Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Golden Living Center – Heber Springs
(CCN: 04-5158),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-08-560

Decision No. CR2280

Date: November 10, 2010

DECISION

Petitioner, Golden Living Center – Heber Springs, was not in substantial compliance with program participation requirements on or about March 3, 2008, due to a violation of 42 C.F.R. § 483.25[1] as alleged by a survey of Petitioner's facility completed on April 4, 2008. There is a basis for the imposition of an enforcement remedy. A per instance civil money penalty (PICMP) of $6,000 is not reasonable, but a $3,000 PICMP is reasonable.

I. Background

Petitioner is located in Heber Springs, Arkansas, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On April 4, 2008, Petitioner was surveyed by the Arkansas Department of Health and Human Services, Office of Long-Term Care (state agency) and found not in compliance with program participation requirements. The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated April 22, 2008, that it was imposing the following enforcement remedies: termination of Petitioner's provider agreement effective July 4, 2008, and a denial of payment for new

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[1] All references to the Code of Federal Regulations (C.F.R.) are to the 2007 version in effect at the time of the survey, unless otherwise indicated.

admissions (DPNA) effective May 7, 2008, if Petitioner did not return to substantial compliance before those dates; a PICMP of $6,000, based upon an alleged violation of 42 C.F.R. § 483.25; and withdrawal of approval to conduct a nurse aide training and competency evaluation program (NATCEP) for two years from the date the survey ended.[2] CMS notified Petitioner by letter dated June 11, 2008, that the state agency determined by a revisit survey that Petitioner had returned to substantial compliance with program participation requirements, and the termination and DPNA remedies were rescinded. The parties agreed at hearing that the revisit survey found that Petitioner returned to substantial compliance on May 1, 2008. Tr. at 36.

Petitioner requested a hearing before an administrative law judge (ALJ) by letter dated June 17, 2008. The case was assigned to me for hearing and decision on July 22, 2008, and an Acknowledgement and Prehearing Order was issued at my direction. On March 3 and 4, 2009, a hearing was convened in Little Rock, Arkansas, and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS exhibits (CMS Exs.) 1 through 23 that were admitted as evidence. Tr. at 19. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 29 that were admitted as evidence. Tr. at 22, 187. CMS called the following witnesses: Surveyor Linda Corbin, RN, and Dorothy Beckley Doughty, RN, who was qualified as an expert witness. Petitioner called the following witnesses: Terrie Coughlin, Licensed Practical Nurse (LPN); Sara Kilburn, RN, Petitioner's Director of Nurses (DON); and Charles Pound, M.D., who was called as an expert witness. The parties filed post-hearing briefs and post-hearing reply briefs.

II. Discussion

A. Issues

The issues in this case are:

> Whether there is a basis for the imposition of an enforcement remedy; and
> Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 (SNF) and 1919 (NF) of the Social Security Act (Act) and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act vests the Secretary of Health and Human Services (Secretary) with authority to impose enforcement remedies against a SNF for failure to comply substantially with

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[2] Petitioner did not have a NATCEP. Tr. at 35. However, based upon the survey and enforcement remedy in this case, the state agency would be unable to approve such a program to be offered by Petitioner within a period of two years from the last date of the survey. 42 C.F.R. § 483.151(b)(2) and (e)(1).

the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[3] Pursuant to 1819(h)(2)(C), the Secretary may continue Medicare payments to a SNF not longer than six months after the date the facility is first found not in compliance with participation requirements. Pursuant to 1819(h)(2)(D), if a SNF does not return to compliance with participation requirements within three months, the Secretary must deny payments for all individuals admitted to the facility after that date – commonly referred to as the mandatory or statutory DPNA. In addition to the authority to terminate a noncompliant SNF's participation in Medicare, the Act grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, civil money penalties (CMP), appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "*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 causing minimal harm." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. Part 483, Subpart B. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. 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.

CMS may impose a per day CMP for the number of days a facility is not in substantial compliance, or for each instance of noncompliance. 42 C.F.R. § 488.430(a). The regulations specify that 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 a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). "*Immediate jeopardy* means a situation in which 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." 42 C.F.R. § 488.301 (emphasis in original). The lower range of a CMP, $50 per day to $3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). A PICMP may range from $1,000 to $10,000, and the range is not affected by the presence of immediate jeopardy. 42 C.F.R. § 488.438(a)(2).

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[3] Section 1919(h)(2) of the Act gives similar enforcement authority to the states to ensure that NFs comply with their participation requirements established by sections 1919(b), (c), and (d) of the Act.

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *The Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800 at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); 42 C.F.R. §§ 488.330(e), 498.3. However, the choice of remedies, or the factors CMS considered when choosing remedies, is not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance determined by CMS if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. §§ 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). *Woodstock Care Ctr.*, DAB No. 1726 at 9, 38 (2000), *aff'd*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g.*, *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). ALJ review of a CMP is subject to 42 C.F.R. § 488.438(e).

The standard of proof, or quantum of evidence required, is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x. 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *see Hillman Rehab. Ctr.*, DAB No. 1611 (1997), No. 98-3789, 1999 WL 34813783 (D.N.J. May 13, 1999).

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. CMS alleges based upon the survey that ended April 4, 2008, that Petitioner was not in substantial compliance with program participation requirements, based upon a violation of 42 C.F.R. § 483.25 (Tag F309, scope and severity J). CMS proposes to impose a $6,000 PICMP based upon the alleged violation. The alleged violation of 42 C.F.R. § 483.25 is the only deficiency from the survey that is subject to my review, as it is the only deficiency for which CMS imposed an enforcement remedy.

I have carefully considered all the evidence, including the documents and the testimony at hearing, and the arguments of both parties, though not all may be specifically discussed in this decision.[4] I discuss the credible evidence given the greatest weight in my decision-making. The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so.

1. Petitioner violated 42 C.F.R. § 483.25 (Tag F309).

2. Petitioner's violation of 42 C.F.R. § 483.25 did not cause actual harm or pose immediate jeopardy but there was a risk for more than minimal harm, and, therefore, Petitioner was not in substantial compliance due to the violation.

a. Facts

Resident 14 was a 44-year-old man admitted to Petitioner's facility on December 10, 2007. Resident 14 had a history of spina bifida and lower limb full-thickness skin loss on the plantar surface of his left foot. P. Exs. 5, 6, 19.[5] Following treatment in the hospital for his left foot wound, Resident 14 was discharged to Petitioner for rehabilitation. P. Ex. 6, at 3-4. Resident 14's Minimum Data Set (MDS) with an assessment reference date of December 17, 2007, documented that the resident was independent in cognitive skills for daily decision-making, and he was responsible for himself. In addition, he: was usually continent of bowel; was continent of bladder; had an indwelling catheter; required extensive assistance with toileting; had moderate pain less than daily and in the past fourteen days; and had received monitoring for an acute medical condition. The MDS shows that the resident did not participate in his assessment, and he had no family or significant other that participated. P. Ex. 9. Resident 14's MDS with an assessment reference date of February 5, 2008, documented, among other things, that the resident: was independent in his cognitive skills; incontinent of bowel; continent of bladder; had an

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[4] "Credible evidence" is evidence that is worthy of belief. *Blacks Law Dictionary* 596 (18th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625. Evidence that is not credible generally has no probative value or weight. Evidence that is credible may or may not be given probative value or weight based upon its comparison with other evidence of record.

