OAH 5-0900-35128

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE DEPARTMENT OF HEALTH

In the Matter of the Independent Informal Dispute Resolution for Langton Place	**FINDINGS OF FACT, CONCLUSIONS OF LAW, AND RECOMMENDATIONS**

The above-entitled matter came before Administrative Law Judge Jim Mortenson for an independent informal dispute resolution (IIDR) hearing on May 1, 2018. The IIDR hearing took place at the Office of Administrative Hearings in St. Paul, Minnesota. The record closed on May 4, 2018, following submission of closing arguments.

Becky Wong, RN, Nursing Evaluator, represented the Minnesota Department of Health (Department).[1] Katherine B. Ilten, Fredrikson & Byron, P.A., represented Langton Place (Langton Place or Facility).

DISPUTED DEFICIENCY CITATION

The abbreviated standard survey, Case #H5389046, data prefix tag F323[2], scope and severity level G, was submitted to the Administrative Law Judge for consideration in this matter.

SUMMARY OF RECOMMENDATIONS

The Department issued a citation for two separate violations which, at the time the citation was issued, were represented by a single data prefix tag. The two violations must be represented by two citations even though the citations use the same tag, F323. The first deficiency tag F323 is for a violation of 42 C.F.R. § 483.25(d) (2017). The correct

[1] This matter may be a contested case, pursuant to Minn. Stat. § 144A.10, subd. 16(a) (2016). Contested cases are governed by Minn. R. 1400.5010 through .8400 (2017). *See* Minn. Stat. § 14.51 (2016). Minn. Stat. § 1400.5800 provides a party a right to counsel, or representation "by a person of their choice if not otherwise prohibited as the unauthorized practice of law." Thus, representation of the agency in a contested case by a non-attorney may run afoul of applicable rules. However, this matter may also be an arbitration. *See* Minn. Stat. § 144A.10, subd. 16. (2016). It is unclear whether Minn. R. 1400.5800 is applicable to an arbitration pursuant to Minn. Stat. § 14.57(b) (2016). Given this legal ambiguity, and the historical practice by the Department of Health to be represented by non-attorney agency staff in proceedings under Minn. Stat. § 144A.10, subd. 16, the Administrative Law Judge makes no recommendation about non-attorney representation, other than to say it is a questionable practice on behalf of the Department and non-attorney representative, which could run afoul of the Minnesota Bar.

[2] Data prefix tag F323 was changed to tag F689 (Free of Accident Hazards/Supervision/Devices) and tag F700 (Bedrails) effective November 28, 2017. *See* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes.html. Because the survey occurred before November 28, 2017, tag F323 will be referred to in this report.

severity of this citation is level J, immediate jeopardy. The Facility failed to ensure R1 was properly supervised or devices were in place to keep R1 free from accidental falls, a hazard R1 was susceptible to. As a result of this failure, R1 fell and died.

The second deficiency tag F323 is for a violation of 42 C.F.R. § 483.25(n)(1) and (2) (2017). The correct severity of this citation is level D, no actual harm with potential for more than minimal harm that is not immediate jeopardy. The Facility failed to properly assess R1's risk for entrapment in transfer bars prior to installing and using them, reviewing the risks with R1, and obtaining R1's informed consent prior to installation and use. It is not clear that had the risk assessment been completed, and the risk of using the bars shared with R1, that R1 would have declined to have the transfer bars in place and use them.

Based on the evidence submitted, the Administrative Law Judge makes the following:

FINDINGS OF FACT

I. R1

1. R1 was a 73-year-old person who, in January 2017, had a Watchman cardiac device surgically inserted, and received physical and occupational therapy at home until March 4, 2017. On March 4, 2017, R1 underwent a transesophageal echocardiogram (TEE) with throat punctured. R1 went home following the TEE. The next day, March 5, 2017, R1 went to the emergency room and on March 6, 2017, to Abbott Northwestern Hospital to have an abscess surgically removed from the neck. On March 10, 2017, while still hospitalized, R1 had a feeding tube put in place. Rehabilitation services were provided to R1 at Kenney Courage Center until sometime in early April when R1 was discharged to return home.[3]

2. In April 2017, while at home, R1 was able to move around independently for short distances and used a walker when moving from room to room.[4]

3. On April 17, 2017, R1 lost consciousness while at a physician's office. R1 was sent to the hospital and had a low hemoglobin (Hgb) count. R1 had four blood transfusions and bleeding from stomach ulcers.[5]

4. R1 was admitted to Langton Place on April 27, 2017, for continued therapy due to generalized muscle weakness and difficulty walking.[6]

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[3] Exhibit (Ex.) J at 45. While many different records in evidence provide pieces of R1's relevant medical history, Ex. J at 45, the first page of R1's Physical Therapy Plan of Care, provides the most clear, complete, and succinct version in one place.
[4] Ex. J at 45.
[5] *Id.*
[6] *Id.*

5. On May 9, 2017, R1 was readmitted to the hospital due to concerns for cellulitis.[7]

6. On May 14, 2017, R1 was readmitted to Langton Place. R1 had numbness in both legs and required one person's assistance when transferring. R1 was alert and oriented but was sometimes forgetful.[8] R1 had also suffered from Parkinson's disease since 2014, along with orthostatic hypotension, among other conditions.[9]

