remains as free of accident hazards as possible, and that each resident receives adequate supervision and assistive devices to prevent accidents.

The facility was not in substantial compliance with this regulation, because it sprayed pesticides in the rooms of two residents suffering from respiratory disorders; staff failed

[10] Some of these findings were also cited under 42 C.F.R. § 483.15(h)(2), as they demonstrate the facility's failure to maintain a sanitary, orderly, and comfortable environment.

to monitor adequately a resident with prescribed aspiration precautions; and staff failed to supervise adequately a resident who was smoking. Specifically:

R2 suffered from chronic obstructive pulmonary disease (COPD) and obstructive sleep apnea. She was administered oxygen around the clock and used a ventilation machine (BiPAP) in the evenings to improve her breathing. Surveyors observed two live spiders on the wall in her room, a live mosquito by the window, eight small live ants near her toilet, and two dead beetles on the window sill. The resident, who was cognitively intact, told them that a few days earlier, an exterminator, accompanied by a maintenance staff worker, entered her room, announced that they were spraying for bugs, and then sprayed around the window and heater. R2 reported that the smell was unpleasant but that she put on her BiPAP mask to help with the odor. She said that she had experienced some congestion after the pesticide was applied. CMS Ex. 1 at 21-22.

R105 had asthma and obstructive sleep apnea. CMS Ex. 1 at 22.

The surveyor interviewed the maintenance staff and the exterminating vendor's manager and learned that "Tempo 1 percent dust" was applied in these resident's rooms and all the resident rooms and in the hall on that side of the facility. The maintenance worker told her that they sprayed R2's and R105's room while the residents were in them. He said that the technician told him that the pesticide could be applied if the residents were in the room. He also said that the facility administrator told him that the pesticide could be applied while the residents were in their rooms, as long as there was no odor. CMS Ex. 1 at 23.

The surveyor reviewed the exterminating vendor service inspection report, which was dated July 19, 2013, the Material Data Safety Sheet, and the product label. According to the documents, the product has a musty odor. The product's label warned: "Do not apply in rooms while the elderly or infirm are present." CMS Ex. 1 at 23-24. The facility administrator told the surveyor that the supervisor of the exterminating company told him (on July 24) that the product was odorless and safe for use in the residents' rooms. However, when the surveyor read the label warning to the vendor manager, he agreed that residents "probably should not be present in a room when the pesticide is being applied." CMS Ex. 1 at 24.

Another – equally disturbing – incident involved R91. R91 was diagnosed with dementia, dysphasia (difficulty swallowing), and had a history of aspiration pneumonia (which is caused by inhaling foreign materials into the lungs). According to his assessment, his cognitive skills for daily decision-making were severely impaired, and he required eating supervision. In an evaluation dated March 13, 2013, the speech/language pathologist opined that his severe dysphasia was likely caused by silent aspiration. His May 13, 2013 care plan called for aspiration precautions, full assistance with meals, and following the speech/language pathologist's recommendations. His care guide, which

instructed the nurse aides in providing his care, said that he was to be out of his room for meals. Physician orders, dated July 13, 2013, also called for aspiration precautions. CMS Ex. 1 at 24-25.

According to the facility's written policy on aspiration precautions, the resident was to be out of bed for meals, seated in the dining room area for close supervision, or, if eating the meal in his bedroom, he should have received one-on-one constant supervision. CMS Ex. 1 at 26.

Yet, at 12:30 p.m. on July 23, the surveyors observed R91 sitting on the side of his bed, eating lunch in his room with no staff present. When a nurse aide entered the room at 12:43, he had completed eating his solid foods. The nurse aide said that she did not know that he was on aspiration precautions or that he should have been out of his room for meals. Surveyors interviewed the nurse manager, who said that "aspiration precautions" meant that the resident was to be up and out of bed, and "supervision" meant that he had to be visible to someone. CMS Ex. 1 at 26.

A second nurse aide, who was assigned to care for the resident that day, was not aware that he was on aspiration precautions nor that he should eat his meals out of his room and under supervision. The nurse aide said that he had just started caring for the resident, although he claimed that he had read the resident's care guide that morning. CMS Ex. 1 at 26.

In the final incident cited, the surveyors observed Resident A at 9:40 a.m. on July 23, in the facility's designated smoking area (outside the main dining room), seated in a wheelchair, smoking a cigarette. A disconnected oxygen cylinder was on the back of her wheelchair. The surveyor brought this to the attention of the activities director, who said that she thought this was ok, as long as the oxygen cylinder was turned off and disconnected. But review of the facility's smoking policy required that oxygen tanks be turned off and removed before the resident entered the smoking area. CMS Ex. 1 at 26-27.

Facility staff thus endangered two residents with serious respiratory difficulties when, without regard to warning labels, it allowed pesticides to be sprayed in their rooms while they were present. Staff jeopardized R91's health and safety when, ignoring the resident's assessments and care plan, as well as the facility's policy, they left him eating alone in his room. Finally, they put residents and staff at risk when, contrary to the facility's policy, they allowed an oxygen cylinder in a smoking area. These deficiencies put the facility out of substantial compliance with 42 C.F.R. § 483.25(h).

