Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Heritage House of Marshall Health & Rehabilitation Center,
(CCN: 67-6187),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-11-809

Decision No. CR2902

Date: August 22, 2013

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) that Petitioner, Heritage House of Marshall Health & Rehabilitation Center, was not in substantial compliance with Medicare program participation requirements. I also sustain CMS's imposition of civil money penalties (CMPs), in the amount of $700 per day from April 12, 2011 through June 15, 2011, for a total CMP of $45,500.

I. Background

The Social Security Act (Act) sets forth requirements for participation of a long-term care facility in the Medicare program as a skilled nursing facility and the Medicaid program as a nursing facility and authorizes the Secretary of Health and Human Services (Secretary) to promulgate regulations implementing those statutory provisions. Act §§ 1819, 1919. The Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare program, a skilled nursing facility must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

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

In this case, surveyors from the Texas Department of Aging and Disability Services (state agency) completed a recertification and complaint survey on May 26, 2011. CMS Ex. 2. Based on their findings, CMS determined that the facility was not in substantial compliance with multiple programs requirements, specifically:[1]

- 42 C.F.R. § 483.10(b)(11) (Tag F157 – notify of changes), at scope and severity level H ;
- 42 C.F.R. § 483.25(c) (Tag F314 – pressure sores), at scope and severity level H;
- 42 C.F.R. § 483.25(g)(2) (Tag F322 –naso-gastric feeding), at scope and severity level E;
- 42 C.F.R. § 483.65 (Tag F441 – infection control), at scope and severity level E;
- 42 C.F.R. § 483.75(f) (Tag F498 – nurse aide competency), at scope and severity level E; and
- 42 C.F.R. 483.75(j)(2)(ii) (Tag F505 – promptly notify physician of lab results), at scope and severity level E.

CMS Ex. 2.

CMS imposed against the facility CMPs of $700 per day for 65 days beginning April 12, 2011 and continuing through June 15, 2011 for a total penalty of $45,500. July 28, 2011 CMS Notice Letter.

[1] At the hearing, CMS removed the deficiency citations for 42 C.F.R. § 483.25(a)(3) (Tag F312 – care provided for dependent residents), at scope and severity level E and 42 C.F.R. § 483.25(d) (Tag F315 – no catheterization), at scope and severity level E. Tr. at 279, 289.

Petitioner timely requested review. I conducted a hearing in this matter on June 18 through June 20, 2012, in Dallas, Texas, and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS Exhibits (Exs.) 1 through 22, which were admitted. Petitioner offered P. Exs. 1 through 44. I admitted P. Exs. 1-37 and P. Ex. 42 and 43. Tr. at 749. P. Ex. 44 was withdrawn. I did not admit P. Exs. 38-41. Tr. at 749.

CMS called two witnesses: Jennifer Wood, RN, and Pernishia Hunt, RN. Petitioner called Jackie Stephens, Corporate Nurse Consultant for Petitioner, Pearl Merritt, RN, MSN, Ed.D, as an expert witness, and Dr. Kim Barbolla, Medical Director for Petitioner. The parties filed post-hearing briefs (CMS Br. and P. Br.) and post-hearing reply briefs (CMS Reply and P. Reply).

II. Analysis

A. Issues

Whether Petitioner failed to comply substantially with the Medicare requirements.

Whether the CMP of $700 per day for the period of April 12 through June 15, 2011, for a total CMP of $45,500, is reasonable.

B. Factual background

Resident 1

Resident 1, a 91-year old female, had documented diagnoses of pressure ulcers, urinary tract infections, Alzheimer's disease, Clostridium difficile (*C. Diff.*)[2], muscle weakness, and dementia with behavioral disturbances. CMS Ex. 4 at 1, 2; Tr. 190. She was totally dependent for activities of daily living and was on hospice. Resident 1 had many pressure sores, was on a feeding tube, bedfast and required total assistance. CMS Ex. 16 at 3; Tr. 190-91. *C. Diff*. is very contagious and requires contact isolation. Tr. 192. She had an isolation card in her room indicating that contact precautions should be used for her. Tr. 190. Her *C. Diff*. infection began before January 2011 and she was on contact

[2] Clostridium difficile or *C. Diff*. is highly contagious and is a multi-drug resistant organism. It is an anaerobic bacteria that can produce spores. If the resident has diarrhea, large numbers of *C. Diff*. will be released. *C. Diff*. [italicized] can survive in spore form for 6 months. CMS Br. at 3, n.1; State Operations Manual (SOM), CMS Pub. 100-07, App. PP, F411, § 483.65, Infection Control. *C. Diff* [italicized] can cause watery loose diarrhea. Tr. 196.

precautions[3] since January 2011. CMS Ex. 16 at 16; Tr. 191; CMS Ex. 4 at 96; Tr. 194. Resident 1 was always incontinent and known to smear feces and scratch herself frequently. CMS Ex. 4 at 92, 99, 101. Her care plan placed her on standard precautions and contact isolation; staff was to dispose of biohazards in her room. CMS Ex. 4 at 7; Tr. 191, 194. Under the facility's policies for infection control, "standard precautions" required staff to "wear gown to protect skin and clothing during procedures and resident care that are likely to generate splashes or sprays of blood, body fluids, secretions or excretions." CMS Ex. 20 at 13; Tr. 194. The surveyor observed at least four staff provide care to Resident 1 without wearing isolation gowns. Tr. 191, 195. The Licensed Vocational Nurse (LVN) did not wear a gown, but wore just gloves. CMS Ex. 16 at 12. She told the surveyor that the facility did not have any gowns. Tr. 195. The hospice nurse also did not wear a gown. CMS Ex. 16 at 16. A Certified Nursing Assistant (CNA) who had been working at the facility for almost seven months told the surveyor that she had never seen yellow paper gowns. CMS. Ex. 16 at 27; Tr. 195. The CNA said that she put on a regular hospital gown because she did not want to be touched by Resident 1 because of the Resident's habit of smearing feces. The Assistant Director of Nursing (ADON) and the Director of Nursing (DON) told the surveyor that staff could wear regular hospital gowns. CMS Ex. 16 at 29; Tr. 195. The surveyor testified that regular cloth hospital gowns are insufficient as PPE because they can be saturated. Tr. 196. Since this Resident was known to smear feces, if the staff did not wear PPE and they touched something with infectious material, that infectious material could be easily transferred to another resident. Tr. 193. The surveyor testified that the facility therefore needed to provide staff with proper training and appropriate PPE, specifically proper isolation gowns which do not permit blood or other potentially infectious material to pass through to or reach the employee's work clothes, undergarments, skin, eyes, mouth or other mucous membranes. Failure to follow proper infection control techniques could result in the indirect transmission of infection to other residents. Tr. 196.