[5] The record is conflicting as to the cause of the left foot wound, as the record shows it was either a burn or caused by a splint he wore on that foot. P. Exs. 6, at 1; 19. A physician's progress note dated January 30, 2008, reflects wounds on both feet caused by braces. P. Ex. 17, at 1. The DON testified that the wound was due to rubbing caused by a brace. Tr. at 233.

indwelling catheter; required limited assistance of one person with toileting; had mild pain less than daily; and, in the past 14 days, had received monitoring for an acute medical condition. CMS Ex. 10; P. Ex. 11.

Testimony at hearing was that Resident 14 had undergone a number of urologic procedures, which included some sort of devices being implanted in the past. Tr. at 140; Tr. at 255-60; 262. Neither the government expert, RN Doughty, nor the Petitioner's expert, Dr. Pound, was certain of the prior procedures or implants. There is a dearth of documentary evidence reflecting the actual history of urologic procedures. However, Resident 14 reported to emergency room personnel on March 6, 2008, that he had a history of placement of a penile sling. P. Ex. 22, at 2. Resident 14's urologist, Dr. Diaz, indicated that Resident had an AdVance male sling[6] placed in 2007 and that he had had multiple spinal surgeries. P. Ex. 22, at 6.

Resident 14 was assessed as requiring a care plan for his indwelling catheter. P. Ex. 10. His care plan dated December 21, 2007, reflects an assessed risk for urinary tract infection (UTI) due to the indwelling catheter that was required due to his spina bifida. Interventions required by the care plan included observing the catheter and changing the catheter and tubing every 30 days, and, as necessary: observing collected urine for sediment, cloudiness, odor, blood, and amount; reporting any problems with urine or fever promptly to the physician; encouraging fluids; monitoring laboratory reports as ordered; and perineal care every shift and as necessary. P. Ex. 12, at 1; CMS Ex. 5, at 1. The plan of care was reviewed on January 17, 2008, and the determination was made that it would be continued for 90 days. CMS Ex. 5, at 1, 12; P. Ex. 12, at 1. I have received no evidence that the interventions required by that care plan were changed prior to Resident 14 departing the facility on March 6, 2008.[7] Tr. at 78.

The evidence shows that for most of his stay with Petitioner, Resident 14 had an indwelling or Foley catheter. Physician orders support a finding that he had a Foley except February 4 or 5 to February 9, 2008, and February 21 and 22, 2008. The nurse's notes indicate that the resident was also self-catheterizing on February 13, 2008.[8]

Physician Orders forms show that a Foley catheter was ordered December 12, 2007 (P. Ex. 15, at 2). An order dated February 4, 2008, required that the Foley be discontinued when in-out catheters arrived at the facility (P. Ex. 15, at 3, 4). An order dated February 9, 2008 required that a 14 French Foley catheter be placed and changed monthly and as necessary (P. Exs. 15, at 4; 16, at 3). An order dated February 13, 2008, required a 16 French Foley catheter (P. Ex. 15, at 4).

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[6] P. Ex. 23; CMS Ex. 21.

[7] The SOD does not charge Petitioner for failing to update or follow Resident 14's care plan, and I do not find a violation or deficiency where none is charged.

[8] The resident used a device known as a straight catheter for self-catheterizing. A straight catheter is also referred to as an in-out or in-and-out catheter. Tr. at 190-91.

An order dated February 19, 2008, required Foley care with soap and water every shift (P. Ex. 16, at 3). An order dated February 20, 2008, required that the Foley be discontinued on February 21 (P. Exs. 15, at 4; 20, at 3), and orders dated February 22, 2008, required an 18 French Foley catheter with a 30 cc bulb to be changed monthly or as necessary (P. Exs. 16, at 3; 21, at 3-4). Resident 14 had a physician order dated December 11, 2007, for Hydrocodone every four hours as needed for pain associated with the full-thickness skin loss on his lower limb. P. Exs. 15, at 3; 16, at 3; 20, at 5; 21, at 6; CMS Ex. 9, at 7-8. I have no evidence of an order for the administration of Hydrocodone for bladder or scrotal pain.

Nurses' notes from December 14, 2007 to February 5, 2008, indicate that Resident 14 consistently had a Foley catheter in place. P. Ex. 13. Nurse's notes entries on February 5, 2008, show that the resident's Foley catheter was changed; however, subsequently, the resident requested that the Foley catheter be removed, and it was discontinued at his request. There is no indication the physician was consulted. P. Ex. 13, at 33. A nurse's notes entry dated February 6, 2008 at 12:22 a.m. states that the resident self-catheterizes every two hours and as necessary. P. Ex. 13, at 34. Nurse's notes through February 8, 2008, indicate that the resident continued to self-catheterize. P. Ex. 13, at 35. However, a nurse's notes entry dated February 11, 2008 at 11:31 a.m. indicates that the resident has a Foley catheter again. An entry at 11:08 p.m. on February 11, 2008, shows that the resident requested that the Foley catheter be discontinued. A new order to discontinue the Foley was obtained from the physician, and the Foley was drained and clamped. A nurse's notes entry dated February 12, 2008 at 3:55 a.m. indicates that the resident self-catheterizes every two hours and as necessary. However, a note dated February 12, 2008 at 10:53 p.m. indicates that the resident was undergoing bladder training and that the Foley was being unclamped and drained every two hours. The notes indicate that the resident wanted to continue bladder training throughout the night and have the Foley removed in the morning. A nurse's notes entry dated February 13, 2008 at 10:41 p.m. indicates that the resident complained that he could not get enough urine out self-catheterizing. A new order for a Foley catheter was obtained from the physician, and the Foley was placed. P. Ex. 13, at 37, 39. A nurse's notes entry on February 20, 2008, indicates that the resident continued with the Foley catheter in place. P. Ex. 13, at 32. Notes show that the Foley was removed on February 21, 2008, per physician order, and staff was to monitor output. A note dated February 22, 2008, shows that the Foley was reinstated at the resident's request after staff obtained a new physician's order. P. Ex. 13, at 41. A nurse's notes entry on February 26, 2008, shows that the resident was out for an appointment with the urologist, that he was upset in the van when returning from the appointment and crying while speaking with someone on the phone, and that he told staff that he was upset because he did not receive the answer he wanted.[9] P. Ex. 13, at 44. The nurse's notes show that the resident

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[9] A physician's progress note dated February 27, 2008, states that the resident was back from his appointment with his doctor in Little Rock (the appointment appears to have been with the urologist) and that the resident would ultimately need to have an implant surgically removed after his foot healed. P. Ex. 17, at 2-3. The type of implant was not specified, but this may have been the cause for the resident's emotional reaction following his appointment. Tr. at 263.

continued to have a Foley from February 22, 2008 to sometime on March 3, 2008. P. Ex. 13, at 41-46.

