Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically delivered
August 1, 2023

Administrator
Good Samaritan Society - Waconia And Westview Acre
333 Fifth Street West
Waconia, MN 55387

RE: CCN: 245234
Cycle Start Date: June 29, 2023

Dear Administrator:

On July 17, 2023, we notified you a remedy was imposed. On July 27, 2023 the Minnesota Department of Health completed a revisit to verify that your facility had achieved and maintained compliance. We have determined that your facility has achieved substantial compliance as of July 24, 2023.

As authorized by CMS the remedy of:

- Discretionary denial of payment for new Medicare and Medicaid admissions effective August 1, 2023 did not go into effect. (42 CFR 488.417 (b))

However, as we notified you in our letter of July 17, 2023, in accordance with Federal law, as specified in the Act at § 1819(f)(2)(B)(iii)(I)(b) and § 1919(f)(2)(B)(iii)(I)(b), we notified you that your facility is prohibited from conducting Nursing Aide Training and/or Competency Evaluation Programs (NATCEP) for two years from June 29, 2023. This does not apply to or affect any previously imposed NATCEP loss.

The CMS Region V Office may notify you of their determination regarding any imposed remedies.

Feel free to contact me if you have questions.

Sincerely,

Melissa Poepping, Compliance Analyst
Federal Enforcement | Health Regulation Division
Minnesota Department of Health
P.O. Box 64900
Saint Paul, Minnesota 55164-0970
Phone: 651-201-4117
Email: Melissa.Poepping@state.mn.us

Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically Submitted
July 17, 2023

Administrator
Good Samaritan Society - Waconia And Westview Acre
333 Fifth Street West
Waconia, MN 55387

RE: CCN: 245234
Cycle Start Date: June 29, 2023

Dear Administrator:

On June 29, 2023, survey was completed at your facility by the Minnesota Department of Health to determine if your facility was in compliance with Federal participation requirements for skilled nursing facilities and/or nursing facilities participating in the Medicare and/or Medicaid programs.

Your facility was not in substantial compliance with the participation requirements and the conditions in your facility constituted **both substandard quality of care and immediate jeopardy** to resident health or safety. This survey found the most serious deficiencies in your facility to be isolated deficiencies that constituted immediate jeopardy (Level J), whereby corrections were required. The Statement of Deficiencies (CMS-2567) is being electronically delivered.

REMOVAL OF IMMEDIATE JEOPARDY

On June 28, 2023, the situation of immediate jeopardy to potential health and safety cited at F0700 was removed. However, continued non-compliance remains at the lower scope and severity of D.

REMEDIES

As a result of the survey findings and in accordance with survey and certification memo 16-31-NH, this Department recommended the enforcement remedy listed below to the CMS Region V Office for imposition: The CMS Region V Office concurs and is imposing the following remedy and has authorized this Department to notify you of the imposition:

- Discretionary Denial of Payment for new Medicare and/or Medicaid Admissions, Federal regulations at 42 CFR § 488.417(a), effective August 1, 2023.

This Department is also recommending that CMS impose a civil money penalty (42 CFR 488.430 through 488.444). You will receive a formal notice from the CMS RO only if CMS agrees with our recommendation.

The CMS Region V Office will notify your Medicare Administrative Contractor (MAC) that the denial of payment for new admissions is effective August 1, 2023 (42 CFR 488.417 (b)). They will also notify the State Medicaid Agency that they must also deny payment for new Medicaid admissions effective August 1, 2023, (42 CFR 488.417 (b)).

You should notify all Medicare/Medicaid residents admitted on, or after, this date of the restriction. The remedy must remain in effect until your facility has been determined to be in substantial compliance or your provider agreement is terminated. Please note that the denial of payment for new admissions includes Medicare/Medicaid beneficiaries enrolled in managed care plans. It is your obligation to inform managed care plans contracting with your facility of this denial of payment for new admissions.

NURSE AIDE TRAINING PROHIBITION

Please note that Federal law, as specified in the Act at §§ 1819(f)(2)(B) and 1919(f)(2)(B), prohibits approval of nurse aide training and competency evaluation programs and nurse aide competency evaluation programs offered by, or in, a facility which, within the previous two years, has operated under a § 1819(b)(4)(C)(ii)(II) or § 1919(b)(4)(C)(ii) waiver (i.e., waiver of full-time registered professional nurse); has been subject to an extended or partial extended survey as a result of a finding of substandard quality of care; has been assessed a total civil money penalty of not less than $11,995; has been subject to a denial of payment, the appointment of a temporary manager or termination; or, in the case of an emergency, has been closed and/or had its residents transferred to other facilities.

Therefore, your agency is prohibited from offering or conducting a Nurse Assistant Training/Competency Evaluation Programs or Competency Evaluation Programs for two years effective June 29, 2023. This prohibition is not subject to appeal. Under Public Law 105-15 (H.R. 968), you may request a waiver of this prohibition if certain criteria are met. Please contact the Nursing Assistant Registry at (800) 397-6124 for specific information regarding a waiver for these programs from this Department.