7. Upon R1's return to Langton Place, a physical device assessment was completed concerning the use of "grab bars" on R1's bed.[10] R1 participated in the assessment and demonstrated the transfer bars could be used to assist with mobility and repositioning on the bed.[11] R1 agreed to use the transfer bars.[12]

8. The transfer bars are a type of bed side rail that consist of a single piece of metal tubing which attaches to the bed frame below the mattress at a location near the middle of upper half of the bed (nearer the headboard), extending upward and then bending at approximately 30 degrees towards the foot of the bed and then curving back toward the headboard for several inches with a horizontal handle to grasp.[13] The vertical handle portion of the transfer bar was positioned just a few inches above the mattress.[14]

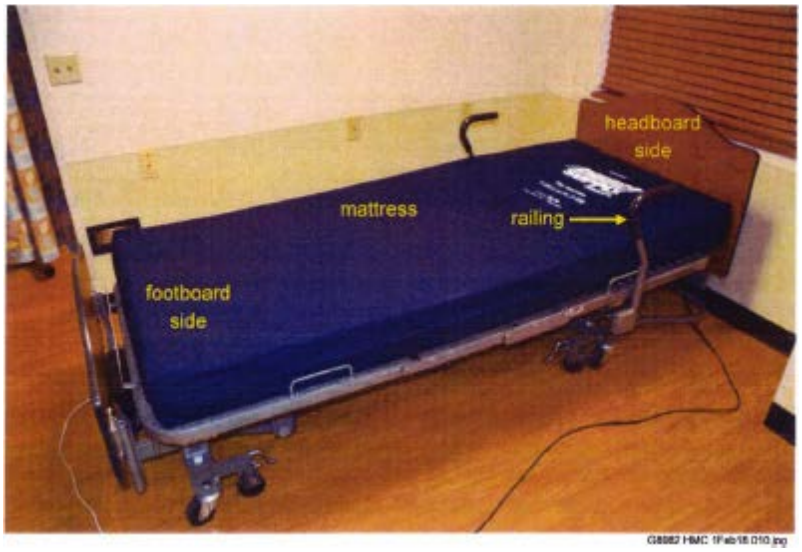

Figure 1.

[7] *Id.*
[8] Ex. J at 36
[9] Ex. J at 1-2. R1 had a list of over 20 diagnoses when admitted to the Facility the second time. One of three admitting diagnoses was weakness. The others highlighted here affect balance and fall risk.
[10] The terms "grab bars" and "bed rails" are often used in the record. However, the term used in the literature for the device in question is "transfer bar." *See, e.g.,* Ex. G.a at 16, 19. Thus, that term is used in this report.
[11] Ex, J at 11-12.
[12] *Id.*
[13] Ex. J Addendum; Ex. 14.
[14] Ex. J Addendum; Ex. 14; Figure 1 (from Ex. 14 at LP 79). The transfer bar is referred to as a "railing" in the photograph.

9. The Facility did not assess R1's risk for entrapment from the transfer bar and did not describe the risks of the transfer bar to R1.[15]

10. On May 15, 2017, the physical therapist assessing R1 at the Facility recorded that R1 had impaired balance and a history of falls. Physical therapy (PT) at the Facility was intended to address this risk. The PT assessment noted that with partial/moderate assistance, the helper contributed less than half the effort to help R1 transfer from sitting to standing.[16]

11. The Facility's care plan for R1 stated that R1 was at "risk for falls [related to] cognitive impairment, gait/balance problems, incontinence[.]"[17] The interventions employed to address R1's fall risk were:

- "Be sure my call light is within reach and encourage me to use it for assistance as needed";
- a fall risk assessment as needed or quarterly;
- ensuring R1 was wearing appropriate footwear;
- ongoing evaluation of R1 for effectiveness of interventions;
- "Follow facility fall protocol";
- Follow R1's toileting schedule;
- Providing R1 pain medication as ordered;
- Monitoring R1 for side effects of pain medication;
- Observing R1 for acute illness;
- A PT evaluation of R1 and treatment as needed;
- Analyze R1's fall history to determine cause of falls and remove potential causes from the environment, if possible.[18]

12. The care plan also stated R1 required "assistance with dressing, toileting, bathing and hygiene." The interventions for this included, among other things, an assistant with ambulating; a nurse to assess R1's transfer ability as needed or annually; and an assistant to help R1 with transfers.[19] With regard to R1's incontinence, an assistant was required for toilet use.[20] R1 had a goal to "be free from abuse by others/neglect by others or myself" due to cognitive and functional limitations. The intervention to help R1 reach this goal was to keep R1 "safe at all times."[21]

13. On May 31, 2017, sometime after 4:00 a.m. and before 5:30 a.m., R1 began to get out of bed. R1 moved both legs out over the right side of the bed (from the perspective of a person lying face up in the bed) and then defecated in the bed. R1 then stood up and collapsed, spinning to the right, defecating more, urinating, and falling. R1