Resident 2

Resident 2 entered the facility on June 21, 2010. CMS Ex. 5 at 133. Tr. 55. Resident 2 developed a new hip wound as of February 25, 2011. CMS Ex. 5 at 1; Tr. 56. On February 28, 2011, her physician ordered that her wound dressing should be changed every three days. CMS Ex. 5 at 10. Her care plan dated March 24, 2011, required physician notification of any signs or symptoms of skin breakdown. The care plan also

[3] Any resident who is a contact transmission risk requires the use of contact precautions to prevent infections that are spread by person-to-person contact. Contact precautions require the use of appropriate personal protective equipment (PPE) (a variety of barriers used alone or in combination to protect mucous membranes, skin, and clothing from contact with infectious agents), including a gown and gloves upon entering the contact precaution room. Prior to leaving the contact precaution room, the PPE is removed and hand hygiene is performed. SOM App. PP, F441, § 483.65.

provided for weekly skin assessments by a nurse and required that these skin assessments must be documented. CMS Ex. 5 at 94. Her care plan had as a stated goal that her hip wound should exhibit "progressive healing." CMS Ex. 5 at 97. A weekly skin assessment dated April 12, 2011, reflected that her hip wound had deteriorated and at that point included "green necrotic tissue." CMS Ex. 5 at 41; Tr. 58. There is no documentation in Resident 2's medical records indicating that her physician was notified of the April 12 change. CMS Ex. 5 at 82; Tr. 58, 733 and 734. On April 12, 2011, the hip wound measured 24 cubic centimeters. CMS Ex. 5 at 41. On April 20, 2011, staff did not perform her scheduled dressing change. CMS Ex. 5 at 38. Her pressure ulcer risk assessment dated April 21, 2011 indicated that she was at high risk for pressure sores with a total score of 12. CMS Ex. 5 at 55. Again, her dressing was not changed as scheduled on April 26, 2011 and April 29, 2011. CMS Ex. 5 at 38. And records indicate that staff performed only one weekly body audit on Resident 2 during the month of April. CMS Ex. 5 at 41. Resident 2's pressure ulcer risk assessment proceeded to decline to a score of 11 for the assessments performed on May 6, 2011, May 13, 2011, and May 20, 2011. CMS Ex. 5 at 52, 54, 55. The weekly skin assessment dated May 1, 2011, documented further deterioration, noting that her wound had a "foul odor" and 2.8 centimeters of undermining. CMS Ex. 5 at 42; Tr. 59. The facility did not notify the physician. Tr. 60. On May 1, 2011, the hip wound measured 33.66 cubic centimeters. CMS Ex. 5 at 42. On May 19, 2011, Resident 2's hip wound measured 40 cubic centimeters and had two undermining instead of one. CMS Ex. 5 at 79; Tr. 60. A staff member told the surveyor that the wound still had an odor as of May 19, 2011, but that she did not notify the physician. CMS Ex. 19 at 13; Tr. 61. Records show that only two weekly body audits were performed on Resident 2 during the month of May. CMS Ex. 5 at 42. The surveyors discovered a new sore on Resident 2's heel on May 23, 2011. CMS Ex. 19 at 26; Tr. 64, 65. From May 23 through May 25, 2011, at least six staff members admitted to the surveyors that they did not notify the physician of changes to Resident 2's wounds. CMS Ex. 19 at 5, 6, 12, 13, 15, and 17; Tr. 61, 63, 66 and 67. The facility finally cleaned Resident 2's hip wound thoroughly, started the Resident on antibiotic, and changed the treatment regimen on May 23-24, 2011. CMS Ex. 5, at 25, and 218; Tr. 72. The facility transferred Resident 2 to the emergency room on May 24, 2011 for a "possible wound infection and to rule out sepsis." CMS Ex. 5 at 216.

Resident 4

Resident 4's care plan dated May 9, 2011 noted that the head of her bed was to be kept at 35 degrees during tube feeding to prevent aspiration. CMS Ex. 7 at 20. On May 23, 2011, the surveyor observed the CNA lowering the head of Resident 4's bed to a flat position while the tube feeding was infusing. CMS Ex. 17 at 13. The CNA told the surveyor on May 26, 2011, that the nurse normally turned off the feeding-tube pump before the head of the bed was lowered for care. CMS Ex. 17 at 20. There were six other residents in the facility who also received tube feedings. CMS Ex. 2 at 92.

Resident 6

A laboratory report for a stool sample collected May 12, 2011, noted a positive result for *C. Diff.* for Resident 6. CMS Ex. 9 at 1. There was no care plan addressing Resident 6's *C. Diff.* or isolation precautions, nor was there a sign or notice on Resident 6's door warning that precautions were required before entering the room. CMS Ex. 18 at 4. Gowns were not available and only gloves were used when the staff cared for Resident 6. CMS Ex. 18 at 4, 7. On May 23, 2011, the DON told the surveyor that any resident on contact isolation should have a sign on the door to alert staff and visitors to use precautions. CMS Ex. 18 at 11. The DON stated that protective gowns should have been made available for the staff. CMS Ex. 18 at 11.