SUBSTANDARD QUALITY OF CARE

Your facility's deficiencies with with one or more of the following: §483.10, Residents Rights, §483.12, Freedom from Abuse, Neglect, and Exploitation, §483.15, Quality of Life and §483.25, Quality of Care, 483.40 Behavioral Health Services, §483.45 Pharmacy Services, §483.70 Administration, or §483.80 Infection control has been determined to constitute substandard quality of care as defined at §488.301. Sections 1819(g)(5)(C) and 1919(g)(5)(C) of the Social Security Act and 42 CFR 488.325(h) require that the attending physician of each resident who was found to have received substandard quality of care, as well as the State board responsible for licensing the facility's administrator, be notified of the substandard quality of care. <u>If you have not already provided the following information, you are required to provide to this agency within ten working days of your receipt of this letter the name and address of the attending physician of each resident found to have received substandard quality of care.</u>

Please note that, in accordance with 42 CFR 488.325(g), your failure to provide this information timely will result in termination of participation in the Medicare and/or Medicaid program(s) or imposition of alternative remedies.

Federal law, as specified in the Act at Sections 1819(f)(2)(B) and 1919(f)(2)(B), prohibits approval of nurse assistant training programs offered by, or in, a facility which, within the previous two years, has been subject to an extended or partial extended survey as a result of a finding of substandard quality of care. Therefore, Good Samaritan Society - Waconia And Westview Acre is prohibited from offering or conducting a Nurse Assistant Training / Competency Evaluation Programs (NATCEP) or Competency Evaluation Programs for two years effective June 29, 2023. This prohibition remains in effect for the specified period even though substantial compliance is attained. Under Public Law 105-15 (H. R. 968), you may request a waiver of this prohibition if certain criteria are met. Please contact the Nursing Assistant Registry at (800) 397-6124 for specific information regarding a waiver for these programs from this Department.

ELECTRONIC PLAN OF CORRECTION (ePOC)

Within ten (10) calendar days after your receipt of this notice, you must submit an acceptable plan of correction (ePOC) for the deficiencies cited. An acceptable ePOC will serve as your allegation of compliance. Upon receipt of an acceptable ePOC, we will authorize a revisit to your facility to determine if substantial compliance has been achieved. The failure to submit an acceptable ePOC can lead to termination of your Medicare and Medicaid participation (42 CFR 488.456(b)).

To be acceptable, a provider's ePOC must include the following:

- How corrective action will be accomplished for those residents found to have been affected by the deficient practice.
- How the facility will identify other residents having the potential to be affected by the same deficient practice.
- What measures will be put into place, or systemic changes made, to ensure that the deficient practice will not recur.
- How the facility will monitor its corrective actions to ensure that the deficient practice is being corrected and will not recur.
- The date that each deficiency will be corrected.
- An electronic acknowledgement signature and date by an official facility representative.

DEPARTMENT CONTACT

Questions regarding this letter and all documents submitted as a response to the resident care deficiencies (those preceded by a "F" and/ or "E" tag), i.e., the plan of correction should be directed to:

Annette Winters, Rapid Response Unit Supervisor
Metro 1, Golden Rule Office
Licensing and Certification Program
Health Regulation Division
Minnesota Department of Health
85 East Seventh Place, Suite 220
P.O. Box 64900
Saint Paul, Minnesota 55164-0900
Email: annette.m.winters@state.mn.us
Mobile: (651) 558-7558

PRESUMPTION OF COMPLIANCE - CREDIBLE ALLEGATION OF COMPLIANCE

The facility's ePoC will serve as your allegation of compliance upon the Department's acceptance. In order for your allegation of compliance to be acceptable to the Department, the ePoC must meet the criteria listed in the plan of correction section above. You will be notified by the Minnesota Department of Health, Licensing and Certification Program staff and/or the Department of Public Safety, State Fire Marshal Division staff, if your ePoC for their respective deficiencies (if any) is acceptable.

VERIFICATION OF SUBSTANTIAL COMPLIANCE

Upon receipt of an acceptable ePoC, a Post Certification Revisit (PCR), of your facility will be conducted to

validate that substantial compliance with the regulations has been attained in accordance with your verification.

If substantial compliance has been achieved, certification of your facility in the Medicare and/or Medicaid program(s) will be continued and remedies will not be imposed. Compliance is certified as of the latest correction date on the approved ePoC, unless it is determined that either correction actually occurred between the latest correction date on the ePoC and the date of the first revisit, or correction occurred sooner than the latest correction date on the ePoC.

FAILURE TO ACHIEVE SUBSTANTIAL COMPLIANCE BY THE SIXTH MONTH AFTER THE LAST DAY OF THE SURVEY

We will also recommend to the CMS Region V Office and/or the Minnesota Department of Human Services that your provider agreement be terminated by December 29, 2023 (six months after the identification of noncompliance) if your facility does not achieve substantial compliance. This action is mandated by the Social Security Act at Sections 1819(h)(2)(C) and 1919(h)(3)(D) and Federal regulations at 42 CFR Sections 488.412 and 488.456.

Please note that this notice does not constitute formal notice of imposition of alternative remedies or termination of your provider agreement. Should the Centers for Medicare & Medicaid Services determine that termination or any other remedy is warranted, it will provide you with a separate formal notification of that determination.