42 C.F.R. § 483.60(b) (Tag F431). The facility must employ or obtain the services of a licensed pharmacist who establishes a system of records of receipt and disposition of all controlled drugs. The records must be detailed sufficiently to enable an accurate

reconciliation of the drugs. The pharmacist determines that drug records are in order and that an account of all controlled drugs is maintained and reconciled periodically. 42 C.F.R. § 483.60(b)(2) and (3).

R117 had physician orders for the narcotic, Hydromorphone. For the period covering May 8 to May 23, 2013, staff could not produce narcotic utilization records for the drug. This put the facility out of substantial compliance with 42 C.F.R. § 483.60(b). CMS Ex. 1 at 41. This was yet another ongoing problem for the facility. The same deficiency was cited in surveys completed **March 19, 2013**, **September 14, 2012**, and **March 9, 2012**.

42 C.F.R. § 483.70(h)(4) (Tag F469). To assure that the facility provides a safe, functional, sanitary, and comfortable environment for residents, staff, and the public, it must, among other requirements, maintain an effective pest control program, so that the facility is free of pests and rodents.

Among the surveyor observations were the following:

- Surveyor Holly Miller, R.N., observed four live centipede-type bugs crawling on the floor beneath a resident's (R2's) chair in the resident's room. Two feet away, a live beetle crawled on the floor. A fly was also in the room. The cognitively-intact resident said that she had been seeing various bugs for about a week and that the maintenance man told her he would take care of the centipedes. She said that she had also seen spiders, moths, and ants in the room. The ants had been around for about a month. CMS Ex. 1 at 42; CMS Ex. 19 at 10 (Miller Decl. ¶ 37).

- R92, who was also cognitively intact, told the surveyors that she sees roaches and ants about once a week, generally on the floor of her room, although once in her chair. Staff recently found a spider under her pillow. CMS Ex. 1 at 43.

- The surveyors observed three flies flying around a resident room. CMS Ex. 1 at 43.

- Several days later, R103, who was cognitively intact, said that she had seen ants and mosquitos in her room and that staff had to wash her roommate's blankets because of the ants. A nurse aide who entered the room said that she had never noticed ants in the resident's room or in the bathroom. CMS Ex. 1 at 43.

- In another resident room, the surveyor saw two live spiders on the wall, a live mosquito by the window, eight live small brown ants near the toilet, and two dead beetles on the window sill. The window frame had a 1½ by ⅛ inch unsealed opening to the outside. The surveyors also observed openings, measuring ½ inch by 8 inches, beneath the heating unit that could harbor pests, such as insects. CMS Ex. 1 at 43-44.

- In another resident room, Surveyor Miller found twenty small brown ants on the floor and around the heating unit. She observed an open area, approximately ¾ inch by 4 feet, along the back side of the heating unit facing the window, which could harbor pests. Throughout the room, the cove base did not fit tightly against the wall, allowing another potential harbor for pests. CMS Ex. 1 at 44: CMS Ex. 19 at 10-11 (Miller Decl. ¶ 38).

The facility had in place a pest services contract, and, according to the administrator, they used those services "on an as needed basis." CMS Ex. 1 at 44.

The facility was thus not free of pests, and its pest control program, such as it was, did not effectively keep it free of pests, which put it out of substantial compliance with 42 C.F.R. § 483.70(h)(4) and jeopardized resident comfort and safety. I agree with Surveyor Miller; exposing vulnerable residents to the quantity and types of pests the surveyors observed does not create a comfortable environment for them. Perhaps even more disturbing, spiders and insects bite and sting. They carry infections. Mosquitos, for example, carry the West Nile virus, to which the elderly are among the more susceptible populations. CMS Ex. 19 at 11 (Miller Decl. ¶ 39).

This was another repeat deficiency. During the survey completed **March 19, 2013**, the facility also had problems with insects, openings that allowed pests to enter, and pest harborage areas. CMS Ex. 1 at 42.

42 C.F.R. § 483.75(l)(1) and (5) (Tag F514). The facility must maintain clinical records on each resident, in accordance with accepted professional standards and practices. The records must be complete, accurately documented, readily accessible, and systematically organized. The clinical record must contain: 1) sufficient information to identify the resident; 2) a record of the resident's assessments; 3) the plan of care and services provided; 4) the results of any preadmission screening conducted by the state; and 5) progress notes. *See* CMS Ex. 1 at 44-45.

For two residents, the facility did not maintain clinical records in accordance with accepted professional standards and practices. Specifically:

R27 was readmitted to the facility on January 3, 2013, with diagnoses including advanced dementia and congestive heart failure. In an order dated April 12, 2013, her physician prescribed morphine injections, as needed. But the corresponding MAR for April did not include the order, and no other records could be found. CMS Ex. 1 at 45.[11]

[11] This represents a fraction of the considerable irregularities found in R27's drug records, which Petitioner concedes were "compromised." I point out other serious problems in my discussion of the deficiencies cited under 43 C.F.R. § 483.25(m)(2).

R27's medical records were wholly inconsistent regarding her allergies.

- Some records (an October 21, 2012 monthly medical history, physical and care plan for the nurse practitioner, and a September 2012 master problem list) indicated that she had no known drug allergies.