[15] Exs. 12 at 67-68, J 11-12; Testimony (Test.) of Tammy Marik.
[16] Ex. J at 45.
[17] Ex. 6 at 25.
[18] *Id.* at 25-26.
[19] *Id.* at 29.
[20] *Id.* at 32.
[21] *Id.*

came down facing the headboard, and R1's head landed between the transfer bar and mattress, with arms hanging down on either side of the body, with knees bent and toes on floor behind R1, with left leg crossed under right leg. R1 asphyxiated in this position and was found at approximately 5:30 a.m. by Colleen Donovan, a Facility nurse.[22]

14. Donovan immediately requested help with R1, and a second nurse, Wilson Mabwai came into R1's room. Mabwai called 911 and was instructed to remove R1 from the bed and begin cardiopulmonary resuscitation (CPR). R1 was pale and R1's lower extremities were cool to the touch while the upper extremities were warm. Donovan and Mabwai easily moved R1 from next to the bed and Mabwai conducted CPR on the floor. Shortly thereafter, the emergency medical technicians (EMTs) arrived and continued the CPR on R1. They pronounced R1 deceased at 5:56 a.m.[23]

II. The Facility's Physical Device Policy and Procedures

15. Langton Place has a physical device assessment policy to "promote the highest level of physical functioning" for its residents.[24] The policy is to ensure residents "are supported in their right to remain safe and to be free from restrictive physical devices."[25] However, staff must balance the right to remain safe with the right to be free from restrictive physical devices.[26]

16. To meet the policy on physical devices, the Facility is to assess each resident with regard to the resident's use of assistive devices upon admission, quarterly, and upon a significant change in the resident's condition.[27] The assessment is to include analysis of alternatives utilized and risks of the use of devices.[28]

17. This policy applies to the use of transfer bars and other bed rails.[29]

18. Furthermore, bed systems are checked to ensure frames and transfer bars are working properly at least twice yearly and upon every discharge of a resident.[30]

19. In late 2016 and early 2017, the Facility transitioned from primarily using side rails on beds to transfer bars.[31] The transfer bars were chosen and installed in conformance with Food and Drug Administration guidance and manufacturer specifications.[32] This included ensuring the space between the transfer bar and mattress (zone 3 of the bed) on every bed was no more than 4 and ¾ inches.[33]

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[22] Exs. 3, 11, J, J.a; Test. of Dr. Victor Froloff; Test. of T. Marik; Test. of Natalie Morland.
[23] Exs. 3, 11, J, J.a.
[24] Ex. 18.
[25] *Id.*
[26] *Id.*
[27] *Id.*; Test. of T. Marik.
[28] Ex. J at 11.
[29] Ex. 18, Test. of T. Marik.
[30] Exs. 1, 25, 35; Test. of Mathew Bedard.
[31] Exs. 25, 26; Test. of M. Bedard; Test. of T. Marik.
[32] Exs. G, G.a, G.b, G.c, G.d, G.e, G.f, G.g, G.i, G.k.1, G.l, 29, 34; Test. of M. Bedard; Test. of T. Marik.
[33] Ex. 24; Test. of M. Bedard.

20. Transfer bars are kept tied down unless it is determined a resident requires its use.[34]

III. The Survey and Findings

21. Lissa Lin and Peggy Boeck from the Department's Office of Health Facility Complaints (OHFC), were assigned to investigate the death of R1.[35] The investigation was an abbreviated standard survey because it was prompted by a complaint about the care R1 received.[36]

22. The survey was conducted over several months, beginning approximately June 2, 2017, and was completed on October 3, 2017.[37] An administrator, maintenance staff, and many nursing staff were interviewed.[38]

23. On June 2 and 5, 2017, the survey team watched the Facility's engineering manager measure the space between the transfer bars and mattresses on all 85 beds in the facility.[39] The space between the bars and mattress is referred to as "zone 3."[40] The FDA recommends the space for zone 3 be no more than 4 and ¾ inches wide.[41] To make the measurement, the mattress must be pushed away from the transfer bar being measured until it stops, and then the measurement is taken.[42]

24. Only one bed, which was used by R2, was determined to have a zone 3 measurement beyond the recommended 4 and ¾ inches, and this was only on one side.[43] On the other side, the engineering manager told Boeck the gap was six inches.[44] Because the measurements of R2's bed produced two different numbers, the measurement was invalid, but the survey team did not conduct a new measurement.[45]

25. On June 2, 2017, the bed R1 had used was examined in a storage room.[46] The bare mattress was on the bed with the "head end" nearer the footboard and the "soft side" up.[47] The survey team was told the bed had not been touched before they saw it, but it had been stripped and cleaned.[48]

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[34] Ex. 25; Test. of T. Marik.
[35] Test. of Lissa Lin.
[36] Ex. E at 1; Test. of L. Lin.
[37] Exs. E, 30.
[38] Test. of L. Lin.
[39] Ex. E. at 3; Test. of L. Lin.
[40] Exs. E at 3, G; G.b, G.c, G.h, G.j; 14.
[41] Exs. G at 19, G.c at 7, 14 at LP 81.
[42] Ex. 14 at LP 81; Test. of Peggy Boeck.
[43] Ex. E at 5; Test. of P. Boeck.
[44] Ex. E at 5; Test. of P. Boeck.
[45] Test. of P. Boeck.
[46] Ex. E at 3; Test. of L. Lin; Test. of P. Boeck.
[47] Exs. E. at 3, J Addendum; Test. of L. Lin; Test. of P. Boeck.
[48] Ex. J Addendum; Test. of L. Lin.