APPEAL RIGHTS DENIAL OF PAYMENT

If you disagree with this action imposed on your facility, you or your legal representative may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board (DAB). Procedures governing this process are set out in 42 C.F.R. 498.40, et seq. You must file your hearing request electronically by using the Departmental Appeals Board's Electronic Filing System (DAB E-File) at https://dab.efile.hhs.gov no later than sixty (60) days after receiving this letter. Specific instructions on how to file electronically are attached to this notice. A copy of the hearing request shall be submitted electronically to:

Steven.Delich@cms.hhs.gov

Requests for a hearing submitted by U.S. mail or commercial carrier are no longer accepted as of October 1, 2014, unless you do not have access to a computer or internet service. In those circumstances you may call the Civil Remedies Division to request a waiver from e-filing and provide an explanation as to why you cannot file electronically or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than sixty (60) days after receiving this letter, by mailing to the following address:

Department of Health & Human Services
Departmental Appeals Board, MS 6132
Director, Civil Remedies Division
330 Independence Avenue, S.W.
Cohen Building – Room G-644
Washington, D.C. 20201
202-795-7490

A request for a hearing should identify the specific issues, findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. At an

appeal hearing, you may be represented by counsel at your own expense. If you have any questions regarding this matter, please contact Steven Delich, Program Representative at (312) 886-5216. Information may also be emailed to Steven.Delich@cms.hhs.gov.

APPEAL RIGHTS NURSE AIDE TRAINING PROHIBITION

Pursuant to the Federal regulations at 42 CFR Sections 498.3(b)(13)(2) and 498.3(b)(15), a finding of substandard quality of care that leads to the loss of approval by a Skilled Nursing Facility (SNF) of its NATCEP is an initial determination. In accordance with 42 CFR part 489 a provider dissatisfied with an initial determination is entitled to an appeal. If you disagree with the findings of substandard quality of care which resulted in the conduct of an extended survey and the subsequent loss of approval to conduct or be a site for a NATCEP, you or your legal representative may request a hearing before an administrative law judge of the Department of Health and Human Services, Department Appeals Board. Procedures governing this process are set out in Federal regulations at 42 CFR Section 498.40, et. Seq.

A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. Such a request may be made to the Centers for Medicare and Medicaid Services (formerly Health Care Financing Administration) at the following address:

Department of Health & Human Services
Departmental Appeals Board, MS 6132
Director, Civil Remedies Division
330 Independence Avenue, S.W.
Cohen Building – Room G-644
Washington, D.C. 20201

A request for a hearing should identify the specific issues and the findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. You do not need to submit records or other documents with your hearing request. The Departmental Appeals Board (DAB) will issue instructions regarding the proper submittal of documents for the hearing. The DAB will also set the location for the hearing, which is likely to be in Minnesota or in Chicago, Illinois. You may be represented by counsel at a hearing at your own expense.

INFORMAL DISPUTE RESOLUTION (IDR) / INDEPENDENT INFORMAL DISPUTE RESOLUTION (IIDR)

In accordance with 42 CFR 488.331, you have one opportunity to question cited deficiencies through an informal dispute resolution process. You are required to send your written request, along with the specific deficiencies being disputed, and an explanation of why you are disputing those deficiencies, to:

Nursing Home Informal Dispute Process
Minnesota Department of Health
Health Regulation Division
P.O. Box 64900
St. Paul, Minnesota 55164-0900

This request must be sent within the same ten days you have for submitting an ePoC for the cited deficiencies. All requests for an IDR or IIDR of federal deficiencies must be submitted via the web at: https://mdhprovidercontent.web.health.state.mn.us/ltc_idr.cfm

You must notify MDH at this website of your request for an IDR or IIDR within the 10 calendar day period allotted for submitting an acceptable plan of correction. A copy of the Department's informal dispute resolution policies are posted on the MDH Information Bulletin website at:
https://www.health.state.mn.us/facilities/regulation/infobulletins/ib04_8.html

Please note that the failure to complete the informal dispute resolution process will not delay the dates specified for compliance or the imposition of remedies.

Feel free to contact me if you have questions.

Sincerely,

Melissa Poepping, Compliance Analyst
Federal Enforcement | Health Regulation Division
Minnesota Department of Health
P.O. Box 64900
Saint Paul, Minnesota 55164-0970
Phone: 651-201-4117
Email: Melissa.Poepping@state.mn.us

DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically delivered

July 17, 2023

Administrator
Good Samaritan Society - Waconia And Westview Acre
333 Fifth Street West
Waconia, MN 55387

Re: Event ID: 22CR11

Dear Administrator:

The above facility survey was completed on June 29, 2023 for the purpose of assessing compliance with Minnesota Department of Health Nursing Home Rules. At the time of the survey, the survey team from the Minnesota Department of Health - Health Regulation Division noted no violations of these rules promulgated under Minnesota Stat. section 144.653 and/or Minnesota Stat. Section 144A.10.

Electronically posted is the Minnesota Department of Health order form stating that no violations were noted at the time of this survey. The Minnesota Department of Health is documenting the State Licensing Correction Orders using federal software. Please disregard the heading of the fourth column which states, "Provider's Plan of Correction." This applies to Federal deficiencies only. There is no requirement to submit a Plan of Correction.

