Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Hillsdale County Medical Care Facility
(CCN: 23-5197),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-289

Decision No. CR4034

Date: July 13, 2015

DECISION

Following a September 19, 2013 complaint investigation survey, the Michigan Department of Licensing and Regulatory Affairs (state agency) found that Hillsdale County Medicare Care Facility (Petitioner) was not in substantial compliance with the requirements for Medicare-participating long-term care facilities. The state agency determined that Petitioner's care of a resident did not comply substantially with the notification requirement (42 C.F.R. § 483.10(b)(11)) or the general quality of care requirement (42 C.F.R. § 483.25). A subsequent revisit survey determined that Petitioner returned to substantial compliance on October 17, 2013. The Centers for Medicare & Medicaid Services (CMS) accepted the state agency's findings and imposed a $450 per-day civil money penalty (CMP) against Petitioner from September 19, 2013 through October 16, 2013 (28 days), for a total CMP of $12,600. Petitioner appealed.

For the reasons set forth below, I find that Petitioner was not in substantial compliance with the requirements of a long-term care facility during the cited period and that the enforcement remedy imposed is reasonable in amount and duration. I therefore affirm the noncompliance determination as well as the $450 per-day CMP for 28 days.

I. Background and Procedural History

Petitioner is a long-term care facility located in Michigan that participates in the Medicare and Medicaid programs. After receiving a complaint from a former resident's family member, the state agency conducted a complaint investigation survey of Petitioner between September 18 and September 19, 2013, and determined Petitioner was not in substantial compliance with Medicare participation requirements. The state agency's findings that led to its noncompliance determination focused on a resident referred to as "Resident 101" who was admitted to Petitioner's facility on April 1, 2013, and died in the facility on April 17, 2013. Based on its survey findings, the state agency alleged that Petitioner's staff did not timely or adequately notify Resident 101's legal representative of several significant changes to the resident's medical status, nor did Petitioner's staff provide Resident 101 with the necessary care and services to address his declining respiratory condition the day before and the day of his death. Specifically, the state agency found that Petitioner did not comply with two regulatory requirements:

- 42 C.F.R. § 483.10(b)(11) (Tag F-157) – facility must inform resident, consult with physician, and notify resident's legal representative or family member of significant changes to resident's physical, mental, or psychosocial status or a need to alter treatment significantly; and

- 42 C.F.R. § 483.25 (Tag F-309) – facility must provide the necessary care and services for a resident to attain or maintain his or her highest practical physical, mental, and psychosocial well-being.

The state agency determined Petitioner's noncompliance was at a scope and severity level "G," an isolated instance of actual harm not rising to the level of immediate jeopardy.

By letter dated October 30, 2013, CMS notified Petitioner that it had accepted the state agency's findings and was imposing a mandatory denial of payment for new admissions (DPNA) effective December 19, 2013, if Petitioner remained out of substantial compliance, and a CMP of $450 per day, effective September 19, 2013. By letter dated December 4, 2013, CMS notified Petitioner that a revisit survey found that Petitioner returned to substantial compliance on October 17, 2013. CMS rescinded the DPNA but continued the $450 per-day CMP through October 16, 2013, for a total of 28 days.

On November 14, 2013, Petitioner, through its administrator, filed its request for a hearing before an administrative law judge to challenge the two cited deficiencies in the September 2013 survey. Petitioner then retained counsel, who continued to represent Petitioner throughout these proceedings. CMS subsequently filed a motion for summary judgment along with 34 proposed exhibits (CMS Exs. 1-34). Petitioner opposed summary judgment, and submitted two exhibits (P. Exs. 1-2), which actually contain four separate affidavits, two of which are from Petitioner's medical director, who also served

as Resident 101's primary care physician. *See* P. Ex. 1 at 8-9; P. Ex. 2 at 1-2. In a ruling dated July 29, 2014, I denied CMS's motion for summary judgment because, although the parties relied on the same documentary evidence in their prehearing arguments, each party presented reasonable factual inferences of the documentary evidence that created a genuine dispute of material facts. I convened a prehearing conference by telephone on August 5, 2014, during which the parties agreed that the case could be resolved without holding an in-person hearing. Accordingly, each party waived its opportunity to cross-examine the opposing party's witnesses. Neither party objected to the admission of the proposed exhibits, so I admitted the exhibits that the parties submitted with their prehearing arguments (CMS Exs. 1-34; P. Exs. 1-2). The parties each submitted a closing brief (CMS Br.; P. Br.) and did not submit any additional evidence. On March 2, 2015, I ordered the parties to file supplemental briefs to address the legal issue of whether it was permissible for CMS to rely on events that occurred sometime between April 1 and April 17, 2013, to support Petitioner's noncompliance between September 13 and October 17, 2013. I also directed CMS to file a copy of Petitioner's plan of correction. Each party filed a supplemental brief (CMS Supp. Br.; P. Supp. Br.) as directed. CMS also filed Petitioner's plan of correction, labeled as "ALJ Ex. 1," which is admitted into the record.

II. Issues

This case presents the following issues:

1. Whether Petitioner was in substantial compliance with the Medicare participation requirement in 42 C.F.R. § 483.10(b)(11) (proper notification of changes) between September 19 and October 17, 2013;

2. Whether Petitioner was in substantial compliance with the Medicare participation requirement in 42 C.F.R. § 483.25 (necessary care and services for the highest practicable well-being) between September 19 and October 17, 2013; and

3. If Petitioner was not in substantial compliance, whether the penalty imposed is reasonable in duration and amount.

The scope and severity of Petitioner's noncompliance is not at issue. A facility may only challenge the scope and severity level of noncompliance if: (1) CMS has made a finding of "substandard quality of care" that impacts the facility's authority to conduct a nurse aid training and competency evaluation program; or (2) a successful challenge to the scope and severity of noncompliance would affect the range of the CMP that may be imposed. 42 C.F.R. § 498.3(b)(14). Here, CMS did not make a finding of "substandard quality of care," which requires either immediate jeopardy, a pattern of actual harm, or widespread potential for more than minimal harm. 42 C.F.R. § 488.301. The state agency found that the two deficiencies cited were isolated instances of actual harm that

were not immediate jeopardy. CMS Ex. 1. Moreover, a successful challenge would not impact the range of CMP that CMS may impose. The only range for a possible CMP based on noncompliance that does not pose immediate jeopardy, such as in this case, is between $50 and $3,000 per day. 42 C.F.R. § 488.438(a)(1)(ii). Thus, the scope and severity of Petitioner's noncompliance is not at issue.