Resident 8

The surveyor observed Resident 8 at 9:06 am on May 23, 2011, in bed on her right side. CMS Ex. 16 at 1. The feeding pump alarm was sounding, the head of the bed was elevated, and there was a urine odor. Tr. 197. Resident 8 was 84 years old and suffered from hypertension, Alzheimer's disease, reflux irregularity, and urinary tract infection. CMS Ex. 10. She was non-verbal and required total care. CMS Ex. 16 at 1; CMS Ex. 10 at 4. The surveyor observed staff perform incontinent care on Resident 8. CMS Ex. 16 at 7; Tr. 199. The surveyor observed that Resident 8 was saturated in urine. The CNA lowered Resident 8's bed and head in order to perform the incontinent care while the tube feeding was infusing. CMS Ex. 16 at 7, Tr. 199. After the surveyor intervened, the CNA turned the feeding pump to "hold." Tr. 199. The facility's incontinent care and G-tube policies both state that a caregiver should not lower a G-tube feeding patient's head below 30 degrees until 30 minutes after infusing. CMS Ex. 20 at 1, 4; Tr. 200, 201. Both the CNA and the DON told the surveyor that the CNA should not have turned the pump to "hold" or lowered the Resident's head; to do so put her at risk for aspiration. CMS Ex. 16 at 20; Tr. 201. The surveyor also observed that the CNA did not properly perform incontinent care on Resident 8 as she did not separate and clean the labia or change her gloves before touching a clean item. Tr. 202, 203. On May 12, 2011, urine samples for this Resident were collected, sent to the lab, and the results reported back to the facility. CMS Ex. 10 at 7, 3. The lab results were communicated to the physician who placed a telephone order for Cipro on May 13, 2011 for the Resident. CMS Ex. 10 at 3. Resident 8 was on Cipro from May 13 to May 19, 2011. CMS Ex. 10 at 11; Tr. 205.
A May 14, 2011 lab report indicated that Resident 8 had *E. coli* in her urine which was resistant to the Cipro she was prescribed. CMS Ex. 10 at 9; Tr. 205. Resident 8 was not prescribed any other antibiotics between May 19 and May 24, 2011. The surveyor talked to the LVN on May 24, 2011 about the need to do a recheck urine sample for this Resident. The LVN admitted to the surveyor that she did not look back to see if the

bacteria was resistant to the medication prescribed. The LVN told the surveyor that if she had looked back she would have faxed the results to the physician. Tr. 206. The facility did not do a recheck until May 24, 2011. CMS Ex. 10 at 5; CMS Ex. 16 at 19. The new labs showed Resident 8 still had bacteria in her urine. CMS Ex. 10 at 5; Tr. 206.

Resident 13

Resident 13 was a 51-year-old female with diagnoses of a cerebrovascular accident, unable to perform activities of daily living, verbally abusive to staff, psychiatric problems, delusional and incontinent. CMS Ex. 13 at 32, 38, 37; Tr. 208. During incontinent care, the surveyor observed the following errors: CNA J used only a wet wash cloth with no soap; she did not wipe the Resident's labial area; the CNA removed her gloves, left the room to get a clean pad, and did not wash her hands before leaving or after returning to the room; she rolled Resident 13 over and CNA Q wiped the Resident from back to front with a dry cloth and did not separate the buttocks to clean the anal area; and CNA J did not clean the Resident's buttocks or thighs. The ADON acknowledged that a resident's labia should be separated when performing incontinent care, that wiping from back to front is improper, and that the staff should know to change gloves. CMS Ex. 16 at 8; Tr. 209.

At the time of the survey, 54 residents were incontinent.

C. Findings of Fact and Conclusions of Law

1. Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(c) (Tag F 314) relating to the prevention of pressure sores and the necessary treatment and services to promote the healing of pressure sores and the prevention of infection.

Program requirements. The introductory language in section 483.25 states: "Each resident must receive, and the facility must provide, the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care."

Subsection (c) of 483.25 specifies:

> Pressure sores. Based on the comprehensive assessment of a resident, the facility must ensure that-
> (1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and
> (2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

42 C.F.R. § 483.25(c). The Board has well-established the application of this pressure sore regulation. Citing the Secretary's refusal to replace the word "ensure" with less demanding language, the Board has held that a facility "should go beyond merely what seems reasonable to, instead, always furnish what is necessary to prevent new sores unless clinically unavoidable, and to treat existing ones as needed." *Koester Pavilion*, DAB No. 1750, at 32 (2000) (citing 56 Fed. Reg. 48,826, at 48,850 (Sept. 26, 1991)); *see also Clermont Nursing & Convalescent Ctr*., DAB No. 1923, at 9-10 (2004)(citing *Koester* and rejecting provider's argument that a "standard of necessity appears nowhere in the regulation"), *aff'd*, *Clermont Nursing & Convalescent Ctr. v. Leavitt*, 142 F. App'x 900 (6th Cir. 2005). Also, simply because a resident's clinical condition may mean that the development of pressures sores is unavoidable does not relieve the facility from the second prong requirement of the regulation; it must ensure that any resident that has pressure sores receives the necessary treatment and services to promote the healing of the sores, to prevent infection of the sores and to prevent new sores from developing. *Woodland Village Nursing Ctr.*, DAB No. 2172 at 12 (2008); *Golden Living Ctr. – Truesville*, DAB CR2634 at 6 (2012). Thus, Petitioner cannot merely claim unavoidability. Even if the development of the sore was unavoidable due to the resident's clinical condition, the facility still must show that it furnished all necessary treatment and services to promote the healing of the acquired sore and to prevent infection. *Id.* Moreover, merely because a resident has elected hospice care does not mean that the facility is absolved from complying with Medicare requirements including the prevention and treatment of pressure sores. A facility "cannot meet its burden of proof on the issue of whether a pressure sore is unavoidable merely by establishing that the resident's clinical condition heightens the risk that pressure sores will develop." *Ivy Woods Health Care and Rehab. Ctr.*, DAB No. 1933 at 9 (2004).