Please feel free to call me with any questions.

Sincerely,

Melissa Poepping, Compliance Analyst
Federal Enforcement | Health Regulation Division
Minnesota Department of Health
P.O. Box 64900
Saint Paul, Minnesota 55164-0970
Phone: 651-201-4117
Email: Melissa.Poepping@state.mn.us

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	245234	A. BUILDING _____ B. WING _____	C 06/29/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
GOOD SAMARITAN SOCIETY - WACONIA AND WESTVIEW ACRE	333 FIFTH STREET WEST WACONIA, MN 55387

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 000	INITIAL COMMENTS On 6/22/23 through 6/29/23, a standard abbreviated survey was conducted at your facility. Your facility was NOT in compliance with the requirements of 42 CFR 483, Subpart B, Requirements for Long Term Care Facilities. The following complaints were reviewed: H52343009C(MN94515) and H52343093C(MN90917). The survey resulted in an Immediate Jeopardy (IJ) at F700 when the facility failed to reduce the risk of bedrail entrapment resulting in R1's neck being wedged between the assist bar and mattress while the rest of his body slid off the bed onto the floor preventing his ability to breathe. The IJ began on 6/14/23 and the immediacy was removed on 6/28/23. The above findings constituted substandard quality of care, and an extended survey was conducted from 6/28/23 to 6/29/23. The facility's plan of correction (POC) will serve as your allegation of compliance upon the Departments acceptance. Because you are enrolled in ePOC, your signature is not required at the bottom of the first page of the CMS-2567 form. Your electronic submission of the POC will be used as verification of compliance. Upon receipt of an acceptable electronic POC, an onsite revisit of your facility may be conducted to validate that substantial compliance with the regulations has been attained.	F 000		
F 700 SS=J	Bedrails CFR(s): 483.25(n)(1)-(4)	F 700		7/24/23

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Electronically Signed | 07/24/2023

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients . (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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F 700	Continued From page 1 §483.25(n) Bed Rails. The facility must 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. §483.25(n)(1) Assess the resident for risk of entrapment from bed rails prior to installation. §483.25(n)(2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation. §483.25(n)(3) Ensure that the bed's dimensions are appropriate for the resident's size and weight. §483.25(n)(4) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails. This REQUIREMENT is not met as evidenced by: Based on observation, interview and document review, the facility failed to follow requirements to ensure safe use of a bed rail assist device resulting in a resident's neck becoming wedged between the assist bar and mattress while the rest of his body slid off the bed onto the floor preventing his ability to breathe for 1 of 4 residents (R1) reviewed for entrapment risk. This resulted in an immediate jeopardy (IJ) for R1. In addition, the facility failed to reduce the risk of bedrail entrapment when they did not attempt to use alternatives, ensure correct installation and maintenance, review risks and benefits, ensure bed dimensions were appropriate, and follow the	F 700	Preparation and execution of this response and plan of correction do not constitute an admission or agreement by the provider of the truth of the facts alleged or conclusions set forth in the statement of deficiencies. The plan of correction is prepared and/or executed solely because it is required by the provisions of federal and state law. For the purposes of any allegation that the center is not in substantial compliance with federal requirements of participation, this response and plan of correction constitute the center's allegation of	

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F 700	Continued From page 2 manufacturers instructions resulting in the potential for harm for 57 of the 68 residents who utilized a bedrail assist bar for mobility. The immediate jeopardy began on 6/14/23, when R1 was found by family to have fallen off his bed with his neck and shoulder caught between the mattress and the assist bar while his bottom was on the floor. As a result R1 was having difficulty breathing. The IJ was identified on 6/27/23. The administrator, director of nursing (DON), regional clinical services director, administrator and senior director, and vice president of operations were notified of the immediate jeopardy at 5:49 p.m. on 6/27/23. The immediate jeopardy was removed on 6/28/23, but noncompliance remained at the lower scope and severity of a D which indicated no actual harm with potential for more than minimal harm that is not immediate jeopardy. Findings include: Food and Drug Administration (FDA) guidelines (''Recommendations for Health Care Providers about Bed Rails'') updated 2/27/23, provides the following guidance: Any decision regarding adult portable bed rail use or removal should be made based on the individual patient or resident assessments. If a bed rail has been determined to be necessary, steps should be taken to reduce the known risks associated with its use. To learn more about the patient or resident assessment, see the Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings. Before you install bed rails: Make sure the individual is an appropriate	F 700	compliance in accordance with section 7305 of the State Operations Manual. Complaint Survey Exit Date: June 29,2023 Center: Waconia Team Leaders: Cheryl Frey -DNS & Emily Henderson -Administrator POC Due date 7/26/2023 Deficiency tag: F 700 1. What corrective actions(s) will be accomplished for those residents found to have been affected by the deficient practice. A comprehensive physical device and restraint assessment has been completed to the resident affected by deficient practice, including educating the resident and family on the risks and benefits of the assist bar and air mattress. Care plan updates were done to include new interventions. The interventions implemented were removing the air mattress and replacing with a concave mattress, removing the assist bar, utilizing soft call light, exchanging current bed for a low rise bed, and adding a soft mat to the bedside floor. 2. How you will identify other residents having the potential to be affected by the same deficient practice and what corrective action will be taken. All residents in the facility have the potential to be affected by the same deficient practice. Facility identified 57 other residents currently residing with assist bars have risk for similar deficient	