III. Statutory and Regulatory Framework

The Social Security Act (Act) establishes the minimum standards of resident care that a long-term care facility must meet in order to participate in the Medicare and Medicaid programs and authorizes the Secretary of Health and Human Services (Secretary) to promulgate regulations implementing those statutory requirements. 42 U.S.C. §§ 1395i-3, 1396r. Specific Medicare participation requirements for long-term care facilities are in 42 C.F.R. Part 483. A long-term care facility must remain in substantial compliance with program requirements to participate in Medicare. 42 C.F.R. § 483.1(b). "Substantial compliance" means "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for minimal harm. *Id.* § 488.301. "Noncompliance" means "any deficiency that causes a facility not to be in substantial compliance." *Id.*

The Act authorizes the Secretary to impose enforcement remedies against a long-term care facility for failure to comply substantially with the federal participation requirements. The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility not in substantial compliance with participation requirements. State agencies survey facilities on behalf of CMS to determine whether the facilities comply with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. Standard surveys must occur at least every 15 months, and complaints of abuse or neglect of residents in a long-term care facility may trigger a survey sooner than a standard survey. *See* 42 U.S.C. § 1395i-3(g)(1)(C), (g)(2)(A)(iii). The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406. These remedies include: termination of a facility's participation in the Medicare program, closure of the facility, temporary management, denial of certain Medicare payments, transfer of residents, state monitoring, directed plans of correction, and various CMPs. *Id.* § 488.408.

CMS may impose a per-day CMP for the number of days a facility is not in substantial compliance or a per-instance CMP for each instance of the facility's noncompliance. *Id.* § 488.430(a). A per-day CMP, which CMS imposed in this case, may range from either $50 to $3,000 per day for less serious noncompliance or $3,050 to $10,000 per day for more serious noncompliance that poses immediate jeopardy to the health and safety of residents. *Id.* § 488.438(a)(2). "Immediate jeopardy" exists when "the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." *Id.* § 488.301.

If CMS imposes an enforcement remedy against a long-term care facility based on a noncompliance determination, the facility may request a hearing before an administrative law judge to challenge the noncompliance finding and enforcement remedies. 42 U.S.C. §§ 1320a-7a(c)(2), 1395cc(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13).

IV. Findings of Fact and Conclusions of Law

A. Petitioner was not in substantial compliance with the notification requirement in 42 C.F.R. § 483.10(b)(11) because Petitioner's staff did not immediately notify Resident 101's legal representative of significant changes to his status or of the need to alter his treatment significantly.

To maintain compliance with the Medicare participation standards, a long-term care facility "must immediately . . . notify the resident's legal representative or an interested family member" if any of four specific circumstances occur, two of which are relevant in this case:

> (B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
>
> (C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment)[.]

42 C.F.R. § 483.10(b)(11)(i)(B)-(C). The Board has explained that the word "immediately" as it is used in section 483.10(b)(11) means "without any intervening interval of time." *Magnolia Estates Skilled Care*, DAB No. 2228, at 8-9 (2009). In addition, the Board has often pointed out that the drafters of the regulation changed the notification requirement from 24 hours, as initially proposed, to "immediately," as stated in the final rule, in response to public comment:

> CMS stated that the February 1989 draft of the rule gave the facility "up to 24 hours in which to notify the resident's physician and the legal representative or family." [56 Fed. Reg. 48,826, at 48,832-33 (1991).] Several commenters, however, objected to the 24-hour period because "a resident could be dead or beyond recovery in that time . . . ." In response, CMS stated: "We agree and have amended the regulation to require that the physician and legal representative or family be notified immediately."

Laurels at Forest Glen, DAB No. 2182 at 12-13 (2008) (second citation omitted), *accord*, *River City Care Ctr.*, DAB No. 2627 (2015); *NHC Healthcare Athens*, DAB No. 2258 (2009); *Magnolia Estates*, DAB No. 2228.

The regulation requires that there be a "significant change" or a "need to alter treatment significantly" before a facility is required to notify a resident's legal representative. 42 C.F.R. § 483.10(b)(11)(i). While the regulation provides examples of what constitute circumstances significant enough to require notification ("life-threatening conditions or clinical complications" and "a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment"), Appendix PP of the State Operations Manual (SOM) also explains:

> For purposes of § 483.10(b)(11)(i)(B), life-threatening conditions are such things as a heart attack or stroke. Clinical complications are such things as development of a stage II pressure sore, onset or recurrent periods of delirium, recurrent urinary tract infection, or onset of depression. A need to alter treatment "significantly" means a need to stop a form of treatment because of adverse consequences (e.g., an adverse drug reaction), or commence a new form of treatment to deal with a problem (e.g., the use of any medical procedure, or therapy that has not been used on that resident before).

SOM, App. PP, *Interpretive Guidelines §483(b)(11)* (Rev. 70, 2011) (as cited in *Laurels at Forest Glen*, DAB No. 2182 at 12-13). The notification requirement is not limited only to life-threatening circumstances but includes situations when "there is a chance that physician intervention is needed." *Claiborne-Hughes Heath Ctr. v. Sebelius*, 609 F.3d 839, 843 (6th Cir. 2010)[1] (citing *Laurels at Forest Glen*, DAB No. 2182 at 12-13).

Petitioner has also developed a written policy addressing the notification of a resident's legal representative, and it is consistent with the regulatory requirements. CMS Ex. 32. That policy, titled "Change of Condition Notification," states:

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[1] *Claiborne-Hughes* did not discuss when a facility must notify a legal representative but rather discussed when it was necessary for a facility to consult with a physician. *See* 609 F.3d at 843. However, consultation with a physician for a "significant change" in a resident's condition necessarily triggers the requirement that the resident's legal representative be notified as well. The regulation uses the conjunctive "and," meaning consultation with a physician and notification of a legal representative must occur if there is a significant change. *See* 42 C.F.R. § 483.10(b)(11). Therefore, the chance that physician intervention is needed triggers both the physician consultation and the legal representative requirements.

> The facility (i.e. Neighborhood Nurse, Supervisor, and Unit Manager) is to notify the elder, physician and appropriate representative when any of the following occur:
>
> a. Accident or Incident involving the elder which results in an injury and has a potential for requesting physician intervention and per policy.
>
> b. A significant change in the elder's physical, mental or psychosocial status, for example:
>
> 1. New Infection.
> 2. Depression.
> 3. Change of status.
> 4. Acute episode.
> 5. Medication change for mood or behavior or significant physical change.
> 6. Life threatening conditions.
> 7. Clinical complications.
> 8. Treatment changes; i.e. therapy, oxygen, etc.

CMS Ex. 32. Thus, Petitioner's own policy recognizes the wide range of circumstances when notification of a resident's legal representative is required. Moreover, I accept Petitioner's notification policy as its interpretation of how the requirements in 42 C.F.R. § 483.10(b)(11) should be carried out by its staff.

Resident 101, an 80-year-old male, was admitted to Petitioner's facility on April 1, 2013, with a history of dementia, urinary tract infection (UTI), sepsis, anxiety, insomnia, chronic obstructive pulmonary disease (COPD), hypertension, dysphagia, depression, and muscle weakness. CMS Ex. 18 at 1-3. Resident 101 had appointed his daughter to serve as his legal representative. CMS Ex. 18 at 27. It is undisputed that Resident 101's legal representative visited him frequently and was "intimately involved in his care." P. Ex. 1 at 11; *see* P. Br. at 3.