- But, a nursing home transfer form, dated December 29, 2012, listed allergies to nitro, mirdazole derivatives, sulfa, opioids, nitrate, erythromycin, and analgesics.

- A hospital discharge summary, dated December 29, 2012, listed allergies to erythromycin, midazolam, nitroglycerin, opioids – meperidine and related, and sulfa.

- Physician orders, signed January 31, 2013, March 21, 2013, and April 12, 2013, listed allergies to nitroimidazoles, sulfa, opioids – morphine analogues, nitrate analogues, and erythromycin base.

- According to a February 4, 2013 monthly medical history, physical and plan of care for the nurse practitioner, the resident was allergic to sulfa, nitrates, morphine, and erythromycin.

- On the MAR for February 2013 and for April 12 through May 13, 2013, some sheets were blank under allergies, and some listed nitroimidazoles, sulfa, opioids – morphine.

- The March 21, 2013 monthly medical history, physical and plan of care for the nurse practitioner said that R27's allergies are "numerous[,] see physician orders."

- On some other MAR sheets, for March and April 2013, some sheets were blank under allergies and some list nitroimidazoles, sulfa.

- But the April 12, 2013 monthly medical history, physical and plan of care for the nurse practitioner said no known drug allergies, and an April 16, 2013 face sheet showed no known allergies.

CMS Ex. 1 at 44-47.

One of the facility's LPNs told the surveyors that she checks the MAR for allergies every time she passes medications. If it does not include allergy information, she checks the physician orders. She claimed that she would notify a supervisor if she found a discrepancy. A second LPN said that she looks on the MAR for allergies, and, if it does

not contain that information, she checks the face sheet or the admission paperwork. CMS Ex. 1 at 47. A third LPN said that she took many physician telephone orders, and if the allergies are not listed, she looks on the immunization record. A fourth LPN said that she expects staff to talk to the resident about allergies and to look at the hospital discharge summary. Any discrepancy should be clarified immediately with the medical staff. CMS Ex. 1 at 48.

The nurse practitioner said that sometimes the pharmacist writes instructions on the physician orders to "see the chart due to multiple allergies," but she did not know where in the chart she should look. She did not know of any one place in the chart to find reliable information as to allergies. She did not remember calling the pharmacy to clarify the differences among the allergy listings for R27, although she had spoken to nursing about the lack of consistency. CMS Ex. 1 at 47.

The consultant pharmacist told the surveyor that he does not keep allergy information or focus on allergies during his monthly pharmacy reviews. He claimed that doing so was the function and responsibility of the "filling pharmacy." CMS Ex. 1 at 48.

The director of nursing told the surveyors that she expected staff to question the resident about allergies at the time of admission and to review the hospital discharge summary.

The facility administrator acknowledged that documentation and transcription had been problems.

Such confusion might be explained by the inadequacy of the facility's policies. Documents titled "telephone orders" (undated) and "Medication Administration" (dated March 2009) include no directions to staff for how to address resident allergies. CMS Ex. 1 at 48.

As discussed above, under 42 C.F.R. § 483.20(k)(3)(i), and in more detail below, R89 had a history of cerebral vascular accident (stroke), venous insufficiency, and bipolar disorder. He had a physician's order, dated June 2, 2013, for morphine every 12 hours, as needed. A nursing progress note, dated July 8, 2013, documents that the resident was administered morphine twice for complaints of left-sided pain. His MAR showed that the drug was administered at 3:00 a.m. only. But the corresponding Controlled Medication Utilization Record, also dated July 8, 2013, showed that morphine was administered at 3:00 a.m. and again at 7:00 a.m. CMS Ex. 1 at 49.

A nurse practitioner told the surveyor that, if the resident were in pain, the LPN on duty would be expected to call the provider for an order to give a second dose of morphine. The LPN would then be required to write down the telephone order to justify giving a second dose so soon after administering the first. The nurse manager could find no such order for the 7:00 a.m. dose and told the surveyor, "I don't know why the nurse would

have given it – there was no order." The nurse manager subsequently prepared a transcription error report to be reviewed by the LPN who administered the morphine. CMS Ex. 1 at 49.

The facility thus had significant problems with its records, which put it out of substantial compliance with 42 C.F.R. § 483.75(l). This was yet another repeat deficiency. During the survey ending **March 19, 2013**, the surveyors also found that the facility was not in substantial compliance with the regulation.

B. The facility was not in substantial compliance with 42 C.F.R. § 483.25 (Tag F309), because it did not provide R6 necessary care and services to address his missing, broken and decayed teeth, and his ill-fitting partial bridge, which left him unable to eat regular food and experiencing sporadic pain and discomfort.

I have already explained the facility's obligations, under the statute and quality-of-care regulation, to provide to each resident necessary care and services. Act § 1819(b); 42 C.F.R. § 483.25.

R6 was an 81-year-old man admitted to the facility on December 27, 2012, with diagnoses that included dysphasia (difficulty swallowing) and cancer of the larynx. CMS Ex. 1 at 13; CMS Ex. 7 at 1; CMS Ex. 18 at 4 (Ortiz Decl. ¶ 10).