26. Only one deficiency was issued, tag F323, but it was for violations of two regulatory requirements: 42 C.F.R. §§ 483.25(d) and .25(n)(1)-(3).[49] The scope and severity for the deficiency was determined to be G, an isolated incident with actual harm that is not immediate jeopardy.[50]

27. The basis for the citation was stated as:

> Based on observation, interview, and document review the facility failed to ensure the safety of 2 of 74 residents, (R1 and R2), reviewed for bed grab bars. R1 was harmed when R1 was found not breathing with . . . head between the mattress and the grab bar on the bed and died. R2 had the potential for entrapment due to the large gap between the mattress and grab bar.[51]

28. Factual findings included:

> The facility had no policy, procedure, or system to ensure the proper sizing of mattresses, the fit of the grab bars, and the space between the mattresses and the grab bars device was safe to reduce the risk of entrapment.[52]

This finding was based on what the surveyors reported that the facility administrator told them. Specifically, that:

> the facility relied on the manufacturer to ensure the rails, mattresses, and beds were all compatible. [And] the facility had no policy for maintenance of grab bars, mattresses, or beds but [they] had maintenance staff fix things as issues came up. [Further] the facility had no schedule for inspection of new bed and mattress sets or ongoing measurement of zones of entrapment.[53]

This finding was also based on the facility engineer telling one of the surveyors that "there was no policy to measure beds for zones of entrapment when new beds arrived or on an ongoing basis."[54]

29. Any finding of fact in the memorandum below, not already mentioned, is hereby incorporated by reference.

Based on these findings of fact, and for the reasons explained in the memorandum below, the Administrative Law Judge makes the following:

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[49] Ex. E at 1.
[50] Exs. C, D, E at 1.
[51] Ex. E at 2.
[52] *Id.*
[53] Ex. E at 6.
[54] *Id.*

CONCLUSIONS OF LAW

Based on these conclusions of law, and for the reasons explained in the attached memorandum, the Administrative Law Judge makes the following:

1. The Commissioner of Health and the Administrative Law Judge have jurisdiction in this matter, pursuant to Minn. Stat. §§ 144A.10 and 14.57 (2016).

2. Skilled nursing facilities (SNFs), which participate in Medicare, must meet the conditions of participation as set forth in federal law.[55]

3. SNFs must be surveyed to determine "whether the quality of care, as intended by the law and regulations, and as needed by the resident, is actually being provided in nursing homes."[56] The emphasis of the survey process is "on resident outcomes" and determining "whether the facility is actually providing the required and needed care and services. . . ."[57]

4. As part of the survey process, data is collected in a Survey Report Form which must contain "information about all of the negative findings of the survey."[58] The findings must be analyzed "for the degree of severity, frequency of occurrence and impact on delivery of care or quality of life."[59] "One occurrence directly related to a life-threatening or fatal outcome can be cited as a deficiency."[60]

5. Agency surveyors must:

> [w]rite the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement(s) that (are) not met. Do not delve into the facility's policies and procedures to determine or speculate on the root cause of a deficiency. . . . Indicate the data prefix tag and regulatory citation, followed by a summary of the deficiency and supporting findings. . . . When the data prefix tag does not repeat the regulations, also include a short phrase that describes the prefix tag (e.g., F117 decubitus ulcer care).[61]

6. The Administrative Law Judge must issue one or more of the following findings with regard to the deficiency citation in dispute:

   a. Supported in full. No deletion of Department findings and no change in the scope or severity assigned to the deficiency citation;

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[55] 42 C.F.R. § 489.10(a) (2017).
[56] 42 C.F.R. § 488.110 (2017).
[57] *Id.*
[58] *Id.* at 488.110(i)(1).
[59] *Id.* at 488.110(i)(2).
[60] *Id.*
[61] *Id.* at 488.110(i)(4).

b. Supported in substance. The citation is supported, but one or more findings are deleted without any change in the scope or severity assigned to the deficiency;

c. Deficient practice cited under wrong requirement of participation. The citation is amended by moving it to the correct requirement of participation;

d. Scope not supported. The citation is amended through a change in the scope assigned to the citation;

e. Severity not supported. The citation is amended through a change in the severity assigned to the citation; or

f. No deficient practice. The citation is deleted because the findings did not support the citation or the negative resident outcome was unavoidable. The findings of the arbitrator are not binding on the commissioner.[62]

7. "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."[63]

8. A facility must ensure that:

(1) The resident environment remains as free of accident hazards as is possible; and

(2) Each resident receives adequate supervision and assistance devices to prevent accidents.[64]

This requirement was identified as data prefix tag F323, and was changed in November 2017 to tag F689.[65]

9. The Department has shown that the Facility failed to ensure the resident environment remained as free of accident hazards as is possible, and that at least one resident did not receive adequate supervision or assistance devices to prevent accidents, which resulted in the death of a resident. Thus, there was a deficient practice.