CMS cites four separate incidents, between April 5 and April 14, 2013, when Petitioner's staff allegedly did not provide the requisite notification to Resident 101's legal representative of a significant change to his status or of a need to alter his treatment significantly. Petitioner does not dispute that these incidents occurred but instead argues that none of them were of such a significant nature to trigger the notification requirement to Resident 101's legal representative.

1. Petitioner's intramuscular administration of Ativan® to Resident 101 on April 5, 2013 did not require immediate notification of his legal representative because it did not constitute a significant change in the resident's status nor a significant alteration of his treatment.

On April 5, 2013, Petitioner's staff administered Ativan, an anti-anxiety medication, to Resident 101 intramuscularly rather than by mouth. CMS Ex. 25 at 2. Just prior to the staff's administering Ativan, Resident 101 set off an alarm several times while trying to get out of bed. He told staff that he was "going to die." He shouted for help and grabbed a certified nursing assistant (CNA). Staff attempted to give Ativan to Resident 101 by mouth, but he refused it. Staff then administered the medication intramuscularly "with [positive] results." CMS Ex. 25 at 2. Petitioner points out that an April 2, 2013 physician's order directed that Ativan be administered to Resident 101 either orally or intramuscularly, every four hours as needed.[2] CMS Ex. 20 at 7. That order stated "Ativan 1 mg PO or IM q 4° PRN #60 5 refills."[3] Staff did not notify Resident 101's legal representative that it had to administer Ativan intramuscularly rather than by mouth. *See* CMS Ex. 25 at 2.

There is little doubt that staff had to resort to intramuscular administration of Ativan rather than by mouth because Resident 101 was combative and refusing to take it. CMS Ex. 25 at 2. However, it is not a significant alteration in treatment when staff follows an existing physician's order, even if the order is "as needed." Also, while Resident 101 was agitated on April 5, 2013, his agitation did not represent a significant change or acute episode in his mental status. The order in this instance was for Ativan, which treats anxiety. Resident 101's anxiety at the time staff administered the Ativan intramuscularly was consistent with his prior behavior, which is why his physician had prescribed an

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[2] Upon Resident 101's admission, on April 1, 2013, the physician had ordered Ativan only by mouth every four hours as needed. CMS Ex. 20 at 2. The physician changed that order the following day to include the option of administering Ativan intramuscularly every four hours as needed. CMS Ex. 20 at 7. A care note on April 2, 2013 states that Resident 101 was "combative with transfers and care," climbing out of his bed, and "swinging at CNAs," which may have precipitated the change in how the anti-anxiety medication was administered. CMS Ex. 25 at 33. Resident 101's physician wrote in his written direct testimony that he ordered the intramuscular administration of Ativan on April 5, 2013, only after Resident 101 refused to take it by mouth. P. Ex. 1 at 9. The order for intramuscular Ativan, however, appears to have been in place for three days prior. *See* CMS Ex. 20 at 7.

[3] Expanding the medical abbreviations used, this order would apparently read "Ativan 1 milligram by mouth or intramuscularly every four hours as needed. . ." *See* Neil M. Davis, *Medical Abbreviations* (13th ed. 2007).

Ativan regimen already.[4] P. Br. at 12-13. Staff administered Ativan to Resident 101 in a prescribed manner to address the very reason for prescribing Ativan in the first place. Ultimately, I conclude that the notification requirement in section 483.10(b)(11) was not triggered, and the fact that staff did not notify Resident 101's legal representative of the administration of Ativan intramuscularly or Resident 101's anxiety-driven behavior that evening did not violate the regulatory standard.

2. Petitioner's decision to change Resident 101's medication from Cipro® to Bactrim® required immediate notification of his legal representative because it constituted a significant change in the resident's status and a significant alteration of his treatment.

On April 8, 2013,[5] Resident 101's physician changed a prescribed antibiotic from Cipro to Bactrim to address lab results that showed the "resistance" of Resident 101's UTI to Cipro. CMS Ex. 25 at 5; CMS Ex. 20 at 9. Resident 101 had been on Cipro to treat his UTI, but results from a urine sample showed the presence of proteus mirabilis, which, according to Resident 101's physician, required the use of Bactrim instead of Cipro in order to provide "a different spectrum of coverage for the usual pathogens." P. Ex. 1 at 8. Bactrim is an antibiotic that treats a wider range of bacteria than Cipro. P. Ex. 1 at 2. Staff did not document any notification of Resident 101's legal representative at the time of the change. *See* CMS Ex. 25 at 5. However, a licensed practical nurse (LPN) at Petitioner's facility wrote in her direct testimony that she "advised [Resident 1's legal representative] regarding the results of [Resident 101's] culture and advised her that

[4] Petitioner argues that CMS improperly changed its basis for claiming the events of April 5, 2013 required notification of Resident 101's legal representative. P. Br. at 12. In its prehearing brief, CMS argued that the failure to notify the legal representative of the intramuscular administration of Ativan was deficient, while in its closing brief, CMS for the first time argued that the failure to notify the legal representative of Resident 101's behavior that evening was deficient. CMS Br. at 3-4. I disagree with Petitioner that CMS improperly or untimely raised this argument. CMS did not add any additional facts or evidence to make its argument but rather provided a different interpretation of the evidence already in the record. Moreover, Petitioner had an opportunity to, and did, adequately defend against this argument. P. Br. at 12-14.

[5] A nurse transcribed the order which the physician made over the phone. The date on the transcribed order is April *7*, 2013. CMS Ex. 20 at 7. The contemporaneous nursing notes, however, date the medication change as April *8*, 2013. CMS Ex. 25 at 5. The parties seem to agree that the change occurred sometime on April 8, 2013. CMS Br. at 5; CMS Ex. 1 at 4; P. Ex. 1 at 2. I accept that the change occurred on April 8, 2013, and the transcribed order was erroneously dated April 7. The lab's culture results precipitating the change, however, were undisputedly reported on April 7, 2013 at 2:01 p.m. *See* CMS Ex. 25 at 64.

instead of treating his urinary tract infection with Cipro, we would instead be treating it with Bactrim." P. Ex. 1 at 11. The LPN notified Resident 101's legal representative only after the legal representative asked the LPN to "go over with her the medications [Resident 101] was taking." P. Ex. 1 at 11.