On March 3, 2008, Resident 14 underwent a cystoscopy, a minor surgical procedure that involved direct visual examination of the interior of his bladder by means of a small, lighted telescope. P. Ex. 18, at 2; Tr. at 263-64. Post-operative instructions indicate that a small amount of blood in the urine would not be unusual and that the physician should be notified if the amount of blood becomes excessive or there is difficulty voiding. P. Ex. 18, at 2. Additional instructions following surgery were to observe the area for signs of excessive bleeding and signs of infection, including increased pain, redness, swelling, and foul odor. Nursing personnel were to reinsert the Foley catheter if the resident was unable to urinate. P. Ex. 18, at 1. It is apparent that the Foley catheter would have been removed to perform the cystoscopy (Tr. at 263-64), and the post-operative instruction form supports an inference that the resident was intended to be returned to Petitioner without a Foley catheter in place. The evidence shows that the resident received Hydrocodone at 9:00 p.m., but the location of his pain is not indicated. CMS Ex. 9, at 10. The nurse's notes from the morning of March 4, 2008, show that a Foley catheter was placed for the resident. P. Ex. 13, at 47.

A nurse's note dated March 4, 2008 at 3:44 a.m. indicates that the resident requested that a Foley catheter be "replaced" but the nurse could not do so, because she did not have a Foley of the correct size. P. Ex. 13, at 46. A nurse's note dated March 5, 2008 at 3:03 p.m. states it is a late entry for March 4, 2008 at 3:00 a.m. and that a nurse inserted a Foley catheter for Resident 14 at his request, because he could not void sufficiently. Approximately three hours later, the resident complained that he was having urine leakage and that he did not think the catheter bulb was in the correct position. The nurse deflated and repositioned the bulb and then refilled the bulb, and the resident said it felt better. P. Ex. 13, at 47. The evidence shows that Resident 14 was given Hydrocodone at 6:00 a.m. and 10:00 a.m. on March 4, 2008, and the 6:00 a.m. dose was for a complaint of bladder pain. CMS Ex. 9, at 8, 10. He received another Hydrocodone for a complaint of scrotal pain around 8:00 a.m. on March 5, 2008. He rated the pain as four, which is mild pain on Petitioner's scale. At 9:10 a.m., the resident rated the pain as two, which is still mild pain. Resident 14 wanted his physician called. CMS Ex. 9, at 9, 10. He was given another Hydrocodone at 1:00 p.m. on March 5, 2008. CMS Ex. 9, at 10. A nurse's note dated March 5, 2008 at 3:10 p.m. indicates that the resident complained of swelling in his groin and that a nurse had repositioned the catheter the previous night. The resident said it felt better for a while. The note indicates that the resident asked that his physician be called. The note shows that LPN Terrie Coughlin called the physician and explained the resident's complaint to the physician's nurse who said she would call back. The physician's nurse called back with a new order for Detrol, because the resident was probably having bladder spasms. The note indicates that LPN Coughlin informed the resident of what the physician's nurse said, and he understood. P. Ex. 13, at 47. A nurse's note dated March 5, 2008 at 9:32 p.m. indicates that a Foley was in place. P. Ex. 13, at 46.

Resident 14 was given a Hydrocodone at 6:30 a.m. on March 6, 2008, but the record before me does not indicate the location of his complaint of pain that caused him to be given the pain medication. CMS Ex. 9, at 10. A nurse's note dated March 6, 2008 at 1:12 p.m. states that

Resident 14 had been up in the morning propelling around the facility in his wheelchair, laughing and talking with staff. He told LPN Coughlin that he continued to feel there was some swelling in his scrotal area. The note states that no visual edema was noted and that the Foley continued to drain yellow urine. The note states that, at 10:45 a.m., LPN Coughlin was called to Resident 14's room, and she immediately saw bright red blood in his Foley catheter tubing. Resident 14 stated that he was swollen more, and LPN Coughlin records that she observed that the scrotal area was very swollen. The note shows that Resident 14 was sent to the emergency room. P. Ex. 13, at 47. There is no dispute that Resident 14 never returned to Petitioner's facility.[10]

On March 6, 2008, Resident 14 was transported to the emergency room. The emergency room report dated March 6, 2008, with a time of service of 11:50 a.m., shows that Resident 14 arrived with complaints of severe scrotal pain, penile swelling with severe pain and blood visible in his urine. It is reported that Resident 14 told emergency room personnel that his symptoms started suddenly when he felt like "something dropped." P. Ex. 22, at 2. The genitourinary examination in the emergency room revealed that the Foley catheter was in place, there was visible blood in the catheter bag, and there was swelling with hematoma to the scrotum and penis with "exquisite tenderness." P. Ex. 22, at 3. The emergency room diagnoses were: torn urethra; scrotal hematoma; and frank hematuria (visible blood in the urine). P. Ex. 22, at 4. Resident 14's urologist was Edwin Diaz, MD. Dr. Diaz's description of the resident's history, on the day of Resident 14's emergency room admission, included the following:

> This is a patient of mine. He is a 44-year-old patient who has spina bifida and life-long urinary incontinence. He underwent and (sic) Avance (sic) male sling last year. He is completely dry. He was admitted to rehab in November because of a left foot ulcer. They put in a catheter and it has been in there ever since with multi-changes. When they tried to remove the catheter recently he was unable to urinate. I did a cysto in the office. It showed no evidence of mesh erosion. He had a catheter placed by the nursing home staff recently and either the balloon is blown up in the urethra or the catheter was pulled on and it damaged the urethra but at any rate he has a urethral perforation causing the swelling of his scrotum and penis. A suprapubic tube was placed by Dr. Ken Robins the urine is clear and yellow and when he did a cystogram it showed the Foley balloon to be in the urethra.