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[62] Minn. Stat. § 144A.10, Subd. 16(d).
[63] 42 C.F.R. § 488.301 (2017).
[64] 42 C.F.R. § 483.25(d).
[65] *See* https://www.cms.gov/Medicare/Provider-Enrollment-and-certification/GuidanceforLawsAndRegulations/Nursing-Homes.html.

10. The Facility's non-compliance with the requirement at 42 C.F.R. § 483.25(d) resulted in the death of a resident. Thus, the violation's severity is properly classified as immediate jeopardy, not actual harm that is not immediate jeopardy.

11. Federal regulations concerning bed rails, which includes transfer bars, require facilities to:

> attempt to use appropriate alternatives prior to installing a side or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements.
>
> (1) Assess the resident for risk of entrapment from bed rails prior to installation.
>
> (2) Review the risks and benefits of bed rails with the resident representative and obtain informed consent prior to installation.
>
> (3) Ensure that the bed's dimensions are appropriate for the resident's size and weight.
>
> (4) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.[66]

This requirement was identified as data prefix tags F323 (for 42 C.F.R. § 483.25(n)(1)-(3)) and F461 (for 42 C.F.R. § 483.25(n)(4)), and was changed in November 2017 to tag F700 (for 42 C.F.R. § 483.25(n)(1)-(4).[67]

12. The Department has shown that the Facility failed to assess R1 for risk of entrapment, review the risks of the transfer bar with R1 and, therefore, obtain R1's informed consent to use the transfer bar prior to its use. This is a distinct violation, and therefore citation, from the Facility's violation of 42 C.F.R. § 483.25(d). Severity level G (actual harm that is not immediate jeopardy) is not supported and the citation is amended to severity level D (no actual harm with potential for more than minimal harm that is not immediate jeopardy). It is unknown whether a proper risk assessment would have had any impact on the Facility's proposal, or R1's decision, to use the transfer bar. Thus, had this violation not occurred, the same outcome may have happened.

13. There is no regulation requiring a "policy, procedure, or system to ensure the proper sizing of mattresses, the fit of the grab bars, and the space between the mattresses and the grab bars. . . ."[68] Having policies, procedures, or a system in place to ensure the regulations are met is merely suggested guidance.[69]

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[66] 42 C.F.R. § 483.25(n)

[67] *See* https://www.cms.gov/Medicare/Provider-Enrollment-and-certification/GuidanceforLawsAndRegulations/Nursing-Homes.html.

[68] Ex. E at 2.

[69] Compare 42 C.F.R. § 483.25 and Ex. G.

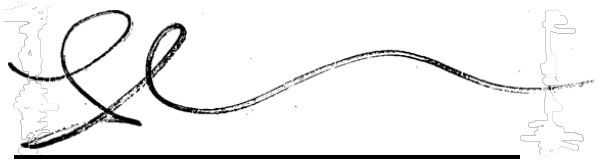
RECOMMENDATION

The Administrative Law Judge respectfully recommends that the Facility be found in violation of two data prefix tags, both F323. The first F323 citation is for violation of 42 C.F.R. § 483.25(d). The facts and law demonstrate that the correct severity level for the first citation is J, immediate jeopardy and not severity level G, actual harm that is not immediate jeopardy. This is because R1 was a known fall risk who was not properly supervised or provided with appropriate assistive devices designed to keep R1 reasonably safe from accidental falls.

The second F323 citation is for violation of 42 C.F.R. § 483.25(n)(1) and (2). The facts and law demonstrate that the correct severity level for the second citation is D, no actual harm with potential for more than minimal harm that is not immediate jeopardy. The Facility failed to properly assess R1's risk for entrapment in transfer bars, reviewing those risks with R1, and obtaining R1's informed consent prior to the installation and use of the transfer bars.

The findings regarding R2's bed should be deleted because there are no credible facts demonstrating the bed and transfer bars for that bed were unsafe. Furthermore, it is recommended that any findings regarding the Facility's policies or procedures be deleted because federal regulations prohibit deficiency statements from delving into facility policies and procedures to determine or speculate on the root cause of a deficiency.

Dated: May 18, 2018



JIM MORTENSON
Administrative Law Judge

Reported: Digitally Recorded; No transcript prepared

NOTICE

Pursuant to Minn. Stat. § 144A.10, subd. 16, this recommended decision is not binding upon the Commissioner of Health. Pursuant to Minn. Stat. § 14.61, subd. 1, the Commissioner will not make a final decision until the report of the Administrative Law Judge has been made available to parties to the proceeding for at least ten days and an opportunity has been afforded to each party adversely affected to file exceptions and present argument to a majority of the officials who are to render the decision.