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F 700	Continued From page 3 candidate for bed rails. Bed rails should not be used as a substitute for proper monitoring, especially for people at high risk for entrapment such as those with cognitive impairment. Follow the recommendations in the ASTM F3186-17: Standard Specification for Adult Portable Bed Rails and Related Products for home care facilities and long term care facilities. Only use bed rails that conform with ASTM F3186-17. Follow the recommendations in the FDA guidance "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment" for health care facilities and the Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings. Be aware that not all bed rails, mattresses, and bed frames are interchangeable and not all bed rails fit all beds. Check with each manufacturer to make sure the bed rails, mattress, and bed frame are compatible, because most bed rails and mattresses are purchased separately from the bed frame. Bed rails should be selected and placed to discourage climbing over rails to get in and out of bed, which could lead to injury or death from falls. Avoid the routine use of adult bed rails without first conducting an individual patient or resident assessment. https://www.fda.gov/medical-devices/adult-portable-bed-rail-safety/recommendations-health-care-providers-using-adult-portable-bed-rails The FDA guidelines ("Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment 2006, pp. 10-24) identified key body parts at risk for life-threatening entrapment the head, neck, and chest in the seven zones of a hospital bed system, focusing on the most common zones for risk of	F 700	practice. The assist bars were removed due to the lack of manufacturer's installation guidelines per regulations. These residents have had a comprehensive physical device and restraint assessment completed. This included educating resident or family on the risk versus benefit of an assist bar on the resident bed. If a bed or side rail is used, the facility will ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements: a) Documented attempted to use appropriate alternatives prior to installing a side or bed rail. b) Assess the resident for risk of entrapment from bed rails prior to installation. c) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation. d) Ensure that the bed's dimensions are appropriate for the resident's size and weight. e) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails. 3. What measures will be put in place or what systemic changes will you make to ensure that the deficient practice does not recur. To ensure systemic changes are sustained, facility has reviewed policy on Restraints – Rehab/Skilled and it's appropriate at this time. All licensed nurses will be educated on	

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F 700	Continued From page 4 entrapment zones 1-4. Zone 1 - within the rail is any open space with the perimeter of the rail. Recommended space be less than 4 ¾ inches representing head breadth. Zone 2 - under the rail, between the rail supports or next to a single rail support. This space is the gap under the rail between a mattress compressed by the weight of a patient's head and the bottom edge of the rail at the location between the rail supports or next to a single rail support. Recommended space limit for entrapment in this space is less than 4 ¾ inches. Zone 3 - between the rail and the mattress. The space between the inside surface of the rail and the mattress compressed by the weight of a patient's head. The space should be small enough to prevent head entrapment. Recommended space between the area between the inside surface of the rail and compressed mattress should be of less than 4 ¾ inches. Zone 4 - under the rail at the ends of the rail. This space poses a risk for entrapment of a patient's neck. In this space, a gap forms between the mattress compressed by the patient, and the lowermost portion of the rail, at the end of the rail. Recommended dimension for this zone measure both less than 60 mm in size and greater than 60 degrees in angle. Zone 5, 6, and 7 are identified as potential for entrapment with the least reporting. Zone 5 is the area between the split of bedrails, zone 6 is the between the end of rail and the side edge of the head or footboard, and zone 7 is between the head of footboard at the end of the mattress. Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment. (2006). Retrieved from https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocumen	F 700	comprehensive assessments of physical device and/or restraint evaluation. Also, comprehensive physical device assessments will be completed as outlined in the policy titled Restraints – Rehab/Skilled policy. At the weekly IDT meeting the following items will be discussed and evaluated: All new residents will be reviewed to ensure that a comprehensive physical device and/or restraint evaluation was completed per Restraints-Rehab/Skilled policy including but not limited to: a) Documented attempted to use appropriate alternatives prior to installing a side or bed rail. b) Assess the resident for risk of entrapment from bed rails prior to installation. c) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation. d) Ensure that the bed's dimensions are appropriate for the resident's size and weight. e) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails. 4. How the corrective actions(s) will be monitored to ensure deficient practice will not recur, i.e., what quality assurance program will be put into practice. Random audits will be conducted by the DNS or Designee on residents with assist bars 3x/week for 4 weeks, then weekly for 4 months and as needed. Findings will be shared with the QAPI committee monthly	

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	245234	A. BUILDING _____ B. WING _____	C 06/29/2023