His teeth were a mess. An assessment, dated January 5, 2013, describes "obviously or likely cavity or broken natural teeth." P. Ex. B at 12. He had a partial bridge that did not fit properly. His care plan, initially dated January 16, 2013 and updated periodically, identified dental care as a problem, noting that he was missing teeth. The plan directed staff to monitor him for loose, missing, or carious teeth, poorly fitting or broken dentures, and to arrange a dental consult yearly and as needed. According to the plan, the resident "will have oral hygiene performed every day." CMS Ex. 7 at 13; P. Ex. B at 57.

On January 17 a dental hygienist performed what her report characterizes as an "initial comprehensive exam." She noted heavy plaque and food debris and recommended periodic cleaning. With respect to his oral hygiene needs, she wrote "monitor *daily*" under the "staff participation" box. P. Ex. A at 1 (emphasis added). Curiously, her purportedly "comprehensive" exam says virtually nothing about the resident's broken and missing teeth and does not mention his dentures at all.

R6 saw a dentist on March 2, 2013, complaining of a broken tooth. According to the dentist, the roots to that tooth were asymptomatic, without pain or swelling. The dentist also said that staff should monitor him *daily*. CMS Ex. 7 at 6; P. Ex. A at 3.

The record contains minimal progress notes for R6, with the bulk of the notes dated after July 18. P. Ex. B at 27 *et seq*. I see no evidence that staff monitored his mouth and teeth

on a regular basis – much less daily. Nevertheless, some notes record the resident's occasional complaints of tooth and mouth discomfort. On March 11, he asked to be evaluated for softer foods. P. Ex. B at 14. Progress notes dated March 13 indicate that he complained that a broken tooth was bothering him. P. Ex. B at 14. The following day, however, a note says that he denies tooth pain. P. Ex. B at 14. An entry dated March 14 on a Nursing Summary for Physician Visit says "complained of broken tooth and pain in lower jaw, currently denies pain," but calls for a follow-up dental visit with an evaluation. P. Ex. B at 16.

The facility's speech pathologist evaluated R6 on March 18, 2013. She reported that R6 had many missing teeth and that his dentition (array of teeth) was in "very poor condition." His chewing was impaired because of his ill-fitting partial plate and many missing teeth. CMS Ex. 7 at 1. She recommended a "mechanical, soft (ground) diet" and a dental consult because of the ill-fitting plate and the "many missing/broken teeth." CMS Ex. 7 at 2, 4; P. Ex. A at 5. This report was supposed to have been forwarded to R6's physician for review and signature, but the report did not have a medical signature, which suggests that his physician/nurse practitioner did not review it. CMS Ex. 7 at 1, 2; CMS Ex. 18 at 5 (Ortiz Dec. ¶¶ 12, 16).

A dental hygienist report dated March 21, 2013 again describes heavy plaque and food debris, as well as fractured teeth, and again says that staff should monitor his dental health *daily*. CMS Ex. 7 at 7; P. Ex. A at 5.

An assessment dated April 1, 2013 describes broken or loosely fitting dentures and "mouth or facial pain, discomfort, or difficulty with chewing." P. Ex. B at 20; CMS Ex. 18 at 5 (Ortiz Decl. ¶ 14).

Thus, R6 plainly had significant problems related to his teeth, and his care plan called for daily care and staff monitoring. Both the dentist and the hygienists who saw him advised facility staff to "monitor daily." CMS Ex. 7 at 7, 13; P. Ex. A; P. Ex. B at 57. Yet no evidence shows any monitoring or follow-up until after July 18, when he happened to end up in the survey sample, and Surveyor Ortiz asked him (as part of a routine series of questions) whether he felt any pain. He told her that he had mouth and facial pain and that his teeth hurt. CMS Ex. 7 at 7; CMS Ex. 18 at 4 (Ortiz Decl. ¶ 11).

Surveyor Ortiz interviewed the resident again on July 23, and he told her that the wires on his dental bridge bothered him, so he asked for ground food. Because teeth were missing, the wires had nothing to grab onto, so they hurt his gums. CMS Ex. 18 at 6 (Ortiz Decl. ¶ 19). Surveyor Ortiz spoke to the dietary technician that same day, who told her that R6 had trouble chewing, but she did not know why. She could not remember seeing his speech language pathology report, and did not ask why he wanted ground food. CMS Ex. 18 at 6 (Ortiz Decl. ¶ 20).

A nursing note dated July 23, 2013 says that R6 prefers ground food "due to trouble with mastication due to ill-fitting dentures." CMS Ex. 7 at 19; CMS Ex. 18 at 6 (Ortiz Decl. ¶ 21).

The nurse practitioner evaluated R6 for oral pain on July 23, 2013. She reported that the resident had oral/gum pain, especially when his partial plate was in, because the metal rubbed on his gums. She described several "ulcerated" areas on the upper and lower gums. He also had several rotted teeth and partial teeth, as well as "pockets" where teeth used to be. The nurse practitioner changed his diet to soft and ordered an "urgent" dental consultation for teeth extractions. CMS Ex. 7 at 17; P. Ex. B at 30.