MEMORANDUM

I. General Regulatory Background

Skilled nursing facilities participating in the Medicare program must meet certain requirements, which are set forth in 42 C.F.R. Part 483, Subpart B (2017). Compliance with these requirements is determined through different types of surveys (inspections)[70] conducted by the Department, under agreement with the Federal Department of Health and Human Services' Centers for Medicare and Medicaid Services (CMS), pursuant to 42 C.F.R. Part 488 (2017).[71] The Department reports any compliance deficiencies (citations or tags) to CMS on a standard form called a "Statement of Deficiencies."[72]

The standards by which the Department determines compliance are found at 42 C.F.R. § 488.26:

> (b) The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition. Evaluation of a provider's or supplier's performance against these standards enables the state survey agency to document the nature and extent of deficiencies, if any, with respect to a particular function, and to assess the need for improvement in relation to the prescribed conditions.
>
> (c) The state survey agency must adhere to the following principles in determining compliance with participation requirements:
>
> (1) The survey process is the means to assess compliance with federal health, safety and quality standards;
>
> (2) The survey process uses resident and patient outcomes as the primary means to establish the compliance process of facilities and agencies. Specifically, surveyors will directly observe the actual provision of care and services to residents and/or patients, and the effects of that care, to assess whether the care provided meets the needs of individual residents and/or patients.
>
> (3) Surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance;

[70] Minn. Stat. § 144A.10, subd. 2 (2016).
[71] *See* 42 C.F.R. § 488.301 (Abbreviated standard survey, extended survey, partial extended survey, standard survey, and validation survey).
[72] *See, e.g.,* Ex. E (Statement of Deficiencies, CMS 2567); Minn. Stat. § 144A.101, subd. 2 (2016).

(4) Federal procedures are used by all surveyors to ensure uniform and consistent application and interpretation of federal requirements;

(5) Federal forms are used by all surveyors to ensure proper recording of findings and to document the basis for the findings.

(d) The state survey agency must use the survey methods, procedures, and forms that are prescribed by CMS.

(e) The state survey agency must ensure that a facility's or agency's actual provision of care and services to residents and patients and the effects of that care on such residents and patients are assessed in a systematic manner.

A deficiency is a "failure to meet a participation requirement specified in the Act or in part 483, subpart B of this chapter."[73] Deficiency findings are organized in the Statement of Deficiencies under alpha-numeric tags, with each tag corresponding to a regulatory requirement in Part 483.[74] The facts alleged under each tag may include a number of survey findings, which (if upheld) should support the conclusion that a facility failed to meet the regulatory standards.[75]

A survey agency's findings also include a determination as to the seriousness of each deficiency.[76] The seriousness of a deficiency depends upon both its scope and its severity.[77] When citing deficiencies, state surveyors use the CMS Guidance on Deficiency Categorization. The scope and severity options are set out on a three-column, four-level grid. Each square on the grid has a letter designation. "A" is the least serious and "L" is the most serious. The fourth level of the grid (including designations J, K, and L) is reserved for the most serious deficiencies which place residents in immediate jeopardy.[78] The phrase "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.[79]

"The commissioner may not issue any findings of immediate jeopardy after the conclusion of a regular, expanded, or extended survey unless the survey team identified the deficient

[73] 42 C.F.R. § 488.301.
[74] CMS State Operations Manual, Appendix PP, Section IV.
[75] *See* 42 C.F.R. § 488.110.
[76] *See* 42 C.F.R. § 488.404.
[77] *Id.*
[78] Ex. C.
[79] 48 C.F.R. § 488.301.

practice or practices that constitute immediate jeopardy and the residents at risk prior to the close of the exit conference."[80]

If a facility disputes a survey citation the facility may request an opportunity for independent informal dispute resolution (IIDR) hearing or arbitration.[81] The IIDR process operates pursuant to contested case requirements under Minn. Stat. §§ 14.57 to 14.62, under an Administrative Law Judge.[82] Following the arbitration, the Administrative Law Judge must make one or more of the six specified findings about the citations disputed.[83]

A facility is considered to be noncompliant with one or more requirements of 42 C.F.R. Part 483 if there is deficiency that "causes a facility to not be in substantial compliance."[84] "Substantial compliance" is "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."[85] If a facility is found to be noncompliant based on the results of a state survey, various remedies can be imposed including civil monetary penalties.[86]

In this proceeding, Langton Place challenges deficiency tag F323 (now F689 and F700). The tag addresses 42 C.F.R. §§ 483.25(d) and .25(n). 42 C.F.R. § 483.25(d) requires that a facility must ensure that the resident environment remain as free of accident hazards as is possible and that each resident receive adequate supervision and assistance devices to prevent accidents.[87] 42 C.F.R. § 483.25(n) concerns the use of bed rails, including transfer arms.[88] The citation was based on the death of R1, which involved entrapment in a transfer arm on the bed, and a six inch gap between the transfer arm and mattress of R2's bed.[89] R1's death triggered an abbreviated standard survey.[90]

II. Analysis

A. R1

The Department determined that "R1 was harmed when . . . found not breathing with [R1's] head between the mattress and the grab bar on the bed and died." This sentence is internally inconsistent and illogical. R1 was not harmed when she was found