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F 700	Continued From page 5 ts/UCM072729.pdf During observation on 6/22/23 at 2:45 p.m., the facility assist bar was in the shape of a walking cane. The top part of the cane measured six inches before bending downward at an angle creating a 7-inch curved C shaped open space. Per the FDA, Zone 1 should measure 4 3/4 inches or less. The top of the assist bar measured 14 inches above the bed frame and 23 1/2 inches from the floor. During observation and interview on 6/27/23 at 12:32 pm., the DON and administrator demonstrated how R1 was found on 6/14/23. The DON stated he fell out of bed when his feet and the bolster slid off the foot of the bed pulling the rest of his body down to the floor. She added R1 had his back up against the side of the bed sitting on the bolster and floor. She stated R1's head was between the mattress and assist bar and she was able to untangle him. She added his neck was not entrapped by the assist bar, and she did not view the incident as an entrapment. When asked for a copy of her interviews with the staff involved during the incident, the DON stated she was sure she documented the interviews and would have to find them. R1's Admission Record indicated R1 admitted to the facility on 3/20/23 with multiple diagnosis including cerebral arthrosclerosis, dementia, heart disease, dysphagia, anxiety, and adult failure to thrive. R1 was receiving hospice care. R1's MD Orders dated 3/20/23, identified an order for alternating pressure mattress (APM) to prevent pressure ulcers, and an assist device to aid with bed mobility.	F 700	for 4 months for input on the need to increase, decrease or discontinue audits. 5.The date for correction and the title of the person responsible for correction of deficiency. The date of correction will be: 06/28/2023 Cheryl Frey, DNS Emily Henderson, Administrator	

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F 700	Continued From page 6 R1's Physical Device and/or Restraint Evaluation and Review form dated 3/21/23 indicated it was recommended/reviewed the device of an assist/grab bar for R1 for participation in bed mobility and identified the potential resident safety risks were evaluated and reviewed with R1 to include potential entrapment, accident hazards, potential negative outcomes, a Federal Drug Administration (FDA) brochure and policy packet, and R1 had cognitive learning barriers related to the educational material provided but was able to verbalize understanding. The box for family or other individuals who received education was not checked. The boxes for alternatives that have been attempted before the use of assist/grab bars were not checked. The boxes for care planning the use of physical devices were not checked. R1's admission Minimum Data Set (MDS) dated 3/26/23, identified R1 had severe cognitive impairment, anxiety, and received hospice care for a terminal disease. In addition, he required extensive assistance from two nursing staff for bed mobility. R1's progress note dated 6/14/23, indicated R1 fell off his bed at 4:16 p.m. when his family member (FM)-A yelled from R1's room, "Help he is choking." R1 was found in a seated position on the floor facing the right where his neck and shoulder was caught between the mattress and the assist bar. In addition, R1 was tangled up in his sheets. FM-A was holding onto his right shoulder when the nurse was able to reposition him away from the assist bar. R1's nurse practitioner (NP) notification text dated	F 700		

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F 700	Continued From page 7 6/14/23 at 5:42 p.m. from the DON stated R1 fell out of bed and his head was caught on the assist bar. She added, "Could have been bad!" R1's progress note dated 6/15/23 indicated an incident meeting from fall on 6/14/23. The facility incident description indicated R1 was found sitting on the floor next to the bed with his head on the bed and his neck on the bedrail, tangled in his bedding, and wife in the room kneeling beside him holding his right shoulder. Contributing factors indicated R1 had severe cognitive impairment, can be restless with attempts to get out of bed. The facility plan was to implement new fall interventions for a high/low bed, safety sided mattress, floor mat, and soft touch call light. R1's NP-A visit dated 6/16/23, identified R1 was seen for an acute follow up related to neck pain. The note indicated R1 suffered a fall a couple days earlier out of his bed, where his head remained on the bed by the assist bar and his bottom was on the floor. R1 was confused and pointed towards his neck while appearing to be in pain. An order was placed for an ice pack four times a day to his neck and morphine 2.5 milligrams (mg) every hour as needed for pain and shortness of breath. R1's Physical Device and/or Restraint Evaluation and Review form dated 6/16/23 indicated R1's use of an assist/grab bar and bolsters cushion be discontinued for use because R1 did not use the grab bars for mobility and his head was "hung up" on the grab bar. There was no injury but a risk for injury. In addition, the air mattress with the bolsters cushions was also discounted due the R1's risk to slid off. The recommendation was for R1 to have a concave mattress to prevent him	F 700		

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F 700	Continued From page 8 from sliding out of bed, a high/low bed to prevent injuries from falls out of bed. The concave mattress and high/low bed with its risk and benefits was reviewed with R1's representatives with no barriers to learning. The boxes of care planning were initiated. Email correspondence dated 6/26/23 at 11:31 a.m. with Hill-Rom representative (R)-A included Hill-Rom Siderail, Assist Bar, and Headrail Upgrade Kits Operation & Maintenance Manual dated 1/04 indicated new upgrades available to the bed assist devices in response to "changing needs" in health care. In addition, a "Warning" alert for owners to keep this manual with their existing service manual listing failure to do so could result in "patient injury." Email correspondence dated 6/26/23 at 5:05 p.m. Hill-Rom technician (T)-A included Resident LTC Bed Brochure dated 12/6/17, indicated the special options available for this bed. The assist bar used at the facility was shown on the brochure installed at the foot of the bed and the open C space faced the foot of the bed. During interview on 6/22/23 at 1:16 pm. FM-A stated she found her husband sitting on the floor next to his bed, and his head was caught on the assist bar. She added he was a big guy, and she was unable to pull his neck away from the bar so he could breathe. She ran into the hall yelling, "Help, help he is choking." She stated R1 was unable to communicate, and he was frightened. She added R1 was very restless and always trying to get out of bed or his wheelchair prior to his admission to the facility. She was afraid he would fall out of bed and told the facility staff about her concern when he was admitted to the	F 700		

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F 700	Continued From page 9	F 700		

facility. Now the facility provided a high-low bed capable of lowering to a few inches off the floor. In addition, the facility placed a thick fall mat next to the bed to catch him if he fell out of bed again.