CMS argues that there is no documentary evidence to support the LPN's statement that she notified the legal representative. CMS Br. at 4 n.1. That is certainly true. However, the LPN also testified that she remembered notifying Resident 101's legal representative about the change from Cipro to Bactrim because she was surprised that the legal representative, a medical professional herself, was reportedly not familiar with Cipro, a very common antibiotic. P. Ex. 1 at 11. Therefore, there was a unique circumstance that caused the LPN to remember this specific interaction with Resident 101's legal representative. However, with no documentation, I find that the LPN told Resident 101's legal representative about the change from Cipro to Bactrim more likely when the LPN and the legal representative were discussing Resident 101's medications, not at the time that the change occurred. Thus, there is no compelling evidence that the notification was "immediate," and I find that it was not. The LPN's own statement suggests, and I infer from it, that Resident 101's legal representative first asked about his current medications, which then prompted the LPN to tell her about the change in medication.[6] P. Ex. 1 at 11. Specifically, the LPN who notified the legal representative testified that "[Resident 101's legal representative] *asked me to go over with her the medications [Resident 101] was taking*. *As we were reviewing the medications*, I advised her that instead of treating his urinary tract infection with Cipro, we would instead be treating it with Bactrim." P. Ex. 1 at 11 (emphasis added). In addition, where prompted on the physician's order form dated April 7, 2013, staff left blank a check box asking whether the family "has been notified of the above treatment change." CMS Ex. 20 at 9. There is no evidence that Petitioner's staff intended to or otherwise would have notified Resident 101's legal representative about the culture results and change in antibiotics. Instead, I find it more likely that the persistence and involvement of Resident 101's legal representative in his care resulted in

[6] The LPN also stated that Resident 101's legal representative was "at the Facility following our receipt of [Resident 101's] culture, which demonstrated the bacterial infection . . . was resistant to Cipro . . . ." P. Ex. 1 at 11. The LPN's statement, however, does not explain how or when staff notified the legal representative of the culture results and medication change. I do not infer from the LPN's statement that simply because the legal representative was present in the facility at the time the culture results came back to facility staff, the legal representative also had notice of those results. I read the LPN's statement as explaining that Resident 101's legal representative was in the facility and asked to review Resident 101's medications soon after the change to Bactrim had been ordered, but not that any notification about the change to Bactrim precipitated her inquiry about Resident 101's medications.

staff eventually advising the legal representative of the culture results and change in medication.

The diagnosis of an antibiotic-resistant condition represents a significant change in status and a clinical complication that triggered the requirement to notify Resident 101's legal representative. *See* 42 C.F.R. § 483.10(b)(11)(i)(B). As the SOM notes, a "clinical complication" includes such things as "onset or recurrent periods of delirium, recurrent urinary tract infection, or onset of depression." SOM, App. PP, *Interpretive Guidelines §483(b)(11)*. While not recurrent, Resident 101's UTI showed resistance to the treatment in place at the time, which I find is consistent with the type of clinical complications listed in the SOM. Had the same course of treatment (Cipro) continued, the UTI would have never been properly treated. Any clinical finding that prompts a necessary change in treatment represents a clinical complication and significant change in status, which in turn, requires the facility to notify the resident's legal representative. Also, the laboratory results prompted Petitioner to stop one form of treatment (Cipro) and commence a new form (Bactrim), which triggered the notification requirement. 42 C.F.R. § 483.10(b)(11)(i)(C). Even under Petitioner's own notification policy, the results of Resident 101's urine sample, which showed resistance to Cipro, was a clinical complication that prompted a change in medication and should have triggered immediate notification of Resident 101's legal representative. *See* CMS Ex. 32.

Despite Petitioner's claim that the change was merely the use of a common alternative to treat a UTI and that Resident 101 did not experience any actual change in condition, the evidence suggests that the complication was serious enough to warrant physician intervention in order to ensure Resident 101's condition was properly addressed. CMS Ex. 20 at 9; *see Claiborne-Hughes*, 609 F.3d at 843. Moreover, it is disingenuous to claim that Resident 101's condition did not change. It is certainly true that from April 7 to April 8, there is no evidence that Resident 101's physical condition was significantly different as a result of his UTI, for example, that symptoms of his UTI were in some way worsening in that time. However, when staff learned that his UTI was Cipro-resistant, it represented a significant change in his clinical status, enough to warrant physician intervention to ensure proper treatment of the UTI. Simply pointing out that it was a switch from one antibiotic to another, as Petitioner does here (P. Br. at 14-15), does not persuasively minimize the significance of the culture results and medication change. A necessary change in medication to address a persistent, Cipro-resistant infection represents a "need to alter treatment significantly," even if it is a change from one antibiotic to another. Thus, I conclude that Petitioner did not comply with the regulatory requirement because it did not immediately notify Resident 101's legal representative of the culture results or the change in medication from Cipro to Bactrim.

3. Petitioner's intravenous administration of fluid (dextrose 5%) to Resident 101 required immediate notification of his legal representative because it constituted a significant change in the resident's status and a significant alteration of his treatment.

Just after midnight on April 13, 2013, Resident 101's physician ordered staff to administer "D5W[7] 60 mL/hr IV or clysis[8] x 48 [hours]" to Resident 101. CMS Ex. 20 at 13. At 12:30 a.m., a nursing note states that staff initiated the IV in Resident 101's right hand, it "flushed [with] ease," and was "infusing well" at 60 milliliters per hour. CMS Ex. 25 at 7, 59. The nursing notes from that time, however, do not indicate any specific reason for the order, but Petitioner's administrator wrote in her direct testimony that Resident 101 was "not eating food as he normally did and he was struggling." P. Ex. 1 at 4. The nutrition intake and output record confirms that on April 12, 2013, Resident 101 refused breakfast, and he only ate a small portion of his lunch and dinner. *See* CMS Ex. 25 at 14. His blood pressure also appeared to be dropping slightly, from 116/66 during the day on April 12, to 96/66 during the morning of April 13, 2013. *See* CMS Ex. 25 at 30. There is no indication that staff notified Resident 101's legal representative of the need for the administration of fluids or the start of the IV line. *See* CMS Ex. 20 at 13 (unchecked box when asked whether the family "has been notified of the above treatment change"); CMS Ex. 25 at 7.

The need to provide fluid to Resident 101 intravenously or by clysis because he was not eating normally and was "struggling" represents both a significant change in his physical status as well as a need to alter treatment significantly. Petitioner argues that starting an IV line and fluid replacement was simply maintaining hydration for Resident 101 at an "unremarkable" level. P. Br. at 16-17. But Petitioner's claim misses that staff started an IV in Resident 101's hand just after midnight and in response to a physician's order at that time because staff observed that he was "struggling." P. Ex. 1 at 4. I do not accept that the newly started IV line and fluid infusion for Resident 101 in the middle of the night was simply a routine event to maintain hydration. Instead, by noting that he was "not eating food as he normally did and he was struggling" at the time the doctor ordered additional fluids, Petitioner's staff acknowledged that Resident 101's condition had deteriorated to a point where he needed this new form of treatment immediately. Prior to the start of the IV line and infusion of fluid, Resident 101 did not have the need for fluid replacement nor was he receiving any. *See* CMS Ex. 25 at 35, 59 ("I.V. Schedule" for Resident 101 showing initial IV started on April 13, 2013). Thus, when staff initiated the

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[7] "D5W" is an abbreviation for dextrose 5% in water. *See* Davis, *supra*, note 4.

[8] "Clysis" is the "introduction of large amounts of fluid into the body usually by parenteral injection to replace that lost (as from hemorrhage or in dysentery or burns), to provide nutrients, or to maintain blood pressure." Merriam-Webster Medical Dictionary, *available at* http://www.merriam-webster.com/medical/clysis.

new form of treatment based on the observed clinical complication that he was not eating and "struggling," staff was required to notify Resident 101's legal representative immediately.

4. The physician's order for Norco® required immediate notification of Resident 101's legal representative because it constituted a significant change in the resident's status and a significant alteration of his treatment.