When, on July 24, Surveyor Ortiz asked R6 if his teeth were being looked at and treated, he replied, "Yes, thank you. I am so glad you helped me." CMS Ex. 18 at 7 (Ortiz Decl. ¶ 24).

A dentist finally saw R6 on July 29, 2013. She found inflammation of the gums due to carious root tips and opined that the resident needed ten teeth extracted. P. Ex. A at 7.

Petitioner submits the written declaration of Craig A. McClure, D.D.S., whose dental office provides care to the residents of over sixty nursing homes, including Petitioner. P. Ex. 1 at 1 (McClure Decl. ¶ 1). Dr. McClure is vague about his interactions with R6. He alludes to "personal observations and interactions," but I see no evidence that he ever examined or treated the resident. He did not perform the initial assessment on January 17; a dental hygienist did that. He did not treat the resident on March 2; that provider is identified as David Reed, D.D.S. Another dental hygienist saw the resident on March 21. Dr. McClure did not treat the resident on July 29; that provider is identified as Chaya Carl D.D.S. CMS Ex. 7 at 6; P. Ex. A at 1, 3, 7.

Dr. McClure claims that someone in his office "suggested" that R6 undergo root extractions to alleviate his carious roots, but that the resident declined extraction, stating that the carious roots were not bothering him. P. Ex. 1 at 3 (McClure Decl. ¶ 7). Dr. McClure does not say when or by whom the recommendation was made. In fact, the dental records, which Dr. McClure characterizes as "accurate," show that the issue of extraction was raised for the first time on July 29, *after* Surveyor Ortiz identified R6 as suffering mouth and facial pain. On January 17, the dental hygienist recommended "periodic cleaning" and nothing else. P. Ex. A at 1. On March 2, Dr. Reed reported that R6's roots were "asymptomatic" and wrote "will treat for symptoms." He wrote nothing about extracting teeth. P. Ex. A at 3. On March 21, the dental hygienist wrote that she completed his cleaning. She described fractured teeth, but, as in the other reports, said nothing about recommending an extraction. P. Ex. A at 5. No "X's" appear on the tooth charts of any of these reports, signifying "extract." All reports describe the resident as "cooperative" and "desirous" of care.

Moreover, if services are not provided due to the resident's exercise of his right to refuse treatment, the resident's care plan must describe the offered service and the refusal. R6's care plan mentions neither the offer of the service nor the refusal. 42 C.F.R. § 483.20(k)(1)(ii).

The first suggestion that anyone in Dr. McClure's practice suggested extractions occurred on July 29, when Dr. Carl wrote that the resident "needed" extractions of ten teeth. P. Ex. A at 7. Her report does not suggest any reluctance from the resident, but again describes him as cooperative and desirous of care. P. Ex. A at 7.

Thus, the facility well knew that the resident's teeth would and did cause him pain – if not constantly, at least sporadically – and limitations.[12] He was unable to eat regular food, but needed a soft diet. His condition would not improve without significant interventions, and would likely deteriorate (as it did) without persistent monitoring. Thus, his care plan called for monitoring and daily oral hygiene. The reports from his relatively few dental visits informed staff that he required daily monitoring. Yet, no evidence establishes that staff monitored his dental health daily. The dire state of his teeth was only recognized by happenstance, because he was selected randomly as a part of the survey sample. Only then did someone look into his mouth, see that he required "urgent" care, and send him to a dentist, who then determined that dramatic interventions were necessary. Had someone checked his teeth and gums, even sporadically, they'd have seen the "ulcerated" appearing areas on his gums that the nurse practitioner saw on July 23.

R6 was not able eat normal food and experienced sporadic pain, all because of the sorry state of his mouth. Yet, the facility provided minimal monitoring and services.[13] It was therefore not providing the "necessary care and services to allow [him] to attain . . . the highest practicable physical, mental, and psychosocial well-being," and was not in substantial compliance with 42 C.F.R. § 483.25.[14]

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[12] To treat other conditions, R6 took a significant amount of morphine, which likely helped to mask the pain attributable to his dental problems.

[13] Referring the resident to an outside source for professional services does not relieve the facility of its obligations. It must assure that those services meet professional standards of quality and are sufficient to meet the resident's needs. 42 C.F.R. § 483.20(k)(1) and (3).

[14] Petitioner notes that R6, who arrived at the facility significantly underweight, gained weight during his stay. I am not persuaded that this weight gain, likely attributable to liquid dietary supplements, excuses the facility from its obligation to monitor his dental status in order to achieve his highest practicable well-being. P. Ex. B at 11, 25.

C. The facility was not in substantial compliance with 42 C.F.R. § 483.25(m)(2) (Tag F333), because it did not ensure that staff administered narcotics as ordered; water had been substituted for morphine; and staff falsified medication administration records, so that no reviewer could verify how much of a narcotic had been administered.

The "quality-of-care" regulation also requires that the facility "ensure" that its residents are free of any significant medication errors. 42 C.F.R. § 483.25(m)(2).