Whether it was clinically unavoidable or not, Resident 2 developed, according to the hospice interdisciplinary notes, a new unstageable pressure sore with blackened eschar to her the right hip. The note documenting this new sore is dated February 25, 2011 and the record shows a physician's order, dated February 28, 2011, directing the facility to apply wound gel to the sore, to cover with Mepilex dressing and to change that dressing every three days and as needed. CMS Ex. 5 at 1, 10. Resident 2's comprehensive care plan required, among other things, physician notification of any signs or symptoms of skin breakdown, the performance of documented weekly skin assessments by a nurse, completion of weekly skin grids to document the location, staging, size, any exudates, and wound bed for each wound. CMS Ex. 5 at 94, 95, 97. The stated goal of her plan was for progressive healing of the hip wound. CMS Ex. 5 at 97.

The contemporaneous documentary evidence shows that Petitioner failed to follow the physician's specific orders and failed to follow the directives of the Resident's comprehensive care plan. It is undisputed that Petitioner did not change Resident 2's dressing every three days as directed by the physician's order; Petitioner failed to change

the dressing on April 20, April 26, and April 29, 2011. CMS Ex. 5 at 38. The facility performed only one weekly body audit (on April 12, 2011) for the Resident for the entire month of April and two weekly body audits (on May 1 and May 17, 2011) for the month of May even though the comprehensive care plan required weekly body audits to be performed by a licensed nurse and to be documented. CMS Ex. 5 at 41, 42, 94, 95. The facility only had documentation of weekly skin grids titled Weekly Pressure Ulcer Record for the wound to the right hip for May 2 and May 9, 2011. P. Ex. 6 at 1-2; CMS Ex. 5 at 45-6. And, Resident 2's records further establish that this new wound to her right hip, discovered on February 25, 2011, changed in size and characteristics over the course of 41 days, yet there is no evidence that the facility contacted Resident 2's physician as provided for in her care plan. CMS Ex. 5 at 95. The evidence shows that initially Resident 2's hip was documented as "unstageable" according to the March 24, 2011 care plan, but the "Weekly Body Audit" of the right hip wound on April 12, 2011 measures the wound at 2.4 cm depth by 2.5 cm length and 4 cm width with green necrotic tissue to the wound bed. CMS Ex. 5 at 41. On May 1, 2011, the skin assessment then indicates the wound is 3.4 cm long and 4.5 cm wide with 2.2 and 2.8 cm undermining with a moderate amount of greenish slough and foul odor.[4] CMS Ex. 5 at 42. The only other weekly assessment by the facility documenting this wound is dated May 17, 2011, and it contains no measurements, staging, or description of any exudates or of the wound bed. However, a May 19, 2011 Hospice Interdisciplinary Visit Note indicates that the wound at that point measured 4 cm by 4cm with a depth of 2.5 cm and had undermining

[4] Petitioner contends that the weekly assessments for this time period confirm that no odor was present, yet the medical records indicate otherwise. I can only surmise that Petitioner is referring to the Weekly Pressure Ulcer Record for the dates May 2 and May 9 which indicate that no odor was present. P. Ex. 6 at 1. However, this document directly contradicts Petitioner's other records, its Weekly Body Audit, dated May 1, 2011, as well as a Nurse's note from the Hospice Nurse on May 19, 2011 indicating there was an odor. I must say that I find Petitioner's brief somewhat disingenuous. As an example, Petitioner makes a broad statement that skin assessments were done weekly in accordance with the care plan and cites to three exhibits, P. Exs. 6, 15, 11, without citation to specific page numbers. However, these exhibits do not support the statement made. P. Exs. 11 and 15 are the Hospice Plan of Care and the plan of care from the facility for Resident 2; while these documents outline what should be done for the patient with respect to her skin integrity they do not document that the care is or was actually given. As for P. Ex. 6, this exhibit by no means supports the statement that the facility performed weekly assessments as directed by the care plan for the period of March 24 through May 23, 2011. I note that I have found several other statements made in its brief contending that exhibits support the assertion made where, again, no page number is cited, but the reference given is the exhibit number only, and upon poring through the exhibit, I do not find that the exhibit actually fully supports the assertion made by Petitioner. For example, there is no indication in P. Exs. 5 and 33 that either Dr. Barbolla or her physician's assistant saw Resident 2 on May 23.

in two locations. The hospice nurse also noted that there was a foul odor and yellow drainage on dressing. P. Ex. 7 at 10. There is no documentation in the record that at any time during the period of March 24 through May 19, 2011 the physician was notified and consulted regarding the changes to this wound as directed by the Resident's care plan. In any event, the surveyor observed the wound herself on May 23, 2011. She also observed an open area on Resident 2's right heel that the LVN said was new. CMS Ex. 2 at 24; Tr. 62. The surveyor testified that immediately upon entering the room there was a noticeable odor which the nurse confirmed was from the hip wound. The odor was so bad that the Resident used her hospital gown to cover her nose. CMS Ex. 2 at 25; Tr. 62. The fact that odor was detected on May 1 and then again on May 19, and that the physician was not notified of this until the surveyor detected it during the survey on May 23, 2011 and insisted that the physician be consulted, is particularly egregious. Whether the wound was finally determined to be infected or not, there is absolutely no reason why the doctor was not informed and consulted regarding this change. It is of primary importance in dealing with pressure sores and wounds that the wounds be accurately documented on an ongoing basis and that any changes or worsening to the wound be reported to the physician immediately so that the physician can make an informed determination as to whether the current course of treatment should be continued or whether new or additional treatments should be ordered.