During interview on 6/26/23 at 9:05 a.m. the administrator stated the only bed operation and maintenance manual they could find was the Resident LTC Bed Service Manual for P870 model from Hill-ROM. The manual was originally issued on 12/1/1996. She stated the manual did not include the assist bars operator instructions or maintenance requirements for use.

During interview on 6/26/23 at 11:11 a.m. Hill-Rom representative (R)-A stated the assist bars open C space should face the foot of the bed to prevent an entrapment. He said the facility would have installed the assist bars and must have placed them incorrectly facing the front of the bed. He added the facility could remove the assist bars and place them on the opposite side.

During interview on 6/26/23, at 1:00 p.m. facility maintenance (M)-A stated the facility beds were the Resident LTC Bed from Hill-Rom model number P970, showing R1's bed now located at the facility garage. The assist bars were attached to the bed frame. The assist bar was capable of locking in the up position for use or stored in a locked position along the bed frame when not in use. He stated the assist bar came with the bed, and it was welded in place to be the frame preventing it from being switched to the other side of the bed so the open C area would face the foot of the bed. M-A confirmed he annually inspected each bed at the facility by shaking the bed to identify loose bolts and looking for frayed cords.

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F 700	Continued From page 10 During interview on 6/26/23, at 1:17 p.m. with M-A, R-A and the administrator, R-A said the assist bars were an accessory to the bed and would not have come installed. The facility must have installed the bars on the wrong side of the bed. He said all they would have to do was remove two bolts to remove and reinstall them on the other side of the bed. He reiterated the assist bars C space open must face the foot of the bed for safety. During interview on 6/26/23 at 3:00 p.m. the physical therapist (PT)-A stated one of his responsibilities included an assist bar evaluation for all the facility's residents upon admission, and after a change in condition. PT-A stated the assist bar is shaped like a cane, and the opening facing the head of the bed could be a potential risk for entrapment. PT-A stated prior to R1's falling out of bed he did not see the risk but now he could. PT-A stated he had no formal training on different assist devices for a nursing home bed, "I just make sure it's on the bed appropriately and make sure the resident can use it." During interview on 6/26/23 at 3:35 p.m. the director of nursing (DON) stated what happened to R1 on 6/14/23, was not a case of entrapment because his neck was not caught in the assist bar's C shaped opening, and he was never choking. In addition, the shape and position of the assist bar did not pose a risk to any of their residents. She had worked at the facility for 42 years, and the assist bars on the beds had not changed. On 6/14/23, after R1's fall she arrived at the incident and found him sitting on the floor. She completed a head-to-toe skin evaluation and did not find any bruising or redness. She stated even though she did not feel there was an	F 700		

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F 700	Continued From page 11 entrapment risk, she switched R1's bed to a high low bed because she did not want it to happen again. During interview on 6/26/23 at 5:00 p.m. Hill-Rom T-A stated the bed was manufactured with four side rails. As the bed became popular for nursing home use, the assist bar was developed for use. Later, after FDA regulations and changing guidance the original assist bar had too big of an opening and the company developed a conversation kit to eliminate the spacing created by the device. During interview on 6/27/23 at 2:01 p.m. administrator and senior director (SD)-A stated she spoke with T-B at Hill-Rom who told her the assist bars could face in any direction. During interview on 6/27/23 at 2:33 p.m. the DON confirmed R1's Physical Device and/or Restraint Evaluation and Review dated 3/21/23, did not include the requirements to try alternative approaches before using an assist bar, complete a risk verse benefits assessment and because R1 had severe cognitive impairment he was unable to give informed consent. In addition, she stated the nursing staff failed to update R1's bed mobility limitations and he was approved to use an assist bar in his care plan. R1's family did not receive the required Federal Drug Administration (FDA) brochure and policy resource packet. She stated after the 6/14/23 fall, she exchanged R1's bed with low-high bed and a fall mat next to his bed to prevent R1 from being trapped and choked again. She added after a fall the facility holds an incident meeting, fall review to determine the cause of the fall and any new practice to prevent future falls. She stated the	F 700		