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[80] Minn. Stat. § 144A.10, subd. 14.
[81] *Id*. at subd. 16.
[82] *Id.*
[83] *Id*. at subd. 16(d). The statute's use of the term "finding" for the possible decisions should not be confused with the Administrative Law Judge's findings of fact or the survey team's findings in the Statement of Deficiencies.
[84] *See,* 42 C.F.R. § 488.301.
[85] *Id.*
[86] *See* 42 C.F.R. §§ 488.402, .406, .412.
[87] 42 C.F.R. § 483.25(d).
[88] 42 C.F.R. § 483.25(n); Ex. G.a at 19.
[89] Ex. E at 2.
[90] Ex. 30; *See* 42 C.F.R. § 488.301. "Abbreviated standard survey means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received, . . . or other indicators of specific concern."

dead. R1 died as a result of a fall. When R1 fell, her head became wedged between the transfer bar and mattress on her bed. R1 died as a result of asphyxia, which may be a result of where she landed when she fell. Thus, the finding should be: "R1 fell when rising from the bed, and died from asphyxia when R1's head landed between the transfer bar and mattress of the bed."

The surveyors focused on the transfer bar. They found no problems with the transfer bar attachment, such as spacing.[91] The surveyors made findings about facility policy, Food and Drug Administration (FDA) guidance, manufacturers' guidelines, R1's medical status, how and when R1 was found by facility staff, and the autopsy.[92] The findings did not explain what the violation concerning the transfer bar was and how such a violation led or contributed to R1's demise. Instead, the surveyors delved into the Facility's policies and procedures to determine or speculate on the root cause of the deficiency. The law prohibits surveyors from doing this.[93]

R1 was found dead with head between the transfer bar and the bed. It was R1's attempt to standup, and then the fall, that led to R1's death. It was not the use or installation of the transfer bar. Had the bar not been there, R1 may still have fallen. We cannot say whether or not R1 would have been injured or even died from the fall. What is important is that R1's care plan addressed weakness and imbalance. R1's medical records show a variety of diagnoses leading to risk of falling, such as weakness, orthostatic hypotension, Parkinson's disease, and difficulty walking, among others.[94] R1 required assistance in transferring, yet would frequently do so without help.[95]

The Facility's solution was to encourage or remind R1 to use the call light when R1 needed to get up or into bed.[96] This was not adequate to prevent R1 from falling. The Facility could have used an alarm or some system to better supervise R1 to prevent a fall. It was this failure to provide appropriate supervision for R1, a fall risk, which led to R1's death. The transfer bar was properly installed. With one assistant to aid R1 getting up and down, the transfer bar may have been entirely appropriate to help R1 gain back independence from the weakness R1 had been suffering from.

Because R1 was found with head between the transfer bar and the mattress, the focus of the surveyors was on the transfer bar. They did not adequately address other important facts that were part of the scene. R1's body was not on the bed. It was facing the bed, with head pointing towards the headboard, between the transfer bar and the mattress. There was stool on the bed, and on the floor behind R1. R1's legs were behind her body with toes on the floor. R1 did not slide off the bed and get stuck between the transfer bar and mattress. Rather, R1 stood up and almost immediately fell down, twisting to the right and back towards the bed. R1's head just happened to fall between the bar and mattress. While it is true R1 would not have lodged there if no transfer bar was in

[91] *Id.* at 3.
[92] *Id.* at 2-5.
[93] 42 C.F.R. § 488.110(i)(4).
[94] Ex. J at 1-2.
[95] Ex. 6; Ex. J.
[96] Ex. 6 at 28.

place, the fall would have continued to the floor. It is this fall, and the failure to guard against it, that should have been the focus of the survey team. R1 was to have the assistance of at least one staff person with transferring, but this was not done consistently. R1 would often behave independently, which is an outcome R1 was working towards, but this was still unsafe and was why R1 required the assistance. More supervision was required to ensure R1's safety, and the failure to provide this supervision is what led to R1's death. This was a violation of 42 C.F.R. § 483.25(d).

The Facility was informed of the deficient practice of failing to keep R1's environment as free of accident hazards as reasonably possible. This failure resulted in the death of R1 and meets the definition of immediate jeopardy under federal law.[97]

There was no flaw with R1's transfer bars. They were installed correctly and there was no excessive gap between the mattress and the bars. The survey finding noted that there was "no policy, procedure, or system to ensure" grab bars were "safe to reduce the risk of entrapment."[98] The Department repeated this argument in closing, but also claimed that the policy the Facility had in place was not implemented.[99] Obviously, both positions cannot be true. The evidence in the record demonstrates that the Facility had a policy in place.[100] Having a policy in place is not a legal requirement.[101] Furthermore, the law requires that surveyors "not delve into the facility's policies and procedures to determine or speculate on the root cause of a deficiency. . . ."[102] Yet, this is exactly what the surveyors did in this case, and which the Department largely relied on in its position supporting the F323 deficiency tag. This was in error.