The failures by Petitioner here in following the physician's orders for treating and changing the wound dressing, as well as its failures to follow the specific care plan interventions amply establishes that Petitioner failed to substantially comply with the Medicare requirements. Also Petitioner cannot claim as an affirmative defense that Resident 2's pressure sores were unavoidable. *Woodland Village Nursing Ctr.*, DAB No. 2172 at 13. A facility cannot claim unavoidability as an affirmative defense unless it first demonstrates it furnished all necessary treatment and services and clearly that is not the case here where Petitioner failed to follow the specified care plan directives and interventions prescribed as well as the physician's orders for treatment and dressing changes.[5]

2. Petitioner was not in substantial compliance with 42 C.F.R. § 483.10(b)(11) (Tag F 157) which requires Petitioner to consult with the resident's physician when there is a significant change in the resident's status or there is a need to alter a resident's treatment.

Program requirement. Section 483.10(b)(11)(i) of 42 C.F.R. entitled, "Resident rights," requires:

[5] Since I find that Petitioner did not substantially comply with the requirements of 42 C.F.R. § 483.25(c) with respect to Resident 2, there is no need for me to consider whether Petitioner also failed to comply with respect to Resident 12.

> (11) Notification of changes. (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or an interested family member when there is—
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> * * * *
>
> (B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
> (C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or
> (D) A decision to transfer or discharge the resident from the facility as specified in Sec. 483.12(a).

The regulatory requirements are clearly stated, yet they are often misquoted and misconstrued. Among the resident rights recognized by the regulation is that the facility "**must immediately . . . consult with the resident's physician** . . . when there is a significant change in the resident's physical, mental, or psychosocial status" (meaning a deterioration in the resident's condition). 42 C.F.R. § 483.10(b)(11)(emphasis added). The requirement is not discretionary and it requires more than merely informing or notifying the physician, which is evident from the plain language of the regulation. The drafters chose the language carefully. The regulation is specific that the facility is **required immediately** to "**inform** the resident; **consult** the physician; and . . . **notify** the legal representative or an interested family member." *Id.* (emphasis added). The preamble to the final rule indicates the drafters' specific intention that the facility should "inform the resident of the changes that have occurred but should consult with the physician about actions that are needed." 56 Fed. Reg. 48,826, at 48,833 (Sept. 26, 1991). Thus, it is clear from the language of the regulation and its history that the requirement of the regulation to consult means more than to simply notify. *Magnolia Estates*, DAB No. 2228 (2009).

> Consultation requires a dialogue with and a responsive directive from the resident's physician as to what actions are needed; it is not enough to merely notify the physician of the resident's change in condition. Nor is it enough simply to leave just a message for the physician. Also, the facility must provide the physician with all the information necessary to properly assess any changes to the resident's condition and what course of action is necessary. Failure to provide even one aspect of the change in a resident's condition can significantly impact whether the physician has been properly consulted.

Id. at 9.

The regulation also requires consultation "immediately" upon discernment of a change in condition of the resident. The use of the term "immediately" in the regulatory requirement indicates that consultation is expected to be done as soon as the change is detected, without any intervening interval of time. It does not mean that the facility can wait hours or days before consulting with the physician. The preamble to the final rule indicates that originally the proposed rule would have granted the facility up to 24 hours in which to notify the resident's physician and the legal representative or family. However, after the drafters' receipt of comments pointing out that time is of the essence in such circumstances, the final rule amended that provision to require that the physician and legal representative or family be consulted/notified "immediately." 56 Fed. Reg. at 48,833. The point of using the word "immediately" was the drafters' recognition that in such situations a delay could result in a situation where a resident declines beyond recovery or dies. Furthermore, when the relative inconvenience to a physician and the facility staff to consult about a resident's change in condition is weighed against the possibility for dire consequences to the resident if the physician is not consulted, it seems that any inconvenience certainly is inconsequential and outweighed by the potential for significant harm if the facility fails to consult the physician.[6] This requirement is included in the regulation entitled "Resident rights" and the requirements of this specific regulation provide that every resident has the right to a dignified existence and access to and communication with persons and services inside and outside the facility. Therefore, the regulatory requirements clearly regard as inconsequential any inconvenience under the regulation to the resident's physician or to the facility staff when compared to the protection and facilitation of the rights of the resident. *See* 56 Fed. Reg. at 48,834.

The Board has found that this regulation "directs the facility to consult with the physician immediately not only where a resident's 'significant change' is in a 'life-threatening' condition, but also when the change involves non-emergency clinical complications such as the development of a stage II pressure sore . . . ." *The Laurels at Forest Glenn*, DAB No. 2182 at 12 (2008). The Board further determined that a physician's "awareness of a significant change does not discharge the facility's express obligation under section 438.10(b)(11)(i) to "consult" with the physician. *Stone Cnty Nursing & Rehab. Ctr.*, DAB No. 2276 at 10 (2009) affirmed the ALJ finding that a simple factual description of the pressure sore in the medical records without an indication that the physician was actually consulted on the matter or that he or she gave new treatment instructions, does

[6] It hardly needs emphasizing that it is better to err on the side of consulting a physician regarding a change in a resident's condition rather than not or debating about whether the change is significant, particularly since nursing home staff may not be qualified to identify the significance of signs and symptoms.

not constitute a valid consultation. *Stone Cnty Nursing & Rehab. Ctr*, CR1918 at 11-12 (2009). Moreover, compliance with the physician consultation requirement "is not contingent on how the physician might respond, but on the existence of facts requiring notification." *NHC Healthcare Athens*, DAB No. 2258 at 6-7 (2009).