Resident 27 (R27). R27 was a terminally ill resident, who was suffering significant pain, and for whom the facility was providing comfort measures only. P. Ex. C at 24, 27. Her physician prescribed 3 mg of intramuscular morphine every four hours as needed for pain: "Morphine Sulfate 5 mg/mL – give 3 mg IM for pain." CMS Ex. 13 at 2, 17, 18; P. Ex. C at 1, 3.[15]

At the time of the survey, the New York State Bureau of Narcotics Enforcement was investigating the facility for narcotics violations that included the facility staff's actions with respect to R27's intramuscular morphine. Surveyor Holly Miller was involved in that investigation as well. The narcotics investigators found that the temper resistant caps had been removed on *sixteen* vials of morphine and the vials had been filled with water, an appalling discovery, which Petitioner neither denies nor explains. CMS Ex. 19 at 4 (Miller Decl. ¶ 10). If facility staff (or others) are substituting water for a powerful narcotic that was designated for its residents, the facility is not ensuring that the resident is receiving any of that ordered medication.

The facility also admits that unidentified staff had altered ("written over") R27's physician orders and MAR, changing the dosages ordered and those purportedly administered. P. Post-hrg. Br. at 4; P. Reply at 4; CMS Ex. 13 at 1 (March 3 telephone order in which "3 mg" has been changed to "4 mg"); CMS Ex. 13 at 23 (altered MAR); CMS Ex. 19 at 4, 5-6 (Miller Decl. ¶¶ 10, 15-18). Thus, it seems, the facility records are completely unreliable, and the facility cannot establish that R27 was free of significant medication errors. As CMS correctly notes, the facility has no idea how much morphine R27 received.[16]

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[15] 5 mg/1 mL represents the concentration of the liquid morphine.

[16] Narcotic Utilization Sheets show that staff administered the wrong amount of morphine on numerous occasions. They document 22 instances in which 4 mg (0.8 ml) were administered and 21 instances in which 5 mg (0.6 ml) were administered. CMS Ex. 13 at 43-47; CMS Ex. 19 at 5 (Miller Decl. ¶ 14).

Petitioner argues that it cannot be held accountable for the "isolated lapses of a staff member, who altered the medication order for Morphine, and the March MAR which could not have been detected by the facility." P. Br. at 16. First, why the facility could not detect such obvious alterations is a mystery. The surveyor found them. The changes are plain on the faces of the documents, and, presumably, staff referred regularly to the physician orders and the MAR. Second, the Departmental Appeals Board has long rejected the notion that the facility cannot be held responsible for the unforeseeable actions of its employees. A facility "cannot disown the consequences" of inadequate care by the simple expedient of pointing the finger at staff, who are the agents of the facility. *Emerald Oaks*, DAB No. 1800 at 7 n.3 (2001); *accord Ridge Terrace* DAB No. 1834 at 8 (2002); *Cherrywood Nursing & Living Ctr.*, DAB No. 1845 (2002).

Petitioner also argues that CMS has not established that R27, in fact, received an incorrect dose. Petitioner has the burdens here upside-down. The *facility* must ensure that medications are administered as ordered. A facility cannot avoid this responsibility by presenting records that make it impossible to verify the amount of the drug actually administered. Where water is substituted for drugs and drug records are falsified, the facility has obviously failed in its responsibility.

Resident 89 (R89). As discussed above, under 42 C.F.R. §§ 483.20(k)(3)(i) and 483.75(l), R89 was administered the narcotic morphine, instant release (IR), without a physician order. R89's diagnoses included renal failure, encephalopathy, and bipolar disorder. He had suffered a cerebral vascular accident (stroke). CMS Ex. 8. On June 2, 2013, his physician ordered Morphine Sulfate IR, a narcotic, 15 mg twice a day as needed for breakthrough pain. CMS Ex. 8 at 2, 4.[17] According to a nursing note, dated July 8, 2013 at 7:20 a.m., he complained of pain and was twice administered morphine. CMS Ex. 8 at 1. According to the facility's controlled medication utilization record, he was administered the narcotic at 3:00 a.m. and again at 7:00 a.m. CMS Ex. 8 at 5.

Petitioner seems to acknowledge that a facility should not administer dosages of narcotics unless a physician has ordered them, but argues that the nurse practitioner authorized it by telephone. In her written declaration, Nurse Practitioner Michelle Sienna claims that she spoke to the facility nurse by telephone at 6:00 a.m. and "gave permission" to administer the dose. P. Ex. 4 at 9 (Sienna Decl. ¶ 27). The problem with this claim is that no written documentation supports it. A nurse's note dated July 8 at 7:20 a.m. says that the nurse practitioner "was notified" about the resident's pain and an "acute sheet [was] done for evaluation," but it does not say that the nurse practitioner ordered an additional dose of the narcotic. P. Ex. G at 7. Nurse Practitioner Sienna does not claim

[17] The resident also received 15 mg morphine sulfate, extended release (ER), twice a day. CMS Ex. 8 at 2.

that she ever signed an order, which she was required by law to do. Tr. 65, 107-108.[18] The facility produced no record of a telephone order, and, for her part, Nurse Practitioner Sienna produced no written record showing that she ordered the drug. Based on the contemporaneous nurse's note, I accept that the facility spoke to her about the resident's pain; I do not accept that she ordered an additional dose of morphine.