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F 700	Continued From page 12 incident meeting and fall review was held for the 6/11/23 fall but not for the 6/14/23 fall because they did not have time to do so. During interview on 6/27/23 at 4:42 p.m. spoke with Hill-Rom T-B regarding his conversation with SD-A. He stated he did not tell SD-A the assist bars could face in any direction. He said during the conversation he told her several times there was a left and a right assist bar and when placed correctly on the bed the open C space would face towards the foot of the bed. He even showed them the Resident LTC Bed Brochure picture of an assist bar facing the foot of the bed. T-B was unable to find the part number P00070848 for the assist bar listed in the Hill-Rom Siderail, Assist Bar, and Headrail Upgrade Kits Operation & Maintenance Manual because it was now obsolete. During interview on 6/28/23 at 9:07 a.m. NP-A stated she was contacted by someone at the facility regarding R1's fall on 6/14/23. She was told he did not suffer any injury, but she was unable to visualize how it happened. She asked the staff to describe how his neck was caught on the assist bar, but the staff told her at that time he did not get his neck caught on the assist bar, but it could have. She was updated on 6/16/23 after R1 was showing signs of neck pain. She assessed him at that time and did not find any deficit while he performed different range of motion exercises. She questioned why he would need an assist bar since he was an extensive assistance with two staff for bed mobility. During interview on 6/28/23 at 9:40 a.m. RN-B stated on 6/14/23, she found R1 sitting on the floor and leaning to the right towards the assist	F 700		

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F 700	Continued From page 13 bar with his right shoulder tucked between the assist bar and the mattress. R1's neck was lodged in the C shape space causing his skin to turn blue and slow down his ability to breathe normally. His wife was trying to push him up so he could breathe. She said R1 was a large man, and his body weight made it difficult to reposition his neck and right shoulder away from the assist bar. R1 was incontinent of urine at the time and had a history of trying to climb out of bed. During interview on 6/28/23 at 11:00 a.m. SD-A stated all of the assist bars were removed from all the beds and reinstalled on the appropriate side to face the foot of the bed. During group interview on 6/28/23 at 12:29 p.m. with the administrator, DON, SD-A, and the regional clinical director (CD)-A call was placed to discuss the assist bars with a Hill-Rom technician and obtain the required maintenance and service manual for the assist bar. T-B stated Hill-Rom no longer had any maintenance and service manuals for their assist bar. In addition, the up-grade assist bar information is now obsolete. He was unable to tell when or why it became obsolete. SD-A stated she called Hill-Rom the day before and they told her they could be installed either way. Informed SD-A, T-B was interviewed and he denied telling the facility the assist bars could be installed in any direction. The facility policy Bed Safety Including: Bed Rails, Side Rails, Assist Bars-Rehab/Skilled, Therapy & Rehab dated 9/6/22 identified an entrapment would be any event involving a resident being "caught, trapped, or entangled" in the space between the bed and the bar. Review alternative devices before installing an assist bar. Only	F 700		

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F 700	Continued From page 14 suitable residents who can grab the assist bar independently or with nursing staff and used for bed mobility would receive one. In addition, a risk verse benefit assessment would be reviewed with the resident or family along with a signed consent. The immediate jeopardy that began on 6/14/23, was removed on 6/28/23, when the facility removal plan was verified by observation, interview, and record review. Noncompliance remained at a lower scope and severity level of 2, D-isolated because the facility needs to document steps taken for substantial compliance. -The facility reviewed its policy titled Bed Safety including Bed Rails, Side Rails, Assist Bars-Rehab/Skilled, Therapy & Rehab and found it current. -A system was initiated for bed inspections following the policy title Bed Safety. -Educated all licensed nurses on assessing the use of assist/grab bar device. -All 57 resident currently using assist/grab bars were reassessed based on the on the assessment criteria, which when appropriate the grab bars were removed from resident use and/or applied according to manufacturing instruction. -Resident care plans were updated to reflect the use of assist/grab bar device.	F 700		

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2 000	Initial Comments *****ATTENTION****** NH LICENSING CORRECTION ORDER In accordance with Minnesota Statute, section 144A.10, this correction order has been issued pursuant to a survey. If, upon reinspection, it is found that the deficiency or deficiencies cited herein are not corrected, a fine for each violation not corrected shall be assessed in accordance with a schedule of fines promulgated by rule of the Minnesota Department of Health. Determination of whether a violation has been corrected requires compliance with all requirements of the rule provided at the tag number and MN Rule number indicated below. When a rule contains several items, failure to comply with any of the items will be considered lack of compliance. Lack of compliance upon re-inspection with any item of multi-part rule will result in the assessment of a fine even if the item that was violated during the initial inspection was corrected. You may request a hearing on any assessments that may result from non-compliance with these orders provided that a written request is made to the Department within 15 days of receipt of a notice of assessment for non-compliance. INITIAL COMMENTS: On 6/22/23 through 6/29/23, a complaint survey was conducted at your facility by surveyors from the Minnesota Department of Health (MDH). Your facility was IN compliance with the MN State Licensure The following complaints were reviewed with no	2 000		

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GOOD SAMARITAN SOCIETY - WACONIA AND WEST\	333 FIFTH STREET WEST WACONIA, MN 55387

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2 000	Continued From page 1 deficiency issued. H52343009C(MN94515) H52343093C(MN90917) Minnesota Department of Health is documenting the State Licensing Correction Orders using Federal software. The facility is enrolled in ePOC and therefore a signature is not required at the bottom of the first page of state form. Although no plan of correction is required, it is required that the facility acknowledge receipt of the electronic documents.	2 000		