A nursing note from April 13, 2013, reported that Resident 101 was "holding his [right] side" during the 7:00 a.m. to 3:00 p.m. shift, although the evening shift noted "no complaints of pain or discomfort." CMS Ex. 25 at 8. On April 14, 2013, nursing staff again noted "no complaints of pain or discomfort." CMS Ex. 25 at 9. However, by 1:30 p.m. on April 15, 2013, Resident 101 was "grimacing, guarding ribs [with] cough; [complaining of] pain when asked if hurting." CMS Ex. 25 at 9. Staff consulted with Resident 101's physician, who ordered the narcotic Norco, by mouth, twice daily for pain as needed. CMS Ex. 20 at 13. However, by the 3:00 p.m. to 11:00 p.m. shift, Resident 101 had no signs or symptoms of pain or discomfort. CMS Ex. 25 at 9. There is no evidence that staff ever actually administered Norco to Resident 101 before his death two days later. *See* CMS Ex. 25 at 9-12, 41. Instead, staff twice provided Roxanol®, a narcotic ordered on April 16, 2013, to address Resident 101's pain and anxiety. [9] CMS Ex. 25 at 41-42. Petitioner's staff did not notify Resident 101's legal representative of the need for, or physician's order for Norco. CMS Ex. 25 at 9; CMS Ex. 20 at 13. The legal representative also noted in an interview with surveyors that staff did not inform her about the Roxanol order or administration until she called the facility to inquire about Resident 101. CMS Ex. 1 at 5. In its briefing, however, CMS relies on the April 15, 2013 Norco order and facility staff not notifying the legal representative about that specific order as demonstrating noncompliance with the regulatory requirements. CMS Br. at 5.

The rib pain noted on the afternoon of April 15 was a change in Resident 101's physical status. *See* 42 C.F.R. § 483.10(b)(11)(i)(B). Prior to that afternoon, his rib pain had only been noted once, two days earlier, but at that earlier time the pain was not at a level that warranted physician consultation or an order for a narcotic pain reliever. Staff gave Resident 101 Motrin, a nonsteroidal anti-inflammatory drug (NSAID) pain reliever, on April 13, 2015, because he was "moaning" and "holding his [right] side." CMS Ex. 25 at

[9] I reject Petitioner's suggestion that the "likelihood is the pain was negligible" because Resident 101 did not later complain of pain. P. Br. at 17. Staff administered Roxanol at least three times the following two days for "pain/anxiety." CMS Ex. 25 at 42. The record therefore shows that Resident 101's pain was more persistent that Petitioner now recognizes, and its staff treated the pain with a separate narcotic.

8. Resident 101's pain on April 15 was therefore a *significant* change in his physical status because staff determined for the first time that it was serious enough for a stronger pain reliever.[10] The Motrin was apparently no longer adequate to address the pain he exhibited. *Compare* CMS Ex. 25 at 8 (providing Motrin after signs of rib pain) *with* CMS Ex. 25 at 9 (receiving order for Norco after signs of rib pain). In addition, the April 15 order for Norco represented a new course of treatment to address Resident 101's rib pain. Prior to that time, Resident 101 received a general NSAID, not a narcotic. *See* CMS Ex. 20 at 1 (April 1, 2015 order for Motrin 600 mg by mouth as needed). Thus, the order for a narcotic pain reliever was a new course of treatment and a significant change in Resident 101's medical treatment. In addition, pursuant to Petitioner's policy, the order for Norco represented a "medication change for. . . a significant physical change," which should have prompted appropriate notifications. CMS Ex. 32. Overall, Resident 101's rib pain and the April 15 order for Norco both triggered the regulatory requirement that staff immediately notify Resident 101's legal representative.[11] Petitioner's staff did not make that immediate notification.

In three out of the four instances outlined above, Petitioner did not provide the requisite notice to Resident 101's legal representative of significant changes to his status or the need to alter his treatment significantly. Petitioner, therefore, did not comply with the regulatory requirements in 42 C.F.R. § 483.10(b)(11). Moreover, Petitioner's deficiencies posed the potential for more than minimal harm. By not immediately notifying Resident 101's legal representative of his clinical complications and medication changes, Petitioner effectively cut off the individual that Resident 101 intended to speak on his behalf and make important medical decisions for him. *See Magnolia Estates*

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[10] The April 15, 2013 rib pain, which was a significant change in Resident 101's physical status, is distinguishable from the anxiety that Resident 101 exhibited on April 5, 2013, which was not a significant change in his status. Prior to April 15, Resident 101 had not experienced rib pain to a level that required physician consultation or intervention. The prior order for Motrin was simply as needed, but it does not appear to be directed at rib pain. *See* CMS Ex. 20 at 1. April 15, therefore, was a new onset of serious rib pain. In contrast, Resident 101's April 5 anxiety was exactly the type of behavior that staff had experienced and consulted with Resident 101's physician about previously. The standing order for Ativan intramuscularly demonstrated that staff anticipated such behavior. CMS Ex. 20 at 7. Thus, Resident 101's April 5 anxiety requiring intramuscular Ativan was expected behavior and therefore not a significant change in status.

[11] Staff immediately consulted with Resident 101's physician about rib pain, which demonstrates that staff believed it to be a significant change in status. CMS Ex. 20 at 13; CMS Ex. 25 at 8. I recognize, however, that physician consultation alone does not trigger the regulatory requirement that a resident's legal representative be notified, but it may reasonably indicate that facility staff understood that there was a significant change in the resident's status.

Skilled Care, DAB CR1804, at 15 n.12 (2008) ("[The resident] was unable to communicate or, presumably, to participate in medical decision-making with her physician or the physician's extender. Thus, the importance of immediate notification should not be minimized."), *aff'd*, DAB No. 2228 at 18 ("We also note and agree with the ALJ about the importance of family notification in this case because [the resident] was unable to communicate or participate in decision-making about her care.").

Petitioner's claim that the failure to notify the legal representative could not have caused Resident 101 any actual harm is inconsistent with the regulatory language requiring notification of a resident's legal representative. *See* P. Br. at 7-8. Petitioner argues that if "all long term care facilities had to notify a resident's [legal representative] or guardian when a minimal IV dose, for example, is administered for hydration . . . operations would effectively be brought to a halt. Imposing such a requirement on long term care facilities is unreasonable, impractical, and is not contemplated by the law." P. Br. at 11. I have already rejected the underlying premise of Petitioner's argument that the changes to Resident 101 were not significant. More importantly, and contrary to Petitioner's argument about the unreasonableness of notifying a resident's legal representative, the Secretary has recognized the important role a resident's legal representative plays in that resident's overall medical care. The Secretary mandated that all Medicare-participating long-term care facilities immediately notify a resident's legal representative of significant changes in a resident's status or a need to alter the resident's treatment significantly. 42 C.F.R. § 483.10(b)(11). This requirement is *in addition to*, not simply secondary to, the physician consultation requirement. The Secretary thus included notification of the resident's legal representative at the same level of importance as consultation with the resident's physician. Indeed, the legal representative can provide consent for treatment, recommend treatment based on past experiences that the facility staff may not know and, critically, express the interests of the resident receiving care. In this case, not immediately notifying Resident 101's legal representative was especially likely to cause more than minimal harm because the legal representative was a medical professional who had ample experience in directing the care of her father. *See* P. Ex. 1 at 11. The lack of immediate notification may have prevented her from making informed decisions about his health care and likely clouded her overall picture of Resident 101's condition. An uniformed, or even under-informed legal representative cannot carry out the functions with which the resident entrusted him or her. By creating such a situation, Petitioner's failure to notify Resident 101's legal representative on three separate occasions of a significant change in Resident 101's condition and the need to alter his treatment significantly did not comply substantially with the requirements of 42 C.F.R. § 483.10(b)(11).