P. Ex. 22, at 6. Dr. Diaz, as Resident 14's treating urologist, was most familiar with the resident and his history of urologic problems, and I find his opinions weightier than those of the experts

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[10] On March 11, 2008, five days after being admitted to the hospital, the resident underwent scrotal debridement and removal of his testes due to gangrene and necrotizing fasciitis. CMS Ex. 19, at 7.

called by the parties in this case who admitted that they did not have the resident's complete history and had no opportunity to examine the resident. Dr. Diaz's report establishes that an x-ray of the bladder (cystogram) showed that the Foley catheter balloon was in the urethra. Dr. Diaz stated two possible causes, either the balloon was inflated in the urethra or the catheter was pulled on, which pulled the balloon into the urethra. Surveyor Corbin testified that she interviewed the resident's urologist, Dr. Diaz, at the hospital during the survey, and he opined that the resident's injury was due to inflating the balloon in the urethra, causing trauma, or the tubing was dislodged, causing trauma, but he did not know which occurred. Tr. at 88. The resident's clinical record in evidence before me shows that the catheter was placed on March 4, 2008, in the morning. Between the insertion of the catheter on March 4 and the morning of March 6, 2008, the resident complained of urine leakage that was resolved by repositioning the catheter, and he complained of a feeling of swelling in his scrotum. On the morning of March 6, 2008, the nurse's note shows that he was laughing and talking with staff. However, about 10:45 a.m., Resident 14 complained of more swelling, and there was visible blood in his catheter tubing. The emergency room record shows that the resident was complaining of extreme pain. I find that this evidence is consistent with Dr. Diaz's opinion that the catheter tubing was pulled, and the bulb was pulled into and ruptured the resident's urethra around 10:45 a.m. on March 6, 2008, causing the sudden onset of blood in the urine and pain. The evidence is not consistent with a finding that staff inflated the bulb of the catheter in the resident's urethra on either March 4 or 5.[11] Resident 14's treating physician, Granville Vaughn, MD, opined in his affidavit dated March 3, 2009, that if the balloon of the catheter was inflated in the urethra, the resident would have had a sudden onset of excruciating pain, and he did not complain of pain on March 4 or 5, 2008. P. Ex. 29.

Petitioner called Terrie Coughlin, LPN, to testify. She testified that she worked for Petitioner on the 6:00 a.m. to 2:00 p.m. shift and that she was Resident 14's primary care-giver. She described the resident as independent and well-groomed. She noted that he: did a lot of his own care; was alert and oriented; could self-transfer; had a lot of upper body strength; and could state if he was in pain or had discomfort. He used a straight catheter himself to urinate. He wanted privacy when he used the catheter. If he felt he was not getting sufficient output using the straight catheter, he requested a Foley catheter. Dr. Vaughn was his primary care physician. On March 4, 2008, LPN Stacy Hewitt called her just as she was clocking-in and asked for assistance to insert a catheter into Resident 14. LPN Coughlin testified that the catheter was already in his penis, the area was draped, and she washed and put on gloves. The resident told her he had just used the straight catheter. LPN Coughlin completed inserting the Foley, and the resident reported no discomfort. She inflated the bulb, and she finished gathering the equipment. The resident was fine, and he dressed and went into the hall. LPN Coughlin testified that she had inserted Foley

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[11] An infectious disease consultation by Susan Delap, MD, dated March 8, 2008, suggests that the placement of the catheter at Petitioner caused the torn urethra. However, she also states that she was unsure of whether it was the insertion of a Foley catheter or an in-out catheter that caused the tear, and she noted that Resident 14 was a fairly poor historian. CMS Ex. 19, at 1, 3. Dr. Delap's statements suggesting that the insertion of a catheter by Petitioner's staff caused the urethral tear are inconsistent with evidence of record before me and are not considered weighty.

catheters many times. She testified that she knew that the resident had several sizes of catheters due to problems with leakage. She testified that a physician has to order the catheter to be used. The resident could not urinate without a catheter. The resident's normal practice was to catheterize himself. LPN Coughlin identified the nurse's note for March 5, 2008 at 3:03 p.m. (P. Ex. 13, at 47) as her note that was a late entry for March 4, 2008, but that "3:00 a.m." was a typographical error, as she did not get to work until about 5:45 a.m. She testified that the note referred to her placing the catheter on March 4 when LPN Hewitt requested her assistance. She said that, as the note reflects, after about three hours, he complained that the bulb felt like it was only 10 cc's[12] and that he was having leakage. She testified that she looked at his brief and there was no wetness, and she looked at the genitals and saw no swelling, redness, or edema. She testified that she went ahead and deflated the bulb, repositioned and re-inflated it, and the resident said it felt better. The resident did not complain of any swelling or discomfort. LPN Coughlin identified the nurse's note dated March 5, 2008, at 3:10 p.m. as her note (P. Ex. 13, at 47) and testified that the time was when she was writing the note at the end of her shift. She testified that the resident came to the nurse's station complaining and asking that his urologist be called. She testified that she did not examine him, because he wanted the urologist called right away. She testified she called, but the urologist was out. LPN Coughlin testified that she spoke with the nurse and gave the resident the phone, and he spoke with the nurse and explained his symptoms. She testified that, after the resident spoke with the nurse, she and the resident went back to the resident's room, and she examined him and found nothing that was not normal. The resident did not complain of pain. The physician's nurse subsequently called back with an order for Detrol. The resident had had bladder spasms before and indicated understanding when LPN Coughlin explained to him that the nurse had said spasms could make him feel like he had leakage or swelling. He had also used Detrol before. LPN Coughlin testified that her note dated March 6, 2008, correctly states the resident was up that morning propelling around the facility in his wheelchair, laughing and talking with staff. She testified that about 7:00 a.m., while she was passing medication, the resident asked if his Detrol was in. He did not complain of pain. However, he said that he still felt pressure, and he thought maybe it was a spasm and wanted to get started with the medication. LPN Coughlin testified that the resident would periodically empty his catheter bag himself, so she had to ask him about his urine output. She testified that, at about 10:45 a.m., she was called to the resident's room where she found him sitting in his wheelchair, and there was a lot of bright red blood in his catheter tubing. She asked him what happened, and he said he was transferring from the toilet to his wheelchair when he felt something pop. He denied that he had pulled on the catheter. She testified that she visualized the scrotum, saw the area was very swollen, and immediately went to call for orders to send the resident to the hospital. Tr. at 189-208. I find that LPN Coughlin's testimony is generally credible. Her testimony suggesting that Resident 14 normally used an in-out or straight catheter to catheterize himself is inconsistent with the clinical record that shows he had a Foley catheter the majority of his stay with Petitioner. Otherwise, her testimony is unrebutted, consistent with the clinical record in evidence, and credible.

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[12] I do not interpret this complaint to be that the Foley catheter had a 10 cc bulb, but that whatever size the Foley bulb was, Resident 14 felt as if its inflated size was only about 10 cc.

Petitioner also presented the testimony of DON Sara Kilburn, RN. DON Kilburn testified that she did not provide direct care to Resident 14 but that she investigated his case, including reviewing his chart after Petitioner was cited by the survey. She described the process for placing a Foley catheter and testified that, if the bulb were inflated in the urethra, there would be resistance, it would cause immediate excruciating pain, and most likely there would be bleeding. She testified that Resident 14 would report anything unusual to the nurses. She testified that bladder spasms may cause a pain like a cramp, a feeling of fullness, or a stabbing pain. DON Kilburn testified that the resident's foot wound caused him pain, and he had an order for the pain medication Hydrocodone, which he received when necessary. She testified that, when the resident returned from his cystoscopy on March 3, 2008, he had instructions for monitoring which would be for complaints of pain, bleeding, inability to urinate, or a fever. She opined that monitoring of the resident was adequate though the documentation of the monitoring was inadequate. Tr. at 220-42.

b. Analysis

The general quality of care regulation requires that each resident receive care and services necessary to attain and maintain the highest practicable physical, mental, and psychosocial well-being. The care and services that must be delivered are based upon the resident's comprehensive assessment and the requirements of the resident's plan of care. 42 C.F.R. § 483.25.