Under this line of precedent, the fact that Resident 2's hip sore increased in size, its observed undermining, its noted drainage, and the remarkable presence of odor are all sufficient to constitute a "significant change" that triggers the physician consultation regulatory requirement. *See Laurels at Forest Glenn*, DAB No. 2182; *Antelope Valley Convalescent Hospital*, DAB CR511 (1997). I find no instance in Resident 2's medical records indicating that at any time the facility did notify, but, most importantly, did consult with Resident 2's physician regarding the status of the right hip wound. Actually, CMS correctly notes that the only documentation of any consultation between facility staff and the physician regarding Resident 2's right-hip sore occurred on the first days of the survey on May 23 and May 24, 2011, and apparently was prompted by the surveyor's concern. CMS Ex. 5 at 84, 218; P. Ex. 6 at 10-12. I would expect that given Resident 2's care plan which required the physician to be notified of any change to the Resident's skin, as well as the regulatory requirement that a physician be consulted of any significant changes, that the facility would have documented contacting her physician not only to inform the physician of the change to the status of Resident 2's right hip but also to determine from the physician whether the current treatment should be continued or whether new or additional treatments prescribed. I do not find that the after-the-fact claims by Resident 2's physician (that she was aware of Resident 2's condition or that she would not have changed the treatment) made after the survey and in response to the surveyors' findings to be as credible as documentation made contemporaneously with the events. Petitioner contends that Resident 2 was seen by the doctor or her physician's assistant on April 13, April 28, April 29, and May 10, 2011, yet the annual exam notes by the physician's assistant dated April 13, 2011 fail to mention the presence of even one pressure sore on this patient when she was known to have not only a Stage IV decubitus ulcer to her coccyx but also the wound to her right hip. *See* P. Ex. 6 at 15, 16. As CMS correctly pointed out, the fact that Resident 2's wound to her right hip increased in size as well as developed undermining, greenish discharge and odor was sufficient to constitute a "significant change" that should trigger the physician's consultation requirement under 42 C.F.R § 483.10(b)(11). *Antelope Valley Convalescent Hospital*, DAB CR511; *The Laurels at Forest Glenn*, DAB No. 2182 at 12; *Stone Cnty Nursing & Rehab. Ctr.*, DAB CR1918 at 11-12 (2009).

Petitioner's failure to consult immediately with the physician put Resident 2 in danger of more than minimal harm; certainly it meant that the physician did not have the ability to accurately monitor and assess whether the prescribed course of treatment worked. That left this Resident at risk for not only increased pain and discomfort due to the worsening condition of the wound but also at risk for other serious complications such as sepsis.

3. Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(g)(2) (Tag F 322 – Naso-Gastric Tube feeding).

Program requirement. The quality of care requirement specific to naso-gastric and gastronomy tube feeding provides:

> *Naso-gastric tubes:* Based on the comprehensive assessment of a resident, the facility must ensure that —
> (2) A resident who is fed by a naso-gastric or gastronomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and naso-pharyngeal ulcers and to restore, if possible, normal eating skills.

42 C.F.R. § 483.25(g)(2). During the survey, the surveyors observed two instances where residents who were being tube fed had the head of their beds lowered to a flat position by the CNA while they were being fed.

Resident 4's care plan dated May 9, 2011 stated that the head of this Resident's bed should be up at a 35 degree angle at all times to prevent her from aspirating. CMS Ex. 7 at 20. On May 23, 2011, the surveyor observed a CNA lower the head of Resident 4's bed to a flat position while the tube feeding was infusing. The surveyor also observed that same day a CNA lower the head of Resident 8's bed while her tube feeding was infusing. CMS Ex. 2 at 41-2; CMS Ex. 16 at 7. Petitioner's own stated policy for Tube Feeding provided that the head of the bed for a tube-feeding patient should be elevated to at least 30 degrees during the feedings and for at least 30 minutes after the feeding was been completed, unless the resident were on continuous feeding and then the head of the bed should be kept elevated at 30 degrees at all times. CMS Ex. 20 at 4. Although Petitioner stated in its closing brief that it would rely on its prior written briefing for this deficiency, there is no prior written briefing on this particular deficiency other than to state that Petitioner would provide testimony to demonstrate that the surveyor's citation of a deficiency has no regulatory basis because the facility provided proper care and services to the residents receiving parenteral nutrition. P. Prehearing Brief at 34. No such testimony was provided. In fact, Petitioner provided no evidence either testimonial or documentary to rebut the direct surveyor observations that staff placed two Residents in a flat position while they were being tube-fed despite the facility's own policies that this should never be done. By putting the Residents' head of bed in less than a 30 degree angle, Petitioner staff placed the Residents in risk of serious harm of aspirating the feeding formula. This failure not only placed these two Residents at risk for actual harm but also put any other resident who received tube feeding at risk because the CNA staff were not aware of these basic safety provisions applicable to tube feeding.

4. Petitioner was not in substantial compliance with 42 C.F.R. §483.65 (Tag F 441 - Infection Control).

Program requirement. The regulation provides that the facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection. 42 C.F.R. § 483.65. The surveyors determined that Petitioner failed to maintain an effective infection control program because it failed to ensure that five of six staff, including a LVN and four CNAs, wore appropriate personal protective equipment when they provided direct care for two Residents who were on contact isolation for *C. Diff.* infections and to ensure that staff and visitors were aware that those Residents were on contact isolation. CMS Ex. 2 at 45.

