Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

St. Anthony's Nursing and Rehabilitation Center,
(CCN: 14-5387),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-16-203

Decision No. CR4690

Date: August 29, 2016

DECISION

I enter summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS) and against Petitioner, St. Anthony's Nursing and Rehabilitation Center. I sustain the imposition of civil money penalties against Petitioner of $750 per day for each day that runs from October 2, 2015 through November 18, 2015.

I. Background

Petitioner requested a hearing to challenge CMS's determination. The case was assigned originally to another administrative law judge and then transferred to me. CMS moved for summary judgment. With its motion it filed a brief plus proposed exhibits, which it identified as CMS Ex. 1-CMS Ex. 29. Petitioner filed a brief in opposition to CMS's motion plus proposed exhibits, which it identified as P. Ex. 1-P. Ex. 10. I receive all of the parties' exhibits into the record for purposes of deciding the motion for summary judgment.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues in this case are whether undisputed material facts establish that Petitioner failed to comply substantially with Medicare participation requirements and whether CMS's remedy determination is reasonable.

B. Findings of Fact and Conclusions of Law

CMS alleges that Petitioner failed to comply substantially with two Medicare conditions of participation. First, CMS asserts that Petitioner failed to comply with the requirements of 42 C.F.R. § 483.25. This section requires, among other things, that a skilled nursing facility must provide each of its residents with the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being in accordance with that resident's comprehensive assessment and plan of care.

Second, CMS contends that Petitioner did not comply substantially with the requirements of 42 C.F.R. § 483.60(b). In relevant part this regulation requires a skilled nursing facility to employ a pharmacist who establishes a system of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation of the drugs. The pharmacist must also determine that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

CMS alleges that Petitioner failed to comply with the requirements of 42 C.F.R. § 483.25 in that it failed to provide incontinence care to a resident (R3) in accordance with that resident's comprehensive assessment and plan of care. The undisputed material facts unequivocally support CMS's contentions.

As a matter of law, a facility's failure to follow a resident's plan of care in providing care to that resident is, on its face, substantial noncompliance with the requirements of 42 C.F.R. § 483.25. *Life Care Ctr. of Bardstown*, DAB No. 2479 (2012) and decisions cited therein; *Spring Meadows Health Care Ctr.*, DAB No. 1966, at 17 (2005). The first question that I consider in evaluating CMS's allegations is whether Petitioner adhered to the plan of care that it developed for R3. I find that it did not.

The resident had a brief stay – from September 15 through September 23, 2015 – at Petitioner's facility. R3 was highly dependent on nursing staff to take care of even the most basic of his daily needs. He was an elderly, extremely debilitated individual whose illnesses and impairments included advanced dementia, chronic

kidney disease, peripheral neuropathy, dysphagia, and odynophagia (painful swallowing). CMS Ex. 13 at 1. He was non-ambulatory and disoriented, with poor/impaired memory and attention span, and had difficulty making choices. CMS Ex. 18 at 6, 12-14.

Petitioner's staff assessed R3 on admission to the facility. The staff noted that the resident had a history of urinary tract infections and found him to be bladder incontinent, needing assistance to reach the bathroom, and to manage his clothing. CMS Ex. 18 at 9. Staff assessed him as only being sometimes aware of his toileting needs and found him to be confused and needing physical assistance with his toileting needs. *Id.* The staff found the resident to be an appropriate candidate for being put on a toileting schedule with timed voiding. *Id.*

The staff prepared an interim plan of care for R3 on September 15, 2015, that, among other things, addressed the resident's obvious incontinence issues. The plan required that the resident receive timed toileting every two hours and as needed and required also that he be checked for incontinence every two hours and as needed. CMS Ex. 16 at 1. Also, on September 15, the staff received an order from the resident's treating physician, transmitted by telephone, that authorized the resident to receive straight catheterization as needed. The order specifically referred to urine retention as a problem that might justify catheterization. CMS Ex. 15 at 3, 8.

Therefore, the undisputed facts of this case establish that Petitioner's staff had specific and clearly defined duties concerning R3's incontinence and urinary retention issues. The staff was obligated to check resident at least once every two hours and they were required to toilet him at least every two hours pursuant to a schedule. They were also under a doctor's orders to assure that the resident did not retain urine and to catheterize him as necessary.

The undisputed facts show that Petitioner's staff failed to perform these duties. The staff assessed the resident's urinary tract issues sporadically at best during the nine days that the resident was at Petitioner's facility. On September 16 and 17 nursing notes show that the resident was continent of bowel and bladder. Another note, on September 22, 2015, made reference to the resident wearing an incontinence brief. CMS Ex. 17 at 2-3. There is one more note on September 20 in which a nurse observed that the resident had not urinated during her entire eight-hour shift. *Id.* at 3. The nurse requested that the resident be monitored during the next shift. However, there is nothing in Petitioner's records showing follow-up monitoring or assessments of the resident's possible urine retention. There is also nothing in the facility's records showing that staff routinely assisted R3 with timed voiding or that it checked him for incontinence at two-hour

intervals. Nor is there anything in the records showing that the staff ever evaluated the resident for possible catheterization.

The plan of care for R3 specifically called for checking the resident for incontinence at two-hour intervals and also for timed voiding every two hours. The staff's failure to document that it was providing these services to R3 is a clear violation of the resident's plan of care. The staff's failure to evaluate R3 for possible catheterization after the resident was reported not to have passed any urine during an entire nursing shift contravened the resident's physician's order. These violations of the plan of care and a physician's order are on their face noncompliance with 42 C.F.R. § 483.25.

But, more than that, they are omissions that put the resident at risk. That is the second basis for me to find noncompliance with the requirements of 42 C.F.R. § 483.25, because in this case the undisputed material facts establish that Petitioner's omissions in providing care caused harm to R3. On September 23, 2015, R3 was transferred to another skilled nursing facility whose staff assessed the resident. The staff found the resident to be in pain with an extremely distended abdomen. CMS Ex. 10 at 9. That staff transferred the resident to an emergency room where he was found to be suffering from acute urinary retention. Acute urinary retention is a potentially life-threatening condition consisting of inability to urinate despite having a full bladder. National Kidney and Urologic Diseases Information Clearinghouse, *Urinary Retention*, https://www.niddk.nih.gov/health-information/health-topics/urologic-disease/urinary-retention/Documents/UrinaryRetention_508.pdf.

In excess of 2000 ml of urine was withdrawn from the resident at the emergency room. CMS Ex. 10 at 1. That is equivalent to the amount of urine a person would produce in a period ranging from one to three days. Medline Plus, *Urine 24-hour volume*, https://www.nlm.nih.gov/medlineplus/ency/article/003425.htm (last visited Aug. 24, 2016). The resident was suffering from acute renal failure, the consequence of his urine retention. *Id.*

The only reasonable inference that I can draw from the undisputed facts pertaining to R3's condition as of his transfer is that he had retained a massive quantity of urine as a consequence of Petitioner's staff's failure to assess and treat the resident for urinary retention, in contravention of the resident's physician's order. There is no other possible explanation for the fact that the resident was found to be retaining so much urine at the time of his transfer to another facility. That is plainly a violation of the quality of care requirement of 42 C.F.R. § 483.25. *Alexandria Place*, DAB No. 2245 (2009).

Petitioner offers several contentions and arguments intended to rebut CMS's case for summary judgment. I find these to be without merit. Petitioner argues first, that its staff's assessment of R3 and its plan of care for that resident did not require the staff to monitor strictly the resident's fluid intake and voiding because there is nothing in the care plan that explicitly requires the staff to do so. Petitioner's pre-hearing brief at 4. That may be so, but the argument is a red herring. Petitioner's deficiencies do not consist of the staff's failure monitor the resident's fluid intake and voiding, but of the staff's failure to comply with the plan of care's explicit requirement that the resident be toileted at two-hour intervals, and its failure to comply with a doctor's order to monitor the resident for signs of urinary retention and to catheterize the resident as may have been necessary.

Second, Petitioner contends that there was no valid order for catheterization of R3 on an as needed basis during most of his stay at Petitioner's facility, arguing that a draft order for catheterization was not signed by the resident's physician until September 21, 2015. Petitioner's pre-hearing brief at 4-5. That assertion begs the question. There was a *verbal* order for catheterization issued on September 15 and Petitioner's staff recorded that order in their notes. CMS Ex. 15 at 3, 8. Petitioner's staff was authorized by a physician to catheterize R3 as needed during his entire stay at Petitioner's facility. And, of course, that order implicitly required the staff to monitor the resident for signs of urinary retention.

Petitioner argues that this order merely reflects a nurse's misunderstanding of what the physician intended and was not the physician's actual order. But, that order – however it was generated – was plainly recorded in Petitioner's staff notes. The staff was obligated to follow that order or to at the least verify it. They did neither.

Petitioner argues also that there is nothing in the resident's record that suggests that he ever needed to be catheterized during his stay. Petitioner's pre-hearing brief at 5. That is completely belied by the undisputed facts. First, and as I have discussed, during at least one nursing shift, the resident failed to produce any urine. That should have been a signal to the staff to consider catheterizing him and yet, staff did nothing. CMS Ex. 10 at 3; CMS Ex. 17 at 2. Indeed, Petitioner's own director of nursing conceded that catheterization should have been considered. CMS Ex. 10 at 3; CMS Ex. 17 at 12. Second, the resident arrived at his new facility on September 23, 2015 with his abdomen swollen with retained urine. The only reasonable inference that I can draw from that fact is that the resident had been retaining urine for a prolonged period prior to his transfer. Had the staff monitored the resident for urinary retention it should have observed the resident's condition. The only reasonable inference that I can draw from the resident's condition as of his transfer is that the staff did not monitor him.

Petitioner argues that its staff documented residents' care "by exception," meaning, apparently, that the staff made no notations unless problems were identified. Petitioner's pre-hearing brief at 5-6. From that, Petitioner contends that R3 must not have had problems during his stay because his record has few notations.

That is obviously a self-serving argument. In evaluating a motion for summary judgment I am obligated to assume that all facts alleged by a party are true and I also required to give that party the benefit of all reasonable inferences that one may draw from its alleged facts. But, that obligation does not impose on me the duty to make flights of fancy. I am under no requirement to draw inferences that are so far-fetched as to be completely unrealistic.

The undisputed facts establish this: the resident's record is virtually devoid of evidence showing that Petitioner's staff provided him with the incontinence care directed by the plan of care; there is nothing in his record showing that the staff monitored him for urinary retention even in the face of evidence showing that a nurse was concerned that he was retaining urine; and at the time of his transfer the resident was found to be retaining a massive quantity of urine, with a distended abdomen and in acute renal failure. Against these undisputed facts Petitioner asserts that I should draw an inference that its staff provided all prescribed care because they never recorded anything showing that they either *did or did not* provide such care. That is a suggested inference that borders on fantasy and I decline to draw it here.

Furthermore, it would be impossible to carry out the requirements of R3's plan of care if Petitioner's staff did not faithfully chart the care that they gave to him. The plan of care required documentation of interventions even if Petitioner's general policy was to document by exception. That is because the plan required that care be delivered pursuant to a timed routine and it would have been impossible to carry out that routine according to the plan without recording when care was delivered.

How would anyone know whether the resident was checked for incontinence and toileted at two-hour intervals if staff didn't record their interventions? How would a nurse at the beginning of a shift know whether the resident received the required care in the previous shift if there was no record of him having received that care? How would staff know when to toilet the resident next if no record were made of the previous intervention? Documenting by exception – if that's what Petitioner's staff did – clearly put the resident at peril because no one on staff would ever know when previous interventions occurred or if someone simply forgot to provide care.

I would be inclined to find Petitioner's assertion that it charts "by exception" to be utterly incredible were I to hold a hearing on the record. I make no such finding here. Rather, my conclusion is that if the staff charts "by exception" they surely missed overwhelming evidence showing that the resident was retaining massive amounts of urine during his stay, so much so that he needed to be treated for urine retention at a hospital immediately after his discharge from Petitioner's facility. Furthermore, the staff clearly missed signs of a serious problem when they failed to react to the resident's nonproduction of urine over an eight hour nursing shift. Even Petitioner's director of nursing admitted that. CMS Ex. 10 at 3; CMS Ex. 17 at 12.

Petitioner argues also its staff recorded no problems with R3 just prior to his transfer. Petitioner's pre-hearing brief at 7. From that argument it suggests that I could infer that any problems that the resident had with urinary retention occurred *after* he left Petitioner's facility. But, that is not a reasonable inference. First, there is nothing in the record to show that Petitioner's staff actually checked R3 for urinary retention prior to his departure. Furthermore, upon his arrival at his new facility, the resident was found to have retained a massive amount of urine, more than 2 liters, in fact. That is up to as much as a three-days' production of urine. Given that, it is simply not reasonable to infer that the resident's urinary retention was a post-discharge development.

Finally, Petitioner contends that there was a gap of several hours between R3's transfer from its facility and his arrival at an emergency room for treatment of urinary retention. From this, it asserts that it is speculative to conclude that the resident was retaining urine as of his discharge from Petitioner's facility, because unknown intervening events could be the cause of his urinary retention. I find that not to be a reasonable assumption. The quantity of urine retained by R3 was massive – a quantity that consisted of up to three days' production of urine – and that cannot be explained by unknown intervening events. The only reasonable inference that I can draw is that the resident retained urine while still at Petitioner's facility.

CMS predicates its assertion that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.60(b) on allegedly undisputed facts showing that Petitioner failed to comply with its own policy governing destruction of unused controlled substances.

Petitioner has a policy covering destruction of unused controlled substances. There must be two witnesses present when controlled substances are destroyed, in order to assure that these drugs are not diverted. CMS Ex. 29, ¶ 16. The medication must be crushed and placed into a sharps container where it is mixed

with cat litter. CMS Ex. 25 at 1. Two licensed nurses must sign any record of medication disposal. *Id.*

CMS asserts that on September 6, 2015, a nurse consultant asked a licensed practical nurse to assist her in destroying some controlled substances. CMS Ex. 23 at 3. In the course of that activity, the nurse consultant asked the licensed practical nurse to sign several controlled substance disposal account sheets, which attested that a variety of controlled substances had been destroyed. CMS Ex. 26; CMS Ex. 29, ¶ 18. The licensed practical nurse did so, but in fact, she had not witnessed the destruction of the medications listed on the account sheets. CMS Ex. 29, ¶ 18. In fact, only a small quantity of liquid Ativan was destroyed on September 6. CMS Ex. 23 at 3.

These facts plainly establish noncompliance with the requirements of 42 C.F.R. § 483.60(b). The regulation requires a facility to have and to utilize a pharmacist-designed plan for destruction of drugs. Here, Petitioner had a plan but it did not follow it.

Petitioner concedes the facts alleged by CMS. Petitioner's pre-hearing brief at 10. However, it asserts that nothing that its staff did on September 6, 2015 contravened regulatory requirements. It argues that CMS does not allege that Petitioner failed to employ the services of a pharmacist, failed to label drugs correctly, or failed to store drugs correctly. *Id.* It argues, effectively, that employing a pharmacist, labeling drugs, and storing them are all that is covered by the regulation.

However, that argument avoids the explicit language of 42 C.F.R. § 483.60(b). The regulation expressly requires a facility to have a system of records for receipt and *disposition* of controlled substances. That language implicitly requires a facility to implement any system that it develops. Otherwise the regulation's requirement would be meaningless.

Here, Petitioner failed to implement its own policy governing destruction of controlled substances. Petitioner admits that. That is sufficient to establish noncompliance with the regulation's requirements.

Petitioner argues that, if it was noncompliant with regulatory requirements, I should lower CMS's scope and severity findings. I have no authority to do that. *See* 42 C.F.R. § 498.3(b)(14).

I find to be reasonable CMS's determination to impose civil money penalties of $750 for each day of a period that began on October 2, 2015 and that ran through November 18, 2015. Petitioner has challenged the daily amount of these penalties

but has not asserted that, if it was deficient it attained compliance on dates that are earlier than those found by CMS. Consequently, there is no dispute as to the duration of remedies.

As to amount, I find that penalties of $750 per day are entirely consistent with the severity of Petitioner's noncompliance and I uphold them for that reason. CMS may impose penalties in a range of from $50 to $3000 per day to remedy deficiencies that do not cause immediate jeopardy for residents, as is the case with the deficiencies here. 42 C.F.R. § 488.438(a)(1)(ii). Daily penalties of $750 are actually quite modest, comprising only 25 percent of the maximum amount that CMS may impose for non-immediate jeopardy level noncompliance.

In determining penalty amount I may consider factors that include: the seriousness of a facility's noncompliance; its compliance history; its culpability; and its financial condition. 42 C.F.R. §§ 488.438(f)(1)-(4), 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)). It is unnecessary that every factor be present in a given case in order to justify a penalty amount.

The seriousness of Petitioner's noncompliance, based on undisputed facts, is sufficient to justify the modest penalties of $750 per day. I have found that Petitioner's noncompliance caused harm to R3. Not only was this helpless individual in pain when he was discharged from Petitioner's facility, but his urinary retention – a potentially dangerous condition – had caused him to suffer acute renal failure. That is more than enough to support the penalty amount.

Petitioner does not assert that it lacks the wherewithal to pay the penalties. It contends, however, that its noncompliance (if it occurred) is of insufficient gravity to justify the penalty amount. I disagree, for the reasons I have stated. It also argues that it does not have a compliance history that would support penalties of this magnitude. However, the undisputed facts show that Petitioner has a history of noncompliance found at a survey that occurred also in 2015. CMS Ex. 4 at 1. Finally, Petitioner asserts that there is no evidence showing that its staff was culpable for its noncompliance.

I find it unnecessary to address the issues of compliance history and culpability in order to affirm the penalty determination. As I have stated, the seriousness of Petitioner's noncompliance is sufficient to sustain the penalty amount.

/s/
Steven T. Kessel
Administrative Law Judge