The Statement of Deficiencies (SOD), Tag F309, focuses upon treatment and services during the period following the March 3, 2008 cystoscopy and the resident's transport to the emergency room on March 6, 2008. The SOD alleges that Petitioner violated the regulation, because Petitioner failed to ensure that necessary care and services were provided to Resident 14 to ensure that he did not have complications from the cystoscopy or his Foley catheter. The SOD alleges specifically that Petitioner failed to: (1) provide accurate, complete nursing assessments following Resident 14's return to the facility on March 3, 2008 after the cystoscopy; (2) monitor for complications following the cystoscopy; (3) monitor for complications after a urinary catheter insertion after the cystoscopy; (4) consistently and accurately assess pain symptoms to determine the cause, location, severity, and response to treatment; (5) ensure symptoms, including pain, swelling, and decreased urine output, were identified as potential post-operative complications or post-catheter insertion complications and were immediately reported to the physician; and (6) ensure the correct size urinary catheter was inserted in accordance with the physician's order. The SOD alleges that the deficiency posed immediate jeopardy to Resident 14, as he suffered a urethral perforation that resulted in a scrotal abscess and surgical removal of his testes. The SOD alleges that the deficiency also had the potential for causing more than minimal harm to nine other residents who had indwelling catheters. CMS Ex. 2, at 3-4; P. Ex. 1, at 3-4. CMS argued at hearing that Petitioner violated 42 C.F.R. § 483.25, because staff failed to follow Resident 14's plan of care, the physician's orders, and the post-operative discharge instructions. Tr. at 27. CMS clarified at hearing that it does not allege that Petitioner actually caused or contributed to Resident 14's urethral tear. Tr. at 42, 250-53. Surveyor Corbin testified that she participated as the team leader of the survey of Petitioner that concluded on April 4, 2008, and that she prepared the citation of deficiency under Tag F309. Her testimony was consistent with the allegations and summary of the evidence that she set forth in the SOD. Tr. at 46-126, 179-85. She testified, that

during Petitioner's annual recertification survey, she focused on Resident 14 due to a complaint that he had suffered trauma from a catheter inserted at the facility. Surveyor Corbin testified that she could not substantiate this complaint that Resident 14. Tr. at 78-86. She testified that she became aware that the resident suffered some gruesome injuries, but she could not determine the cause using the facility and hospital documentation. Tr. at 86-87.

CMS called Dorothy Beckley Doughty, RN, to testify, and she was qualified as a nurse with expertise in wound, ostomy, and incontinence care. Tr. at 126, 136. She testified that she was concerned because Resident 14 was at high risk, and Petitioner's staff failed to do an appropriate assessment on his return from a urologic procedure. She testified that his spina bifida caused persistent problems with urinary continence and retention of urine. She testified that he was at high risk due to his spina bifida and related urologic problems as well as his history of urologic procedures. She testified that, after Resident 14 returned to Petitioner following his cystoscopy, she found no documentation of assessment of his ability to void or for bladder distention. She testified that she was concerned, because the documentation of care was incomplete and inconsistent. She testified that she was also concerned that staff did not respond appropriately to Resident 14's complaint of pain and swelling. Tr. at 140-48. On cross-examination she admitted that there was no evidence that the resident suffered a urethral tear during the cystoscopy. She opined, however, that she believed a urethral tear occurred sometime on March 4 or 5 as that would explain the scrotal swelling due to urine leaking into the scrotal sac. She agreed that a nurse's note on March 6 at 1:12 p.m. indicates no visible edema but subsequently indicates marked swelling. She testified that the complaints of scrotal pain and swelling on March 5 were inconsistent with a traumatic injury on March 6. Tr. at 148-54. I do not find RN Doughty's opinion regarding the occurrence of a urethral tear prior to March 6, 2008, to be entitled to any weight. RN Doughty was not qualified to provide testimony in the area of urology, and CMS stated for the record that it was not seeking to prove that Petitioner caused the urethral tear. Further, RN Doughty's testimony is inconsistent with the credible evidence that a urethral tear would result in extreme pain and observable blood in the urine, which did not occur in this case until March 6, 2008. Her opinion that staff did not respond appropriately to Resident 14's complaint of pain and swelling is based on less than all the evidence and is also not weighty. The clinical record as clarified by the testimony of LPN Coughlin shows that the resident's complaints on March 4, 2008, were addressed by a call to the resident's physician and the receipt of the prescription Detrol to address the diagnosis of possible bladder spasms. The testimony of LPN Coughlin also shows that she did a more complete assessment of the resident following the call to the physician.

Petitioner called Charles Pound, MD, to testify, and he was found qualified to opine as an expert in the area of urology. Dr. Pound described the procedure for performing a cystoscopy. He testified that the post-operative instructions (P. Ex. 18) following the cystoscopy in the case of Resident 14 were typical. He testified that it is most important to monitor that a person can urinate after the cystoscopy, and, if not, it would be necessary to place a Foley catheter. Dr. Pound testified that, after a cystoscopy, nursing staff should be checking for blood in the urine and signs of infection, such as swelling and fever. He testified that it would be most common for problems to develop within the first 24 or 36 hours following the procedure. A patient such as Resident 14 should have received prophylactic antibiotics. Dr. Pound opined that it was possible

that Resident 14 injured his urethra, which caused leakage over a period of time into his scrotum that led to his severe complications. However, he also testified that what the resident described as a popping sensation on March 6, is consistent with the bulb of the catheter being pulled from the bladder into the urethra, causing immediate bleeding and pain. Dr. Pound also testified that the most common circumstance for the catheter to get pulled is during a patient transfer, such as Resident 14 indicated he had just done when the popping occurred. He opined that the resident's complaints of a feeling of swelling on March 4 and 5 were consistent with him having spasms, and, absent other clinical signs or symptoms, the order for Detrol was the usual mode of treatment. Tr. at 247-75. Dr. Pound's testimony is unrebutted, and his testimony is credible. I find his opinion that the incident on March 6, 2008, most likely involved the bulb on the catheter being pulled into the resident's urethra causing extreme pain and bleeding to be credible and consistent with the other evidence and opinions.