The Department argues that R1 was not properly assessed before the use of transfer bars.[103] The Department argues that transfer bars were the new standard in the facility, and were not appropriate for R1 because "they were clearly not safe for her to use."[104] The evidence demonstrates R1's use of the transfer bars was assessed, and it was determined they would be a helpful device for her in transferring out of and in to bed safely.[105] However, the Facility did not assess R1's risk of entrapment. Further, Facility staff did not review the risks of using the transfer bar with R1. The Director of Nursing, Marik, testified that risk was assessed based on whether a resident could use a device.[106] Whether a resident can use transfer bars is not a complete assessment of the risk of entrapment from the transfer bars. A resident may be able to use transfer bars and still become entrapped by them. The law requires an assessment to determine whether or how likely entrapment would be. This must then be communicated to a resident or guardian. Simply because there is a risk of entrapment does not mean the transfer bars

[97] *See* 48 C.F.R. § 488.301.
[98] Ex. E at 2.
[99] Department Closing Argument at 2, 3, 4, and 5 (May 3, 2018).
[100] Ex. 18.
[101] *See* 42 C.F.R. § 483.25.
[102] 42 C.F.R. § 488.110(i)(4).
[103] Dep't Closing Arg. at 3.
[104] *Id.*
[105] Ex. 12.
[106] Test. of T. Marik.

should not be used. It is the level of risk that the regulation requires be communicated to the resident. Without this communication, informed consent to use the transfer bar cannot be provided by the resident.

Here, because there was no assessment of the risk of entrapment by use of the transfer bars, the risk level was not communicated to R1 and R1 could not have provided informed consent to the use of the bars. This was a violation of 42 C.F.R. § 483.25(n).

Simply being able to use the bar is not a sufficient assessment. However, because the proximate cause of R1's death was the fall, not the transfer bar, the severity level of the violation of 42 C.F.R. § 483.25(n)(1) and (2) is D, no actual harm with potential for more than minimal harm that is not immediate jeopardy. While R1 was caught on the bar when R1 fell, R1 could have just as easily died or been harmed if the bar was not there. We simply do not know. Further, had R1 been properly assessed, it is not clear what the level of risk to R1 would have been and whether R1 would have consented to the use of the transfer bar at that point. Thus, it cannot be concluded that the failure to properly assess and obtain informed consent on the use of the transfer bar was the proximate cause of R1's death and, therefore either actual harm or immediate jeopardy. R1 may have consented to the use of the transfer bar, despite the risk of its use, and still fallen and died with her head between the bar and the mattress. This is a close call, but the Administrative Law Judge believes that because of the speculation required to determine what the assessed risk level may have been, and whether R1 would have declined to use the transfer bar with that information, the failure to conduct the risk assessment of the transfer bar for R1 was of lesser severity than the failure to properly supervise R1 and ensure her environment was reasonably free from accident hazards.

B. R2

The Department did not demonstrate any violation with regard to R2. The Department's basis for finding a violation based on R2's bed and transfer bar was because one side of the bed had a gap of six inches between the bar and the mattress. However, the evidence for this is less than clear. It was not shown that it is more likely than not that such a wide gap existed.

The reason is thus: when measuring the maximum gap between the bar and the mattress, the mattress is pushed all the way to one side, up against the opposing transfer bar. When doing this, the measurement on one side of the bed must, as a matter of mathematical law, be the same as the measurement on the other side. This is because there is a certain distance between each transfer bar, points A and B (line X). Further, the width of the mattress is known (line Y). To measure the gap on either side, when the mattress is pushed against point A or B, the equation is always going to be X – Y = Z (the gap). Given the person doing the measurements came up with two different measurements for the gap on R2's bed, some error occurred. Yet, no new measurements were taken. At least one of the measurements of R2's bed is wrong. There is no evidence to show which measurement is correct. Thus, there is no preponderance of evidence that there was an unsafe gap between the transfer bar and mattress.

III. Conclusion

The Department's survey findings were flawed and confusing, and resulted in one, as opposed to two, citations. This stemmed from a serious event, R1's death, and R1 being found with head between a transfer bar and bed mattress. This led the surveyor to focus on the use of transfer bars in the facility. This failure led to the cobbling together of findings that do not reasonably represent the true violations and proximate cause of R1's death. Compounding matters was that, at the time, CMS guidance put violations for 42 C.F.R. §§ 483.25(d) and .25(n)(1)-(3) under the same tag.

The scope and severity determined by the Department did not follow what really happened. The death of R1 was an isolated incident. The death of R1 was not "[a]ctual harm that is not immediate jeopardy." The death of a resident which is the result of a violation squarely meets the definition of immediate jeopardy. Thus, the Department's claimed severity should be corrected.

The facility did fail to ensure an environment as free from accident hazards as possible when it did not provide R1 adequate supervision and assistance devices to prevent accidental falls. R1 was a known fall risk. Thus, the citation, F323, is amended through a change in the severity assigned to J, an isolated event with immediate jeopardy to a resident who died.

The facility also failed to appropriately assess R1's risk of entrapment with use of the transfer bars. This led to the failure to inform R1 about the risk and, consequently, a failure to obtain R1's informed consent. It cannot be determined, by a preponderance of the evidence, that this failure led to R1's death, because she may have ultimately consented to use the grab bar despite any risk doing so may have created. It can only be concluded that this risk assessment violation was an isolated incident with the potential for more than minimal harm that is not immediate jeopardy. The two violations should be corrected to clearly reflect the violations that occurred, the correct severity, and the facts that support the violation determinations.

J. R. M.