B. Petitioner was not in substantial compliance with 42 C.F.R. § 485.25 because it did not provide Resident 101 with necessary care when its staff did not transfer Resident 101 to a hospital in accordance with standing physician's orders or the resident's desire to be hospitalized in any situation.

The lead-in language of 42 C.F.R. § 483.25 states:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

The Board has explained that this regulation "imposes on facilities an affirmative duty designed to achieve favorable outcomes to the highest practicable degree." *Windsor Health Care Ctr.*, DAB No. 1902, at 16-17 (2003), *aff'd*, 127 F. App'x. 843 (6th Cir. 2005). "The facility must take 'reasonable steps' and 'practicable measures to achieve that regulatory end.'" *Golden Living Ctr. - Foley*, DAB No. 2510, at 23 (2013) (quoting *Clermont Nursing & Convalescent Ctr.*, DAB No. 1923, at 21 (2004)). The regulation implicitly imposes on a facility the duty to provide care and services that, "at a minimum, meet accepted professional standards of quality 'since the regulations elsewhere require that the services provided or arranged by the facility must meet such standards.'" *Id.* (quoting *Spring Meadows Health Care Ctr.*, DAB No. 1966, at 17 (2005)). In *Crestview Parke Care Center v. Thompson*, 373 F.3d 743 (6th Cir. 2004), the court concluded that the general quality of care regulation is not a "strict liability" regulation. 373 F.3d at 753-54. The court explained that the word "practicable" suggests that a "'reasonableness' standard inheres in the regulation" and that it would be possible for a facility to show "a justifiable reason for the violation of [section] 483.25." *Id.* at 754.

Resident 101 had a history of COPD, and during his time as a resident of Petitioner's facility his blood oxygen saturation levels were typically around 90% with supplemental oxygen in place. *See, e.g.*, CMS Ex. 19; CMS Ex. 25 at 1-8; *see also* CMS Ex. 25 at 4 (reading of 71% on room air after Resident 101 removed supplemental oxygen, and returning to 91% when oxygen was reapplied). He received continuous oxygen through a nasal cannula at a rate of 3 to 4 liters of oxygen per minute. CMS Ex. 25 at 1-8. Staff had standing orders to treat Resident 101, like any resident suffering from a known respiratory ailment, with a nebulized mist treatment if his oxygen saturation levels were below 88%. CMS Ex. 22. The standing order stated:

> **EMERGENCY CARE:**
>
> 1. Respiratory Distress: Check SaO2[.] Place on oxygen at 2 liters, pulse oximetry should be 88% or higher, check for abnormal lung sounds and use of accessory muscles-then give Proventil NMT'S [nebulized mist

> treatments] every 20 minutes times 3 treatments if resident has known diagnosis of COPD/Emphysema. If not known pulmonary diagnosis, but symptoms mentioned, give 1 NMT treatment of Proventil. If no improvement or condition worsens, contact the Physician and transfer to the hospital.

CMS Ex. 22 at 1 (bold and underlines in original).

On April 14, 2013, Resident 101 had an oxygen saturation level of 84% with absent lung sounds in his left lower lobe and crackles in his right lobe. CMS Ex. 25 at 8. Consistent with the physician's standing order, staff administered a nebulizer treatment, which brought Resident 101's oxygen level to 91% and cleared his lung sounds on both sides. CMS Ex. 25 at 8.

The overnight shift of April 15 into April 16 documented Resident 101 as trying to climb out of his bed and repeatedly setting off alarms at the beginning of the shift (11:00 p.m.). He was combative with staff, "swinging [at] aides" and "slapping aides." CMS Ex. 25 at 10. His oxygen saturation around 11:30 p.m. on April 15 was 98% on 2 liters per minute of supplemental oxygen via nasal cannula. CMS Ex. 25 at 10. Resident 101 awoke at 4:00 a.m. on April 16, 2013, and was "confused, combative, [and] very anxious." CMS Ex. 25 at 10. His oxygen saturation levels had dropped to 69% despite receiving 4 liters per minute of oxygen via nasal cannula. Staff notified the nursing supervisor. They administered three rounds of nebulized treatment, consistent with the physician's standing order, first at 4:15 a.m., then 4:30 a.m., and then at 4:45 a.m. CMS Ex. 25 at 10; *see* CMS Ex. 22 at 1. After the treatment, Resident 101's oxygen saturation ranged between 78-92% on 5 liters of oxygen by nasal cannula. CMS Ex. 25 at 9-10. However, it then dropped to 78-80%. Staff placed Resident 101 on a non-rebreather mask and provided 15 liters per minute of supplemental oxygen, which brought his oxygen saturation level to 90%. Lung sounds were noted as "moist" at that time. CMS Ex. 25 at 9. Staff notified Resident 101's physician, who ordered Lasix, a diuretic, 40 milligrams by IV push, which staff administered. CMS Ex. 20 at 14; CMS Ex. 25 at 35. Staff noted that they notified Resident 101's legal representative of his condition and of the care they were providing. CMS Ex. 25 at 10.

A short time later, at 6:00 a.m. on April 16, staff had Resident 101 on a non-rebreather oxygen mask, providing 15 liters per minute of supplemental oxygen. CMS Ex. 25 at 10. Despite the additional oxygen, Resident 101's oxygen saturation was between 85-88%. CMS Ex. 25 at 10. Staff again notified the physician, who ordered Rocephin®, an antibiotic, 1 gram intramuscularly every 24 hours for 3 days, which staff administered. CMS Ex. 25 at 10.

A subsequent nurse note on April 16 documented Resident 101 as restless and anxious. His respiration rate had increased, but staff was unable to obtain vital signs because it

made Resident 101 too "agitated." CMS Ex. 25 at 11. At 4:00 p.m. on April 16, staff notified the nursing supervisor that Resident 101's right hand and arm were swollen. His oxygen saturation at that time was 86% despite receiving supplemental oxygen at a rate of 15 liters per minute by non-rebreather mask. CMS Ex. 25 at 11. Resident 101 began "abdom[inal] breathing" and was "unresponsive to verbal[ ] stimuli." CMS Ex. 25 at 11. Staff removed the IV from his right hand. At 6:45 p.m., Resident 101 was "alert" and complaining of pain. Staff administered Roxanol 0.25 milliliters sublingually along with his scheduled dose of Ativan, but with little relief. CMS Ex. 25 at 11. At 8:45 p.m., staff again administered Roxanol, but at Resident 101's family's request, staff contacted the physician to address Resident 101's ongoing pain. Resident 101's physician doubled the pain medication and ordered 0.5 milliliters of Roxanol every hour as needed, which staff administered at 9:45 p.m. and again at 10:30 p.m. CMS Ex. 25 at 11.