CMS determined not to proceed on a theory that Petitioner caused or contributed to the injury that caused the hospitalization of Resident 14 on March 6, 2008. Tr. at 42, 250-53. The CMS decision is consistent with the evidence before me, including the opinions of Dr. Diaz, Resident 14's treating urologist, and Dr. Pound. Thus, the issue of whether or not Petitioner violated 42 C.F.R. § 483.25 (Tag F309) turns upon whether Petitioner provided necessary care and services to avoid or address any complications following Resident 14's return to Petitioner on March 3, 2008, following his cystoscopy. Resident 14's injury on the morning of March 6, 2008, is not evidence that Petitioner failed to deliver necessary care and services. The SOD alleges that Petitioner failed to deliver necessary care and services after the cystoscopy on March 3, 2008 in six specific ways. The SOD alleges specifically that Petitioner failed to: (1) provide accurate, complete nursing assessments; (2) monitor for complications following a surgical procedure; (3) monitor for complications after a urinary catheter insertion; (4) consistently and accurately assess pain symptoms to determine the cause, location, severity and response to treatment; (5) ensure symptoms including pain, swelling and decreased urine output were identified as potential post-operative complications or post-catheter insertion complications and were immediately reported to the physician; and (6) ensure the correct size urinary catheter was inserted in accordance with the physician's order. I consider each alleged basis and conclude that Petitioner did fail to deliver necessary care and services to Resident 14.

Petitioner failed to ensure an accurate and complete nursing assessment was done when the resident returned from a cystoscopy and failed to monitor for complications from the cystoscopy. On March 3, 2008, Resident 14 underwent the cystoscopy. P. Ex. 18; Tr. at 263. Post-operative instructions indicate that a small amount of blood in the urine would not be unusual and that the physician should be notified if the amount of blood becomes excessive or there is difficulty voiding. P. Ex. 18, at 2. Additional instructions following surgery were to observe the area for signs of excessive bleeding and signs of infection, including: increased pain, redness, swelling, and foul odor. Additionally, nursing personnel were to reinsert the Foley catheter if the resident was unable to urinate. P. Ex. 18, at 1. Dr. Pound testified that the post-operative instructions (P. Ex. 18) following the cystoscopy in the case of Resident 14 were typical. He testified that it is most important to monitor that a person can urinate after the cystoscopy, and, if not, it would be necessary to place a Foley catheter. He testified that after a cystoscopy, nursing staff should be checking for blood in the urine and signs of infection, such as swelling and fever. Dr. Pound also

testified that it would be most common for problems to develop within the first 24 or 36 hours following the procedure, emphasizing the importance of assessment of the resident during that period. I conclude that the post-operative instructions and Dr. Pound's testimony reflect the standard of care that was to be delivered for Resident 14 following the cystoscopy and upon his return to Petitioner's facility. DON Kilburn also testified that appropriate monitoring upon return from the cystoscopy would have included monitoring urination, for fever, and complaints of pain or bleeding. Tr. at 237.

The time that Resident 14 returned to Petitioner's facility on March 3, 2008, is not reflected in the evidence before me. The only nurse's note dated March 3, 2008 at 6:47 p.m. does not show that staff assessed the resident's ability to urinate, whether he had blood in his urine, or whether he had any swelling or fever. P. Ex. 13, at 46. The clinical record shows that the resident received Hydrocodone at 9:00 p.m., but the location of his pain is not indicated, and there is no information that indicates an assessment was done. CMS Ex. 9, at 10. A nurse's note dated March 4, 2008 at 3:44 a.m. shows that the resident was assessed as resting quietly, with closed eyes. His respirations were even and regular, his skin was warm and dry to touch, and no adverse reaction to either Tamiflu or the administered antibiotic was noted. The resident reportedly requested that a Foley catheter be placed, but the nurse did not do so because she did not have the right size. The note does not show that staff assessed the resident's ability to urinate other than his request for a Foley, whether he had blood in his urine, or whether he had any swelling or fever. P. Ex. 13, at 46. The two nurses who made the above-described notes did not appear and testify at hearing to clarify or elaborate upon their notes. DON Kilburn testified that she did not provide direct care for Resident 14, but she did review his clinical record. Tr. at 224. She opined that monitoring of the resident after his return from the cystoscopy was adequate, as the nurses were able to answer all her questions about whether he had blood in his urine and whether there was urine return when the catheter was placed. Tr. at 238. DON Kilburn's opinion is not credible to the extent that it was intended to include the afternoon and evening of March 3 and early morning of March 4, 2008. DON Kilburn did not testify that she interviewed the two nurses who wrote the nurse's notes during that period. Further, the evidence shows that LPN Coughlin placed the Foley later during the morning of March 4, 2008, after her arrival at work around 5:45 a.m. Based on these facts, I conclude that Petitioner has not shown that necessary care and services were delivered to Resident 14 after his return from the cystoscopy on March 3 and prior to 5:45 a.m. on March 4, as Petitioner has failed to show that Resident 14 received the necessary assessment and monitoring.

However, the documentary evidence and the testimony of LPN Coughlin is sufficient to show that, after she arrived at work at approximately 5:45 a.m. on March 4, 2008, the resident was appropriately assessed when the Foley catheter was placed. The evidence shows further adequate assessment on March 5, 2008, when the resident complained that he felt as if he had some swelling in his groin.

CMS alleges that Petitioner failed to monitor for complications after a urinary catheter insertion. I find this allegation unfounded. The evidence shows that, during the morning of March 4, 2008, LPN Coughlin inserted a Foley catheter. Nurse's notes reflect that the catheter was consistently monitored on March 4, 5, and 6, with an adjustment of position required on March 5, 2008.

When the resident complained of discomfort on March 5, 2008, his physician was contacted, and a new order was received. On March 6, 2008, Resident 14 was assessed, and, when he subsequently developed new symptoms, his physician was consulted and he was sent to the emergency room. P. Ex. 13, at 47. LPN Coughlin's and DON Kilburn's testimony is credible to the extent it is consistent with the nurse's notes. Their testimony provides some clarification of the notes.

CMS alleges that Petitioner's staff failed to consistently and accurately assess pain symptoms to determine the cause, location, severity, and response to treatment. I agree that Petitioner's staff failed to adequately document pain assessments and the reason for administering pain medication. The parties do not dispute that the standard of care or practice with respect to pain assessment is to assess pain, including attempting to determine cause, location, severity, and response to treatment. The evidence shows that the resident received Hydrocodone at 9:00 p.m. on March 3 (I infer this was after his return from the cystoscopy), but the location of his pain is not indicated. CMS Ex. 9, at 10. The evidence shows that Resident 14 was given Hydrocodone at 6:00 a.m. and 10:00 a.m. on March 4, 2008, and the 6:00 a.m. dose was for a complaint of bladder pain.[13] CMS Ex. 9, at 8, 10. He received another Hydrocodone for a complaint of scrotal pain around 8:00 a.m. on March 5, 2008. He rated the pain as four, which is mild pain on Petitioner's scale. At 9:10 a.m., the resident rated the pain as two, which is still mild pain. Resident 14 wanted his physician called. CMS Ex. 9, at 9, 10. He was given another Hydrocodone at 1:00 p.m. on March 5, 2008. CMS Ex. 9, at 10. The evidence also does not show why Resident 14 was given a Hydrocodone at 6:30 a.m. on March 6, 2008, whether for a compliant of bladder pain or foot pain. CMS Ex. 9, at 10. The administration of the drug at 6:00 a.m. on March 4 was noted to be for bladder pain but there is no notation of the cause, severity, or response to the drug. The administration of Hydrocodone at 8:00 a.m. on March 5, 2008, was accompanied by an assessment of the location of the pain, the severity of the pain, and the response to the medication. However, the cause of the pain is not addressed for that instance. I have no evidence, documentary or testimonial, that assessments were done with the other administrations of Hydrocodone between Resident 14's return from the cystoscopy and his departure for the emergency room.