The possible dangers associated with administering too much instant release morphine are documented on the product label and in standard nursing and pharmaceutical texts. CMS Ex. 20 at 5-6 (Werth Decl. ¶¶ 16-18); *see* Lippincott Williams & Wilkins, 2013 Nursing Drug Handbook. They include bradycardia, cardiac arrest, shock, hypertension, hypotension, and tachycardia, apnea, respiratory arrest, and respiratory depression. These could be particularly troublesome for someone like R89, who had a history of cardiac problems as well as stroke.

I note that, although the facility's medical expert, Nodar Janas, M.D., downplays the significance of the facility's other medication errors (including, remarkably, the very disturbing irregularities surrounding R27's drugs), he does not include a discussion of R89 in his declaration. P. Ex. 2.

The facility thus did not ensure that staff administered narcotics as ordered, and was not in substantial compliance with 42 C.F.R. § 483.25(m)(2).[19]

D. The facility was not in substantial compliance with 42 C.F.R. § 483.35(i) (Tag F371), because one of its cooks did not properly cool a roast she intended to serve to facility residents, and she plainly did not understand safe techniques for cooling foods. Further, surfaces used for food service were not kept clean and sanitary.

The facility must store, prepare, distribute, and serve food under sanitary conditions. 42 C.F.R. § 483.35(i).

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[18] New York State regulations governing controlled substances allow staff to administer narcotics pursuant to a verbal order, but that order must be reduced to a writing that documents the emergency justifying the drug and, within 48 hours of the drug's administration, it must be signed by the practitioner who ordered the drug. N.Y. Comp. Codes R. & Regs. tit. 10, § 80.46(f).

[19] I have not discussed every single citation under this (and other regulations), because the deficiencies discussed more than justify a finding of substantial noncompliance. *See Claiborne-Hughes Health Ctr.*, 609 F.3d 839, 847 (6th Cir. 2010); *Carrington Place of Muscatine*, DAB No. 2321 at 20-21 (2010).

Improperly prepared roast. Cooked food must be cooled properly to prevent foodborne illnesses, which can be especially serious for the elderly and infirm. Tr. 111. Surveyor Werth, who is a registered dietician, testified that temperatures between 45º and 140º F are considered to be in the "food danger zone." Tr. 111. Facility policies were in accord and required that hot foods be cooled from 135º to 70º F within two hours or less. The food then must be cooled from 70º to 41º F in four hours or less. Total time cooling may not exceed six hours. P. Ex. O at 4-5.

At 8:34 a.m. on July 18, Surveyor Werth observed in a walk-in cooler a large roasting pan, covered tightly with foil, dated July 17. Beneath the foil were two cooked whole roasts, covered with a layer of congealed fat. She took the temperature of the roasts, using her own and the facility's thermometers, which registered between 55º and 55.8º (with only slight variations between the thermometers). CMS Ex. 20 at 7 (Werth Decl ¶ 25); P. Ex. 6 at 2 (Holiday Decl. ¶ 4); Tr. 111. The facility's director of food services told her that the roast was designated for the day's meal. She did not volunteer that she would dispose of the roast.

Surveyor Werth returned to the kitchen at 10:17 a.m. The roast had not been disposed of, and the food services director again did not volunteer that she would dispose of it. In fact, the cook told her that she was getting ready to cut the roast for the lunch meal. Tr. 113. When Surveyor Werth asked the food services director whether the roasts should be served "given that it was not cooled properly, she replied (i.e., "her exact words") that she "guessed she would need to make a substitute." Tr. 76; CMS Ex. 20 at 8 (Werth Decl. ¶ 27). The testimony of the facility's food service director is generally consistent with that of Surveyor Werth. She testified that, *when asked by the surveyor*, she replied that the roast would not be served, and, ultimately, the roast was not. P. Ex. 6 at 2 (Holiday Decl. ¶ 4).

CMS argues that, but for the surveyor's intervention, the roast would have been served. Petitioner disputes this. That the roast would have been served seems likely. Almost two hours after the surveyor discovered the unsafe temperature, the roasts had not been disposed of, and the cook said that she planned to serve it. The facility's case would have been much stronger had staff disposed of the roast immediately, or, at least, volunteered that they would do so prior to the surveyor's prodding.

However, I need not resolve this question. The parties agree that the roast was not properly cooled and that improper cooling endangers resident health and safety. The uncontroverted evidence also establishes that the facility's cook did not understand or follow the facility's written policies for cooling foods. Indeed, when questioned by the surveyor in the presence of the food services director, the cook said that she removes a roast from the oven, cuts it into quarters, and places it in the walk-in refrigerator. She checks the temperature the next morning to be sure it is down to about 40º. She then added that she would also check the temperature before the end of her shift to see "if the

temperature had gone down to 155º or 170º." After the food services director challenged her, she said, "Wait, after two hours I want the temperature to be down to 70º F." CMS Ex. 20 at 8 (Werth Decl. ¶ 27). When asked how she kept track, she said that she covered the meat with foil, writing the time and temperature on top. Again, the food services director corrected her, telling her that she should not cover the meat with foil, because it does not help the cooling process. CMS Ex. 20 at 8 (Werth Decl. ¶ 27); *see* Tr. 73. The cook did not seem to understand that the cooling had to be completed within six hours. *See* P. Ex. O at 4-5.