During the overnight shift of April 16 into April 17, 2013, staff noted that "several family members" were at Resident 101's bedside, although his legal representative was not one of those family members. Staff notified the legal representative of Resident 101's condition during that shift, although the exact time was not documented. CMS Ex. 25 at 12. Staff kept Resident 101 on 15 liters of oxygen per minute via non-rebreather mask. CMS Ex. 25 at 12. Staff moved Resident 101 into his wheelchair at his family's request and began repositioning him every two hours "to keep comfortable." CMS Ex. 25 at 12. Resident 101 died on April 17, 2013 at 10:50 a.m. CMS Ex. 25 at 12.

CMS argues that staff should have immediately transferred Resident 101 to the hospital on the morning of April 16, 2013 to address his respiratory distress at that time. CMS Br. at 8-10. The physician's standing order required as much. *See* CMS Ex. 22. Petitioner, however, reads the physician's standing order differently and argues that the directive for staff to transfer a resident to a hospital is only when the resident is suffering from respiratory distress for unknown reasons. P. Br. at 20-21; *see also* P. Ex. 1 at 2-3. According to Petitioner, because Resident 101 had a known respiratory ailment, COPD, staff only needed to treat him with a nebulizer treatment three times to satisfy the physician's order. P. Br. at 20.

Under Petitioner's reading of the physician's standing order, those residents in respiratory distress because of a known respiratory ailment would not be transported to the hospital even if the ordered treatment was unsuccessful. Instead, those residents would wait, while suffering a potentially life-threatening medical emergency, until further instruction came from the physician. Petitioner's interpretation of the physician's standing order is unreasonable. The more reasonable reading of the standing order is that transport to a hospital is required for *any resident* experiencing respiratory distress, regardless of its cause, if the ordered treatment resulted in "no improvement or [the] condition worsens . . . ." CMS Ex. 22. There is nothing in the plain language of the order's last sentence that limits its directive to transport the resident to a hospital only if there is respiratory distress of unknown origins. Instead, the ordered treatment differs based on whether a

known versus unknown ailment has caused the respiratory distress. CMS Ex. 22. Here, Resident 101 had a known ailment, so staff was required to treat him with three rounds of nebulized Proventil. CMS Ex. 22. Staff did so on the morning of April 16, 2013. CMS Ex. 25 at 10. Following that treatment, however, Resident 101's oxygen saturation level remained below 88%, indicating that the treatment had not improved the respiratory distress to a non-critical level. CMS Ex. 25 at 10. Resident 101 was still in "respiratory distress" based on the standing order's explanation of that condition to include oxygen saturation below 88%. CMS Ex. 22. At that point, staff was required to follow the standing physician's order and transport Resident 101 to the hospital.

It is now evident that Resident 101 was dying on April 16, 2013, and staff's action to increase his Roxanol and maintain his comfort demonstrates that staff likely recognized what was happening as well. Petitioner's suggestion, however, that keeping Resident 101 at the facility rather than transporting him to the hospital because of his near-death condition and status with a do-not-resuscitate order, is improper. *See* P. Br. at 21-23. There is no indication that Resident 101's physician directed staff not to transport Resident 101 to the hospital. There is no indication that Resident 101's legal representative directed staff not to transport Resident 101 to the hospital. In fact, the only relevant documents addressing whether Resident 101 should have been transported to the hospital to address his respiratory distress on April 16, 2013, all indicate that staff should have transported him to the hospital. In addition to the physician's standing order, discussed above, Resident 101 indicated in his advanced directive that he wanted to be hospitalized "in any situation."[12] CMS Ex. 21. There was an option in the advanced directive to describe situations where hospitalization was not desired, but Resident 101 and his legal representative did not limit his desire to be hospitalized "in any situation." *See* CMS Ex. 21. Resident 101 also indicated in his directive establishing his legal representative that he wanted his life "to be prolonged by life-sustaining treatment unless [he was] in a coma or vegetative state . . . ." CMS Ex. 26 at 4. There is no dispute that Resident 101 was not in a coma or vegetative state on April 16, 2013. *See* CMS Ex. 25 at 10.

Had staff followed any of these stated wishes or orders, Resident 101 should have been transported to the hospital after the ordered nebulizer treatments did not alleviate his respiratory distress. By not transporting Resident 101 to the hospital as required and as

[12] Petitioner's argument that Resident 101's advanced directive did not apply in this case because his respiratory condition on April 16 was not a true "emergency response" does not adequately consider the physician's standing order and its explanation of "respiratory distress" requiring hospitalization. Resident 101's physician directed hospitalization for continued "respiratory distress," to include oxygen saturation below 88%, which Resident 101 undoubtedly exhibited following treatment that morning. His condition, therefore, was "respiratory distress" that required hospitalization and was an "emergency response" according to the physician's order.

he had indicated was his desire, staff did not provide him with the care necessary to maintain his highest practicable physical, mental, and psychosocial well-being, and put Resident 101 at risk for worsening respiratory distress. The standing order was the authoritative medical directive on how to provide Resident 101 with the necessary care to maintain his physical well-being with regard to his declining respiratory status. Resident 101's advanced directive stating his intent to be hospitalized offered the only express indication on how to carry out Resident 101's wishes and thus provide him with what he intended to be the necessary care to maintain his well-being. Petitioner, therefore, was not in substantial compliance with the regulatory requirement.

Petitioner has not offered any valid justification for not hospitalizing Resident 101 on April 16, 2013. I recognize that Resident 101 was near death and suffered from a widerange of ailments. Resident 101's physician wrote in his direct testimony that Resident 101 did not have to be transported to the hospital because he did not want to be resuscitated or placed on a ventilator, meaning the overall treatment options were "somewhat limited." P. Ex. 2 at 2; *see also* P. Ex. 1 at 3 (testimony of Petitioner's administrator, stating that "[s]ending a resident [with COPD] to a hospital would serve no purpose as the hospital is no more equipped to address such a situation than the Facility is"). He also testified that transporting Resident 101 to the hospital would have resulted in his becoming more anxious and combative. P. Ex. 2 at 2. While the physician's retrospective opinion may be accurate, it is untenable that staff can ignore a resident's stated desire to be hospitalized because he ultimately would not want resuscitation or to be placed on a ventilator, or may become more agitated during the transport to the hospital. Moreover, the decision to overlook a resident's stated desire and not transport him to the hospital cannot, under any circumstances, be a unilateral one. Resident 101's physician implies that because he knew there were no better options at the hospital, transporting Resident 101 to the hospital was unnecessary. If staff understood that to be true, then the contemporaneous medical record must include some indication that staff considered Resident 101's condition and treatment options, consulted with the physician about them, and consulted with Resident 101's legal representative – who had already expressed in writing the desire that Resident 101 be hospitalized – prior to diverting from the standing order and not transporting Resident 101 to the hospital. Also, there is nothing in the medical record indicating that the physician actually made a decision not to transport Resident 101 to the hospital, despite his testimony now about why it was not necessary at the time. The current justification that Petitioner offers for not transporting Resident 101 to the hospital was not documented or otherwise supported by evidence during the time surrounding Resident 101's passing.