Resident 1 had *C. Diff.* and was on contact isolation. The surveyor observed her wound care and noted that the LVN who cleaned Resident 1's wounds wore gloves but not a protective gown. CMS Ex. 16 at 12. The LVN told the surveyor that the yellow disposable protective gowns were not available. *Id.* CNA H told the surveyor that she had never seen disposable isolation gowns at the facility but that she would put on a regular hospital gown so Resident 1 couldn't touch her because Resident 1 had feces under her nails . CMS Ex. 16 at 27. The DON and ADON similarly told the surveyor there were no disposable isolation gowns but that staff could wear regular hospital gowns. CMS Ex. 16 at 29

According to the SOM, Appendix PP, Tag F441, a facility's infection control practices are important for preventing the transmission of infections. The SOM further provides that infection control practices include two primary tiers: "Standard Precautions" and "Transmission-based Precautions." SOM, App. PP at 573.

According to the SOM, standard precautions are based upon the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes may contain transmissible infectious agents. *Id.* "Standard precautions are intended to be applied to the care of all persons in all healthcare settings, regardless of the suspected or confirmed presence of an infectious agent. Implementation of standard precautions constitutes the primary strategy for preventing healthcare-associated transmission of infectious agents among residents and healthcare personnel." *Id.*

Standard precautions

> include but are not limited to hand hygiene, safe injection practices, the proper use of PPE (e.g., gloves, gowns, and masks), resident placement, and care of the environment, textiles, and laundry. . . . In addition to proper hand hygiene, it is important for staff to use appropriate protective

> equipment [PPE] as a barrier to exposure to any body fluids (whether known to be infected or not). For example, in situations identified as appropriate, gloves and other equipment such as gowns and masks are to be used as necessary to control the spread of infections. Standard precautions are also intended to protect residents by ensuring that healthcare personnel do not carry infectious agents to residents on their hands or via equipment used during resident care.

Id.

Transmission-based precautions are used for residents who are known to be, or suspected of being, infected or colonized with infectious agents, including pathogens that require additional control measures to prevent transmission. SOM, App. PP at 575. The SOM also states that when transmission-based precautions are in place, PPE should not only be used but should be readily available. *Id.* at 576. The SOM also provides that "contact transmission risk" requires the use of contact precautions to prevent infections that are spread by person-to-person contact. "Contact precautions require the use of appropriate PPE, including a gown and gloves upon entering the contact precaution room. Prior to leaving the contact precaution room the PPE is removed and hand hygiene is performed."[7] SOM, App. PP at 576.

Here the facility had a policy for "Infection Control, Standard Precautions" that provided staff should "wear a gown to protect skin and prevent soiling of clothing during procedures and resident care activities that are likely to generate splashes or sprays of blood, body fluids, secretions or excretions" and that staff were to remove a soiled gown as promptly as possible and wash hands to avoid transfer of microorganisms to other residents or environments. CMS Ex. 20 at 13. Yet, as they were providing routine care to Resident 1, the surveyor observed five staff members who wore only gloves and no PPE gowns. This Resident was on isolation and contact precautions. She had *C. Diff.* which is highly transmittable; Resident 1 as a routine matter smeared her feces and often

[7] The SOM states that indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object and that the following are examples of opportunities for indirect contact: Clothing, uniforms, laboratory coats, or isolation gowns used as PPE may become contaminated with potential pathogens after care of a resident colonized or infected with an infectious agent, (e.g., MRSA, VRE, and Clostridium difficile). SOM, Appendix PP at 571. Yet, Petitioner's expert witness disagreed that indirect transmission of *C. Diff.* [italicized] could occur through clothing of a caregiver. Tr. 621. She also stated that only gloves were necessary in providing care to a resident such as Resident 1. I find overall then her testimony less than credible in light of these SOM provisions which state that indirect transmission of *C. Diff*. [italicized] is indeed a problem particularly where these SOM provisions are based in large part on CDC and other medical research into infection control.

had feces under her nails. Under these circumstances, it is highly likely that Resident 1 could reach out and touch the staff member providing care or their clothing or that fecal matter could be transferred unknowingly to the clothes of the staff member. It is this very type of situation that requires transmission-based precautions which would require the use of at least gowns and gloves. No such policy was provided; only a copy of the "standard precautions" policy was provided. And at no time did the surveyors observe that PPE gowns were used.

The surveyor found that even though lab results for Resident 6 noted a positive result for *C. Diff.* for this Resident from a sample collected on May 12, 2011, Resident 6's care plan failed to address her *C.Diff.* or to provide for isolation precautions for this Resident. Moreover, there was no sign on Resident 6's door indicating that any precautions were required before entering the room. Petitioner's own Infection Control Policy requires a sign informing visitors to please report to the Nurses' Station before entering the room. In this situation, where Resident 6 was now known to be infected by *C. Diff.* which requires particular control measures to prevent transmission, the SOM states that pertinent signage for isolation precautions is necessary to help minimize the transmission of the infection. SOM, App. PP at 575. Petitioner does not present any evidence that such signage was posted.

I therefore find that Petitioner has not rebutted CMS's prima facie case that Petitioner was not in substantial compliance with this requirement.