The food services director does not dispute any of this. P. Ex. 6.

That a facility cook did not know how to cool food safely created the potential for more than minimal harm and, by itself, put the facility out of substantial compliance with 42 C.F.R. § 483.35(i), without regard to the other deficiencies cited under this regulation.

Encrusted conveyer belt on tray line. Surveyor Werth also testified that the conveyor belt on the tray line had "dark-colored food splash and spray on the top surface and between the slats of the belt (entire length of the tray line/about 30 feet)." She lifted the tray line to find a conveyor box below that was full of crumbs and debris, "an accumulation of dust, debris, crumbs/filth in that box." Tr. 116; CMS Ex. 20 at 8 (Werth Decl. ¶ 29). The food services director told her that it was difficult to clean and that she would ask the maintenance director to remove the belt. CMS Ex. 20 at 8-9 (Werth Decl. ¶ 29).

The facility submits a sheet, dated July 22, 2013, that purports to be staff assignments for kitchen duties, including "power wash tray line." P. Ex. P. This sheet has no probative value. It does not establish that any of the listed tasks were performed, much less when the cited surfaces had last been cleaned, how they were cleaned, or by whom. In *Crestview Parke Care Ctr. v. Thompson*, 373 F.3d 743, 751 (6th Cir. 2004), the facility presented evidence of cleaning schedules, procedures and duties in an attempt to demonstrate that the facility was clean, safe, and well-maintained. The court held that the facility's evidence established that it had failed in the execution of its procedures, "because the surveyors' observations showed that the facility was noncompliant." *Id.* And Petitioner's sheet here is not even a cleaning schedule, only a list of duties with names attached. Moreover, it is dated July 22 – four days *after* Surveyor Werth made her observations.

According to the food services supervisor, the tray line is power-washed monthly. P. Ex. 6 at 4 (Holiday Decl. ¶¶ 10, 11). If so, this was not sufficient to keep the area clean and sanitary.[20]

[20] The food services director also complains that "the debris was only observed after the maintenance worker went through significant effort to lift the conveyor belt." P. Ex. 6 at

Finally, the facility argues that "there is no way of knowing exactly when these conditions arose," but they were observed after food had been prepared and before facility staff had a reasonable opportunity to clean food contact surfaces, which would have occurred after the next meal was prepared and distributed. P. Reply at 8; P. Post-hrg. Br. at 23. In Petitioner's view, only "reliable scientific testing" can establish that dirt and debris have accumulated over time. I am not aware of any case – and Petitioner has cited none – requiring such evidence. To the contrary, the Departmental Appeals Board and the courts have accepted surveyor observations establishing unsanitary conditions. As noted above, the *Crestview Parke* court explicitly relied on surveyor observations to establish substantial noncompliance. *Crestview Parke Care Ctr.*, 373 F.3d at 751;*see also Carrington Place of Muscatine*, DAB No. 2321 (2010); *Dialysis Ctr. of Moreno Valley*, DAB No. 1841 (2002); *Community Nursing Home*, DAB No. 1807 (2002). The *Crestview* court also rejected the facility's related contention, similar to that made here, that it could be observed as unclean at any time because it was constantly being used, finding that it did not rebut the evidence of noncompliance.

Moreover, Surveyor Werth is especially well-qualified to recognize the difference between a new stain, easily cleaned, and dirt and debris that have accumulated over time. She is an experienced surveyor and a dietician, who previously worked as a consultant in the food service industry. As a surveyor, she inspects three to four kitchens per month. As a consultant, she inspected twelve to fifteen kitchens per month. She is certified in ServSafe and as an instructor in food service sanitation and safety. Tr. 116. She described in some detail the "dried pieces of crumbs and papers" and was certain that they did not derive from just one meal. Tr. 82. Had the area been power washed recently, the slats on the tray belt would not have had an accumulation of food debris. She also explained that color is a good indication of freshness. "Fresh splash and spray has the color of the food item or beverage that was splashed and sprayed. This was dark brown to black in color, which would indicate that it had been there for a time." Tr. 117.[21]

At least one of the facility's cooks did not properly cool a roast she intended to serve facility residents, and she demonstrated that she did not understand safe techniques for cooling foods. Surfaces used for food service were not kept clean and sanitary. Either of

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5 (Holiday Decl. ¶ 13). The difficulty in removing the conveyor belt might explain why the area beneath was not cleaned regularly, but it does not excuse the facility.

[21] Certainly, a trained surveyor's observations of accumulated food debris and dark brown stains meets CMS's burden of establishing a prima facie case. The facility was, of course, free to respond with its own "reliable scientific testing" that the dirt and debris was fresh (although that might not be very practicable).

these deficiencies alone establishes that the facility was not in substantial compliance with 42 C.F.R. § 483.35(i).

IV. Conclusion

CMS may impose remedies – including termination – if a facility is not in substantial compliance with Medicare program requirements. I have no authority to review the remedy imposed. Here, as the above discussion shows, the facility had multiple deficiencies, any one of which put it out of substantial compliance. I therefore sustain CMS's determination to impose a remedy.

/s/
Carolyn Cozad Hughes
Administrative Law Judge