C. The enforcement remedy CMS imposed is reasonable.

1. The amount of the CMP is reasonable.

CMS must consider several factors when determining the amount of a CMP, which an administrative law judge considers de novo when evaluating the reasonableness of the CMP that CMS imposed: (1) the facility's history of noncompliance; (2) the facility's financial condition, *i.e.*, its ability to pay the CMP; (3) the severity and scope of the noncompliance, the "relationship of the one deficiency to other deficiencies resulting in noncompliance," and the facility's prior history of noncompliance; and (4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. 42 C.F.R. §§ 488.438(f), 488.404(b), (c).

A CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408. 488.438. The upper range of a CMP, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to the health and safety of a facility's residents and, in some circumstances, for repeated deficiencies. *Id.* § 488.438(a)(1)(i), 488.438(d)(2). The lower range of CMP, $50 to $3,000 per day, is reserved for deficiencies that do not pose immediate jeopardy, but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. *Id.* § 488.438(a)(1)(ii). In assessing the reasonableness of a CMP amount, an administrative law judge looks at the per-day amount, rather than the total accrual. *Kenton Healthcare, LLC*, DAB No. 2186, at 28 (2008). The regulations leave the decision regarding the choice of remedy to CMS and the amount of the remedy to CMS and the administrative law judge, requiring only that the regulatory factors at 42 C.F.R. §§ 488.438(f) and 488.404 be considered when determining the amount of a CMP within a particular range. 42 C.F.R. §§ 488.408, 488.408(g)(2), 498.3(d)(11); *see also* 42 C.F.R. § 488.438(e)(2); *Alexandria Place*, DAB No. 2245, at 27 (2009); *Kenton Healthcare, LLC*, DAB No. 2186, at 28-29.

Unless a facility contends that a particular regulatory factor does not support the CMP amount that CMS imposed, the administrative law judge must sustain it. *Coquina Ctr.*, DAB No. 1860, at 32 (2002). CMS determined to impose a per-day CMP in this case. Thus, the minimum CMP I am required to sustain is $50 per day, and the maximum permissible is $3,000 per day. The $450 per-day CMP that CMS imposed is in the very low range of CMPs authorized for noncompliance that is not immediate jeopardy.

Here, the $450 per-day CMP that CMS imposed against Petitioner is well-supported. CMS has presented evidence of Petitioner's history of noncompliance (CMS Ex. 3), which shows several previous noncompliance citations. Petitioner was also culpable for its noncompliance. Petitioner's staff repeatedly did not notify Resident 101's legal representative, who was also a medical professional, of significant changes to her father's status or the need to alter his treatment significantly. As a result, staff provided the legal

representative with less than complete information and effectively excluded her from the decision-making process regarding her father's care. Moreover, staff did not transport Resident 101 to the hospital despite his express intent for that to happen and despite the physician's standing order that staff transfer Resident 101 to the hospital when his respiratory distress did not respond adequately to treatment.

Petitioner offered no direct challenge to the amount of the CMP imposed. There is no evidence, therefore, to suggest that Petitioner is unable to pay the total CMP imposed. In light of all of the factors discussed, the low $450 per-day CMP from September 19, 2013 through October 17, 2013 (28 days) is reasonable.

2. The duration of the CMP is reasonable.

CMS may impose an enforcement remedy against a facility for as long as the facility is not in substantial compliance with participation requirements. 42 C.F.R. § 488.430(a). The burden of persuasion regarding the duration of noncompliance is Petitioner's. In *Owensboro Place and Rehabilitation Center*, DAB No. 2397 (2011), the Board stated:

> The burden of persuasion is on the facility. The Board has made it clear that the facility bears the burden of showing that it returned to substantial compliance on a date earlier than that determined by CMS and has rejected the idea that CMS must establish a lack of substantial compliance during each day in which a remedy remains in effect . . . .

DAB No. 2397, at 12-13 (citations omitted). Based on the survey dates, CMS determined Petitioner was not in substantial compliance with participation requirements beginning on September 19, 2013, when the state agency concluded its complaint investigation survey, and ending October 17, 2013, when the facility implemented an acceptable approach to address the deficiencies cited.

On March 2, 2015, I directed the parties to file supplemental briefs addressing whether it was appropriate for CMS to find noncompliance from September 19, 2013 to October 17, 2013, when the only underlying facts supporting that noncompliance occurred in April 2013. I have read and considered both parties' arguments on the issue and conclude that the determination to cite a facility's noncompliance several months after an incident is appropriate and has been affirmed by the Board in previous cases. For example, in *Lake City Extended Care Center*, DAB No. 1658 (1998), the Board discussed at some length the regulatory history and concluded that the regulatory scheme:

> assumes that any deficiency that has a potential for more than minimal harm is necessarily indicative of problems in the facility which need to be corrected . . . . Since the [administrative law judge] found that the incident in question had a potential for more than minimal harm, he was required to

> find that Lake City was out of substantial compliance from the date of completion of the survey in which this incident was cited until the date of the resurvey in which substantial compliance was established . . . . *No findings that Lake City violated the standard of care between these dates were required* in order to find Lake City out of substantial compliance . . . .

DAB No. 1658 at 14 (emphasis added), *accord, Park Manor Nursing Home*, DAB No. 1926 (2004). Consistent with *Lake City*, I find that the dates of noncompliance that CMS cited are acceptable even though the incidents cited occurred several months before the survey and noncompliance dates.[13] Petitioner has not offered any evidence or argument that the period of noncompliance was shorter than cited. *See* ALJ Ex. 1. Accordingly, I find the duration of the CMP is reasonable.

V. Conclusion

I conclude that Petitioner was not in substantial compliance with Medicare participation requirements for long-term care facilities during the period cited, and the penalty CMS imposed is reasonable.

/s/
Joseph Grow
Administrative Law Judge

[13] In their supplemental briefs, the parties cited Chapter 7 of the SOM, which says that in cases where a per-day CMP is imposed, noncompliance may begin on "the date of the survey because it may be difficult to document precisely when noncompliance begins if before the date of survey." SOM, Ch. 7, § 7518; CMS Supp. Br. at 2; P. Supp. Br. at 3. I find it unlikely that CMS could not determine the dates of noncompliance in April 2013 because Resident 101 was only in the facility for 17 days. However, based on the Board's decision in *Lake City*, Petitioner may be properly deemed out of substantial compliance for any time between April 8, 2013 (the date of the first failure to notify the legal representative) and October 18, 2013. *See Lake City*, DAB No. 1658 at 14. Thus, it appears that the 28-day period cited is only a fraction of the possible noncompliance period and CMP that CMS may have imposed.