CMS alleges that Petitioner's staff failed to ensure symptoms, including pain, swelling, and decreased urine output, were identified as potential post-operative complications or post-catheter insertion complications and were immediately reported to the physician. The evidence does not tell me when Resident 14 returned to Petitioner's facility on March 3, 2008, following his cystoscopy. The only nurse's note dated March 3, 2008 at 6:47 p.m. does not show that staff assessed the resident's ability to urinate, whether he had blood in his urine, or whether he had any

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[13] I have no physician's order in evidence prescribing Hydrocodone for bladder pain. DON Kilburn testified consistent with my interpretation of the evidence that Hydrocodone was for the resident's foot pain, not bladder pain. Tr. at 234-35; P. Ex. 16. CMS does not allege that Petitioner committed any regulatory violation in this regard, and I find none.

swelling or fever. However, no complaints of pain, swelling, or decreased urine output are noted. P. Ex. 13, at 46. The clinical record shows that the resident received Hydrocodone at 9:00 p.m. for pain, but the location of his pain is not indicated. CMS Ex. 9, at 10. A nurse's note dated March 4, 2008 at 3:44 a.m. shows that the resident was assessed as resting quietly, with closed eyes, his respirations were even and regular, his skin was warm and dry to touch, and no adverse reaction to either Tamiflu or the administered antibiotic was noted. The resident reportedly requested that a Foley catheter be placed but the nurse did not do so, because she did not have the right size. The note does not reflect any pain, swelling, or evidence of decreased urine output. P. Ex. 13, at 46. Resident 14 was given Hydrocodone at 6:00 a.m. and 10:00 a.m. on March 4, 2008, and the 6:00 a.m. dose was for a complaint of bladder pain. CMS Ex. 9, at 8, 10. Resident 14 received another Hydrocodone for a complaint of scrotal pain around 8:00 a.m. on March 5, 2008. CMS Ex. 9, at 9, 10. When Resident 14 complained to LPN Coughlin on March 5, 2008, that he felt as if he had swelling in his groin, the physician was consulted, and a new order was received. P. Ex. 13, at 47. According to LPN Coughlin's testimony, she did an assessment of the resident at the time and found no signs or symptoms of complications. The evidence does not show that the fact the resident was given Hydrocodone for scrotal pain was reported to the physician, even though increased pain was one of the signs and symptoms staff was to monitor that was listed among the additional instructions following the cystoscopy. P. Ex. 18, at 1. Although LPN Coughlin did consult with the physician regarding the resident's complaint of swelling, the evidence does not show the physician was consulted regarding the resident's repeated complaints of pain for which he was given Hydrocodone.

CMS also alleges that Petitioner violated the regulation, because Petitioner failed to ensure the correct size urinary catheter was inserted in accordance with the physician's order. The last physician order related to Foley catheter size in the evidence before me is the order of February 22, 2008, which required an 18 French Foley catheter with a 30 cc bulb. P. Exs. 16, at 3; 21, at 3. The nurse's note dated March 4, 2008 at 3:44 a.m. shows that LPN Hewitt could not insert a Foley catheter for Resident 14 as he requested, because she had no Foley available in the correct size. P. Ex. 13, at 46. The evidence does show that a Foley was inserted around 5:45 a.m. on March 4, 2008, but the size is not reflected in LPN Coughlin's nurse's note (P. Ex. 13, at 47), and she did not specify the size of the Foley in her testimony. Petitioner has not presented any competent evidence to overcome the inference triggered by its clinical record that a Foley of an incorrect size was inserted around 5:45 a.m. on March 4, 2008.

I conclude that Petitioner failed to deliver necessary care and services to Resident 14 on March 3 to 6, 2008, a violation of 42 C.F.R. § 483.25. Therefore, the issue is whether or not the violation amounted to substantial noncompliance, i.e., whether it posed a risk for more than minimal harm to Resident 14 or any other resident. The surveyors alleged in the SOD that there was immediate jeopardy, because Resident 14 suffered a urethral perforation that resulted in a scrotal abscess and

surgical removal of his testes.[14] P. Ex. 1, at 3-4. However, CMS does not advance that theory before me. CMS correctly states that 42 C.F.R. § 498.60(c)(2) provides that the CMS determination of the level of noncompliance must be upheld, unless it is clearly erroneous. CMS Post-Hearing Brief (CMS Br.) at 3. CMS also correctly states that prior decisions of the Board have found it appropriate to require CMS to make a *prima facie* showing that a facility is not in substantial compliance with program participation requirements. CMS Br. at 4. To make a *prima facie* showing that a facility is not in substantial compliance, CMS must show not only that a facility violated a statutory or regulatory participation requirement but also that the violation had the potential to cause more than minimal harm to one or more residents. 42 C.F.R. § 488.301. CMS argues that it has presented evidence from which one could reasonably conclude that there was immediate jeopardy. CMS Br. at 24. But CMS conceded at hearing that it does not proceed upon a theory that Petitioner caused Resident 14's urethral tear. CMS points to the speculation of its expert that the urethral tear could have occurred during the cystoscopy or when the resident attempted to self-catheterize on March 3. CMS Br. at 20. But I find that speculation not credible given the expert's lack of credentials in urology and the fact that a urethral tear at those times is obviously inconsistent with the credible and weighty testimony that such a tear would cause extreme pain and observable blood in the urine, neither of which was present on March 3, 2008. CMS asserts that the various failings of Petitioner posed immediate jeopardy, but CMS fails to point to any credible evidence that any of the failures of Petitioner posed a risk for serious injury, harm, impairment, or death. CMS Br. at 25-28. CMS's assertions are no substitute for competent evidence, and CMS's assertions are an inadequate basis to find immediate jeopardy. I conclude that the determination of immediate jeopardy was clearly erroneous. However, I also conclude that the evidence shows that Resident 14 and the other nine residents with indwelling catheters were at risk for more than minimal harm as alleged by the surveyors in the SOD. P. Ex. 1, at 4. The evidence does not support a conclusion that Resident 14 was subject to serious injury, harm, impairment, or death based upon the specific violations that I have found. The evidence shows that Resident 14 did receive medication for pain. The evidence also shows that Resident 14 did receive a Foley catheter after a delay of a couple hours. While Resident 14 may have experienced