5. Petitioner was not in substantial compliance with 42 C.F.R. § 483.75(f) (Tag F 498 - Nurse Aide Competency).

Program requirement. This regulation provides—

> *Proficiency of Nurse aides.* The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

42 C.F.R. § 483.75(f). The surveyors found Petitioner deficient with this requirement after observing three CNAs providing care to the residents, particularly Residents 8 and 13. In this case, the surveyors found that Petitioner failed to ensure that its CNAs displayed competency in techniques of incontinent care. Petitioner argues that each of the aides observed providing improper care was certified by the State of Texas, had passed a written test together with a hands-on skills exam. Petitioner contends that even if the surveyor observed the aides incorrectly performing a task on one occasion that does not mean that it failed to meet this requirement. P. Br. at 27. Rather Petitioner contends that these lapses were isolated instances and in all likelihood the aides were nervous because the surveyors were watching them perform resident care tasks. Petitioner cites

my decision in *Mabee Health Care Center*, DAB CR2525 (2012) to support its arguments, but I find the circumstances here a little more problematic because there was a very real likelihood of harm. Moreover, incontinent care is not difficult to perform properly, yet the consequences of failure to follow appropriate protocols can easily result in urinary tract infections. Here Resident 8 was known to be prone to urinary tract infections; proper incontinent care therefore was critical. As for Resident 13, it is a basic of incontinent care to never wipe a female patient from back to front; to do so is to risk contamination. Nevertheless, CNAs were observed doing just that, as well committing five other errors during the incontinent care of Resident 13. Petitioner does not dispute the surveyor's observations, rather it merely claims that these actions did not cause harm to any resident. I disagree. These are basic skill sets and that fact that three CNAs were observed to be deficient in them is enough to support a finding that Petitioner was unable to ensure that its nurse aides demonstrated competency in skills and techniques necessary to care for residents' needs.

6. Petitioner was not in substantial compliance with 42 C.F.R. § 483.75(j)(2)(ii) (Tag F 505 - Promptly notify Physician of Lab Results)

Program requirement. This requirement provides that the facility must promptly notify the attending physician of laboratory findings. 42 C.F.R. § 483.75(j)(2)(ii). The surveyors found that Petitioner failed to promptly notify Resident 8's attending physician of her abnormal lab results. The first lab urine samples were drawn on May 12 and those results were communicated to the physician who called in an order for Cipro on May 13. CMS Ex. 10 at 3; Tr. 204. Resident 3 was prescribed to be on and was taking Cipro from May 13 through May 19, 2011. However, a May 14, 2011 lab report showed that she had *E. coli* in her urine that was resistant to Cipro. CMS Ex. 10 at 9. There is no evidence from the facility records reviewed by the surveyor that this lab report or its findings were sent or communicated to Resident 8's attending physician.[8] Moreover, Resident 8 was not prescribed any other antibiotic between May 19, when she finished the course of Cipro, to May 24, 2011, when the surveyor discovered and communicated the results to Petitioner's staff. Tr. 206; CMS Ex. 16 at 24. Petitioner then performed a recheck on May 24, 2011, and the new labs showed Resident 8 still had bacteria in her urine. CMS Ex. 10 at 5. As CMS stated, the failure to promptly notify Resident 8's physician of these lab results meant that a change in the course of treatment and the care plan for Resident 8 for this infection was significantly delayed: first, she was prescribed a useless antibiotic for a week; and then another week passed without any treatment whatsoever. Clearly, if

[8] I note that P. Ex. 32 at 3 appears to be a report from the lab regarding the *E.coli* and the resistant antibiotics. It has a stamp "Faxed" on it but there is no copy of the fax transmission record which typically is kept as proof of transmission. *See, e.g.*, CMS Ex. 10 at 6, which is a copy of the type of fax transmission report usually kept. Since the physician did not change Resident 8's prescription for Cipro, I can only surmise that this report was not in fact received by the physician.

the surveyor had not found the lab results in Resident 8's records, and questioned the staff about whether the results had been sent to her physician, Resident 8 would not have received the appropriate treatment for the infection at all. Petitioner does not dispute these facts other than to state that Petitioner faxed to the attending physician immediately upon its receipt of the results. P. Ex. 32. Even if it had been, Petitioner bears some responsibility when it did not receive an order to change the antibiotic for Resident 8 to again notify the physician to make sure the May 14 results had been received and to learn what course of treatment the physician wanted to pursue. This was not done. While Petitioner is dismissive in suggesting that there was no actual harm to the Resident as a result of this, I find that if a patient is prescribed an antibiotic which is meant to clear an infection and that the facility receives information that the antibiotic prescribed by the doctor is resistant against the particular infection, but does not inform the physician of this, there is actual harm to the resident because the infection is not treated.

7. The CMP of $700 per day for the period of April 12 through June 15, 2011, for a total CMP of $45,500, is reasonable.

I next consider whether the CMP is reasonable by applying the factors listed in 42 C.F.R. § 488.438(f): 1) the facility's history of noncompliance; 2) the facility's financial condition; 3) factors specified in 42 C.F.R. § 488.404; and 4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort, or safety. The absence of culpability is not a mitigating factor. The factors in 42 C.F.R. § 488.404 include: 1) the scope and severity of the deficiency; 2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

Unless a facility contends that a particular regulatory factor does not support the CMP amount, the ALJ must sustain it. *Coquina Ctr.*, DAB No. 1860 (2002). In its pre-hearing and post-hearing briefs, Petitioner simply argues that the CMP is not reasonable because it contends that "the facility's actions did not cause any resident harm." P. Pre-hearing Br. at 37; P. Br. at 28. Petitioner does not contest the length of time during which CMS imposed the CMP or claim that its financial condition affects its ability to pay.

I sustained each of the deficiencies cited here, and contrary to Petitioner's assertions, I do find that Petitioner's failures did result in actual harm to residents or posed a strong likelihood of actual harm. Taken as a whole, I find that the failures here support the $700 per day CMP imposed from April 12 through June 15, 2011.

I note that the $700 per day penalty is at the lower end of the lower range of penalties, which varies from $50 - $3,000. 42 C.F.R. § 488.438(a)(1)(ii). For the reasons set forth above, I find that the remedy imposed is reasonable.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner, Heritage House of Marshall Health & Rehabilitation Center, was not in substantial compliance with Medicare program requirements during the period at issue. I also sustain as reasonable CMS's imposition of a $700 per day CMP for the period of April 12, 2011 through June 15, 2011.

/s/
Richard J. Smith
Administrative Law Judge