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[14] Petitioner argues that CMS is bound by the recommendation of the informal dispute resolution (IDR) process that the scope and severity finding of the surveyors should be reduced from immediate jeopardy to a potential for more than minimal harm. Petitioner's Post-Hearing Brief (P. Br.) at 4, 25-27; P. Ex. 4. CMS argues that the state never adopted the recommendation of the impartial decision-maker, and CMS had no reason to specifically reject the decision. Immediate jeopardy is not an issue because the amount of the PICMP is not affected by the immediate jeopardy determination, and Petitioner has no right to review of a scope and severity determination when a PICMP has been imposed. CMS Reply Brief (CMS Reply). Petitioner's argument is mooted by my decision. I agree with CMS that Petitioner is not entitled to review of a scope and severity determination in this case. However, it is necessary to determine whether there was a potential for more than minimal harm to determine whether or not Petitioner was in substantial compliance with program participation requirements. It is also necessary for me to make a determination as to the severity of any deficiency for purposes of fulfilling my regulatory duty to make a de novo determination of the reasonableness of the proposed enforcement remedy.

discomfort while waiting for his pain medication to take effect or for his Foley to be inserted to relieve his bladder, I do not conclude that the discomfort amounted to actual harm. However, I do conclude, based upon the surveyor's opinion as expressed in the SOD, that the failure to properly assess a resident following return from a procedure, such as a cystoscopy, and to monitor for signs and symptoms of complications poses the risk for more than minimal harm due to the potential for complications, such as excessive bleeding or infection related to such a procedure.

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.25, and the violation posed a risk for more than minimal harm to Resident 14 and nine other similarly situated residents.

3. There is a basis for the imposition of an enforcement remedy.

4. A $6,000 PICMP is not reasonable in this case.

5. A $3,000 PICMP is reasonable in this case.

I have concluded that Petitioner violated 42 C.F.R. § 483.25 and that the violation posed a risk for more than minimal harm to one or more facility residents. If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a per day CMP for the number of days that the facility is not in compliance or a PICMP for each instance that a facility is not in substantial compliance, whether or not the deficiencies pose immediate jeopardy. 42 C.F.R. § 488.430(a). The minimum amount for a PICMP is $1,000 and the maximum is $10,000. 42 C.F.R. § 488.438(a)(2). I conclude that there is a basis to impose a PICMP in this case.

If I conclude, as I have in this case, that there is a basis for the imposition of an enforcement remedy and the remedy proposed is a CMP, my authority to review the reasonableness of the CMP is limited by 42 C.F.R. § 488.438(e). The limitations are: (1) I may not set the CMP at zero or reduce it to zero; (2) I may not review the exercise of discretion by CMS in selecting to impose a CMP; and (3) I may only consider the factors specified by 42 C.F.R. § 488.438(f) when determining the reasonableness of the CMP amount. In determining whether the amount of a CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies based upon the factors set forth at 42 C.F.R. § 488.404(b) (the same factors CMS and/or the state were to consider when setting the CMP amount); and (4) the facility's degree of culpability, including but not limited to the facility's neglect, indifference, or disregard for resident care, comfort, and safety; the absence of culpability is not a mitigating factor. The factors that CMS and the state were required to consider when setting the CMP amount and that I am required to consider when assessing the reasonableness of the amount are set forth in 42 C.F.R. § 488.404(b): (1) whether the deficiencies caused no actual harm but had the potential for minimal harm; no actual harm with the potential for more than minimal harm, but not immediate jeopardy; actual harm that is not immediate jeopardy; or immediate jeopardy to resident health and safety; and (2) whether the deficiencies are isolated, constitute a pattern, or are widespread. My review of the reasonableness of the CMP

is *de novo* and based upon the evidence in the record before me. I am not bound to defer to the CMS determination of the amount of the CMP to impose, but my authority is limited by regulation as already explained. I am to determine whether the amount of any CMP proposed is within reasonable bounds considering the purpose of the Act and regulations. *Emerald Oaks*, DAB No. 1800 at 10 (2001); *CarePlex of Silver Spring*, DAB No. 1683 at 14–16 (1999); *Capitol Hill Community Rehab. and Specialty Care Ctr.*, DAB No. 1629 (1997).

I have received no evidence that Petitioner had a history of noncompliance. I have also received no evidence that Petitioner is unable to pay a PICMP. I do conclude that Petitioner's violation was serious and that Petitioner was culpable for disregarding the post-operative instructions of Resident 14 for several hours after his return to the facility on March 3, 2008. The evidence shows that Petitioner's deficiency posed a risk for more than minimal harm to Resident 14 and other residents. However, as already discussed, I do not find that Resident 14 or any other resident suffered actual harm due to the deficiency. I also do not find, based on evidence before me, that there was a risk for serious injury, harm, impairment, or the death of a resident due to the deficiency. I further conclude that the evidence shows only one deficiency based upon the case of Resident 14, and, therefore, it was an isolated occurrence. The state agency and CMS selected to impose a CMP, a decision I have no authority to review. However, the reasonableness of the amount of the CMP must be reviewed. The state agency and CMS determined that $6,000 was a reasonable PICMP. However, pursuant to 42 C.F.R. § 488.404(b), CMS and the state were required to consider that the deficiency posed immediate jeopardy, the severity determination at the time. Upon my review, I have found that there was no immediate jeopardy or actual harm. I conclude in this case, in the absence of actual harm or immediate jeopardy, that a $6,000 PICMP is not reasonable based upon the evidence before me. Rather, considering the purpose for imposing enforcement remedies under the Act and regulations, I conclude that a PICMP of $3,000 is sufficient to encourage Petitioner's prompt return to substantial compliance.[15]

6. The burden of persuasion does not affect the outcome of this case.

7. Review of the reasonableness of the proposed enforcement remedy was de novo and review of how CMS considered the regulatory factors when proposing an enforcement remedy is not relevant to my review.

Petitioner attempts to preserve two additional issues for appeal in its June 17, 2008 request for hearing. Petitioner argues that the allocation of the burden of persuasion in this case according to the rationale of the Board in the prior decisions cited above violates the Administrative Procedures Act, 5 U.S.C. § 551 *et. seq.*, specifically 5 U.S.C.

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[15] Petitioner briefly discusses the CMS "Five Star Quality Rating System." Petitioner's Post-Hearing Reply at 19. Petitioner does not argue that I have jurisdiction to review CMS decisions under that system. Rather, it appears that Petitioner is simply attempting to preserve an issue for any subsequent appeal.

§ 556(d). P. Br. at 15-17. Because the evidence is not in equipoise, the burden of persuasion did not affect my decision, and Petitioner suffered no prejudice.

Petitioner also argues that the Medicare Act is violated, and Petitioner is deprived of due process if CMS is not required to submit evidence to prove it considered the regulatory criteria established by 42 C.F.R. §§ 488.404 and 488.438(f). Petitioner's Hearing Request. As discussed above, my review of the reasonableness of the enforcement remedy is a *de novo* review of the evidence related to the regulatory factors. I am not permitted and have no authority to review the choice of a PICMP, and I have no need to consider whether CMS properly evaluated the regulatory factors. Petitioner does not clearly state what prejudice it may have suffered, and I perceive none.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner violated 42 C.F.R. § 483.25 and that a PICMP of $3,000 is reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge