Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically delivered
February 8, 2023

Administrator
Mayo Clinic Health System - Lake City
500 West Grant Street
Lake City, MN 55041

RE: CCN: 245218
Cycle Start Date: January 3, 2023

Dear Administrator:

On January 19, 2023, we notified you a remedy was imposed. On February 6, 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 January 30, 2023.

As authorized by CMS the remedy of:

- Discretionary denial of payment for new Medicare and Medicaid admissions effective February 3, 2023 did not go into effect. (42 CFR 488.417 (b))

However, as we notified you in our letter of January 19, 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 January 3, 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,

Sarah Lane, Compliance Analyst
Federal Enforcement | Health Regulation Division
Minnesota Department of Health
P.O. Box 64900
Saint Paul, MN 55164-0900
Telephone: 651-201-4308 Fax: 651-215-9697
Email: sarah.lane@state.mn.us

DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically delivered

February 8, 2023

Administrator
Mayo Clinic Health System - Lake City
500 West Grant Street
Lake City, MN 55041

Re: Reinspection Results
Event ID: E9K412

Dear Administrator:

On February 6, 2023 survey staff of the Minnesota Department of Health - Health Regulation Division completed a reinspection of your facility, to determine correction of orders found on the survey completed on January 3, 2023. At this time these correction orders were found corrected.

Please feel free to call me with any questions.

Sincerely,

Sarah Lane

Sarah Lane, Compliance Analyst
Federal Enforcement | Health Regulation Division
Minnesota Department of Health
P.O. Box 64900
Saint Paul, MN 55164-0900
Telephone: 651-201-4308 Fax: 651-215-9697
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Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically Submitted
January 19, 2023

Administrator
Mayo Clinic Health System - Lake City
500 West Grant Street
Lake City, MN 55041

RE: CCN: 245218
Cycle Start Date: January 3, 2023

Dear Administrator:

On January 3, 2023, survey was completed at your facility by the Minnesota Department of Health and Public Safety 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 January 1, 2023, the situation of immediate jeopardy to potential health and safety cited at F760 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 February 3, 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 February 3, 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 February 3, 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 $11,292; 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 January 3, 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, Mayo Clinic Health System - Lake City is prohibited from offering or conducting a Nurse Assistant Training / Competency Evaluation Programs (NATCEP) or Competency Evaluation Programs for two years effective January 3, 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:

Lisa Krebs, Rapid Response
Licensing and Certification Program
Health Regulation Division
Minnesota Department of Health
Rochester District Office
18 Woodlake Drive, Rochester MN, 55904
Email: Lisa.Krebs@state.mn.us
Office (507) 206-2728

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 July 3, 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) 565-9462

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,

Sarah Lane, Compliance Analyst
Federal Enforcement | Health Regulation Division
Minnesota Department of Health
P.O. Box 64900
Saint Paul, MN 55164-0900
Telephone: 651-201-4308 Fax: 651-215-9697
Email: sarah.lane@state.mn.us

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	245218	A. BUILDING _____ B. WING _____	C 01/03/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MAYO CLINIC HEALTH SYSTEM - LAKE CITY	500 WEST GRANT STREET LAKE CITY, MN 55041

(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 12/29/22, 12/30/22 and 1/3/23, a standard abbreviated survey was completed at your facility by surveyors from the Minnesota Department of Health (MDH). The facility was not found NOT to be in compliance with the requirements of 42 CFR Part 483, Subpart B, requirements for Long Term Care Facilities. The survey resulted in an immediate jeopardy (IJ) to resident health and safety. An IJ F760 began on 12/14/22, when nurse practitioner (NP)-A abruptly discontinued R1's baclofen without a required taper (gradually weaning off from medication) resulting in R1 having significant withdrawal symptoms.The administrator, and director of nursing (DON) were notified of the IJ on 12/30/22 at 4:30 p.m. The IJ was removed on 1/1/2023. The above findings constituted Substandard Quality of Care and an extended survey was conducted on 1/3/2023. The following complaints were found to be unsubstantiated: H52186682C (MN89351) and H52186687C (MN89364). The following complaints were found to be SUBSTANTIATED: H52187060C (MN89707) with a deficiency cited at F760. 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	F 000		

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

Electronically Signed | 01/24/2023

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 000	Continued From page 1 be used as verification of compliance. Upon receipt of an acceptable electronic POC, an onsite revisit of your facility may be conducted to validate substantial compliance with the regulations has been attained in accordance with your verification.	F 000		
F 760 SS=J	Residents are Free of Significant Med Errors CFR(s): 483.45(f)(2) The facility must ensure that its- §483.45(f)(2) Residents are free of any significant medication errors. This REQUIREMENT is not met as evidenced by: Based on interview and document review the facility failed to accurately transcribe order for baclofen (medication used to treat muscles spasms) upon admission, identify withdrawal symptoms, and tapered baclofen according to manufacturer's recommendations for 1 of 3 residents (R1) who received baclofen. R1 had significant withdrawal symptoms resulting in hospitalization . The facility failure resulted in an immediate jeopardy (IJ) for R1. The IJ began on 12/14/22, when nurse practitioner (NP)-A abruptly discontinued R1's baclofen resulting in R1 having significant withdrawal symptoms was sent to the emergency department (ED) on 12/18/22 and admitted to the ICU where R1 remained hospitalized. The administrator and the director of nursing (DON) were notified of the IJ on 12/30/22, at 4:30 p.m. The IJ was removed on 1/1/23, but non-compliance remained at the lower scope and severity of level D, which indicated no actual harm with potential for more than minimal harm	F 760	Submission of this Allegation of Compliance is not a legal admission that a deficiency exists or that this Statement of deficiencies was correctly cited and is also not to be construed as an admission against the Facility, Administrator, of any Employees, Agents or other individuals who draft or may be discussed in the Allegation of Compliance. In addition, preparation and submission of the Allegation of Compliance does not constitute an admission or an agreement of any kind by the Facility of the truth of any facts alleged or the correctness of any conclusions set forth in the Statement by the survey agency. Accordingly, the Facility has prepared and submitted this Allegation of Compliance solely because of the requirements under State and Federal law that mandate submission of an Allegation of Compliance within ten days of receipt of the Statement of Deficiencies as a condition of participation	1/30/23

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F 760	Continued From page 2 that is not immediate jeopardy. Findings include: The manufacturer's package insert for baclofen included: Warnings and Precautions * Abrupt discontinuation of baclofen has resulted in serious adverse reactions including death; therefore, reduce the dosage slowly when baclofen is discontinued. 5.1 Adverse Reactions from Abrupt Withdrawal Abrupt discontinuation of baclofen, regardless of the cause, has resulted in adverse reactions that include hallucinations, seizures, high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to Rhabdomyolysis, multiple organ-system failure, and death. Therefore, reduce the dosage slowly when OZOBAX (baclofen) is discontinued, unless the clinical situation justifies a rapid withdrawal. R1's admission record copied on 12/29/22 identified R1 was admitted to the facility on 12/12/22, with diagnoses that included: pain due to internal orthopedic quadriplegia (paralysis of all 4 limbs), chronic pain syndrome, and autonomic dysreflexia (a potential life-threatening medical emergency where an abnormal overreaction of the involuntary nervous system to stimulation resulting in excessive sweating, a change in heart rate and high blood pressure, fever anxiety, and goosebumps with flushed skin above the level of the spinal cord injury). R1's hospital After Visit Summary (AVS) indicated R1 received baclofen 40 milligrams (mg) on 12/12/22, at 12:10 p.m.	F 760	in Title 18 and Title 19 programs. The submission of this Allegation of Compliance within this timeframe should in no way be considered or construed as an agreement with allegations of noncompliance or admissions by the facility. This plan of correction is not to be construed as an admission by the facility or any of its agents that the survey agents findings in this report are true or correct. The plan of correction is written for the purpose of compliance with the rules of participation for the Medicaid and Medicare programs. On 12/30/2022, MDH completed a standard abbreviated survey and noted the facility failed to transcribe medications and monitor for effectiveness or side effects and appropriately taper a medication in accordance with manufacturer□s recommendations resulted in serious harm for R1. Corrective Action: Policies and procedures related to Transcription of Physician orders have been reviewed. No changes have been made. Policies and procedures remain appropriate. Policies and procedures related to Change of Notification policy has been reviewed. No changes have been made. Policies and procedures remain appropriate. Admission Packet checklist was reviewed and revised to include compare medications from After Visit Summary and discharge summary. Report differences to provider.	

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F 760	Continued From page 3 R1's hospital Discharge Summary Brief Overview dated, 12/12/22, under section Medication List at Discharge as of 1:22 p.m included the order: Baclofen 20 mg tablet patient taking differently: (he) takes 20 mg by mouth in the morning, 40 mg at 11:00 a.m., 20 mg at 5:00 p.m., and 40 mg at bed time. The start date of this dosage was 11/8/22, over a month ago. Hospital records did not identify how long R1 had been taking baclofen medication. R1's facility physician order dated 12/12/22 for baclofen upon admission to the NH was inconsistent with the discharging physician order. The order transcribed into R1's record was baclofen 20 mg four times a day, which was 40 mg less than the hospital discharge summary identified. R1's care plan dated 12/12/22, identified R1 had chronic pain and right shoulder surgical pain. R1 required scheduled Baclofen for muscle spasms in his back. Interventions included to administer medications for pain as ordered and monitor response. Further directed staff to evaluate the effectiveness of the pain interventions, review for compliance, alleviating of symptoms, dosing schedules and satisfaction with results, impact on functional ability and on cognition. R1's medication administration record (MAR) for December 2022, indicated R1's baclofen was administered on 12/12/22, 20 mg at 4:00 p.m. and again at 8:00 p.m. Baclofen was given 20 mg four times a day from 12/12/22 and discontinued on 12/14/22 with the last dose given at 4:00 p.m.	F 760	Corrective Action as it applies to other residents: " Other residents with potential to suffer from Baclofen withdrawal have been identified and reviewed for proper dose and medication. " All nursing staff have been re-educated on the following policies: o Transcription of Physician Orders Policy o Change of Condition Notification Policy o Policy re: Withdrawal Symptoms of Baclofen (written by Medical Director) " All RN□s, LPN□s, and HUC staff have been re-educated on: o Knowledge of Acceptable Parameters for Vital Signs with Test o Medication Order Reconciliation Process - Facility will reconcile After Visit Summary for facilities to the Discharge Summary Medication Recapitulation form for every admission. If discrepancy is noted, provider will be notified. " Vital sign parameters to report have been posted on all vital sign towers " Medical Director educated Nurse Practitioner on 12/16/2022 " Nurse Manager or Designee have been re-educated regarding the revised Admission Checklist " Staff will be educated via email and in-person training. Staff will be competency tested on Change of Condition, Baclofen withdrawal, medication transcription, vital sign parameters, admission process related to medication reconciliation prior to working on the units	

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F 760	Continued From page 4 R1's progress note dated 12/13/22, at 4:39 a.m. indicated R1 was so uncomfortable in bed; wanted to lay flat but complains of shortness of breath (SOB), hydrocodone (narcotic pain med) given for comfort. R1 had been repositioned over 5 times this shift. -At 7:00 a.m. R1 was asking for his medications and refused to put the head of the bed (HOB) up because R1 stated that he gets back spasms. Blood pressure (B/P) 210/111 (normal is 120/80). -At 2:59 p.m. indicated R1 was in pain and had spasms most of the day. B/P was 178/96, heart rate (HR) 78 (normal heart rate 60-100), respirations at 24 (normal 12-16). -At 5:35 p.m. R1 was given ibuprofen (medication to treat pain, fever, and inflammation) and the follow up pain scale was a 6/10, still having back pain and muscle spasms. R1 stated, could not wait until 7:00 p.m. to get scheduled meds. -At 7:20 p.m. R1's HOB lowered per request due to being uncomfortable and muscle spasms while raised. R1's monitoring sheet, dated 12/14/22 indicated R1's had frequent spasms to the extent of causing him to start falling out of bed and required repositioning to prevent falls. R1's progress note dated 12/14/22, at 1:38 p.m. indicated R1 had requested a different bed because of spasms caused his legs to come out of the bed. Vital sign records at 2:33 p.m. BP was 166/86, HR-88, and respirations were 18. At 2:59 p.m. progress note indicated R1 had been calling out for assistance every 1.5 hours if not more frequently for positioning because of the spasms. R1's physician visit dated 12/14/22, indicated R1 was seen by nurse practitioner (NP)-A for muscle spasms in R1's legs. The note identified NP-A	F 760	Reoccurrence will be prevented by: " Nurse Manager or Director of Nursing will review the 24-hour report to review any resident changes that may indicate a change in condition Mon-Fri. Charge Nurse or Director of Nursing will review the 24-hour report to review any resident changes that may indicate a change in condition on weekends. Audits will be completed 5 times a week for 5 weeks. Audits will be brought to QAPI for review and further recommendation. " DON or Designee will audit the 24-hour report for changes in condition 5 times a week for 5 weeks, the 2 times a week for 2 weeks thereafter. Audits will be brought to QAPI for review and further recommendation. " Nurse Manager or Designee will reconcile After Visit Summary for facilities to the Discharge Summary Medication Recapitulation form for every admission. If discrepancy is noted, provider will be notified. " DON or Designee will audit admission orders to ensure all medications are transcribed on admission. 3 random chart audits will be completed weekly for 5 weeks, then 2 chart audits a week for 3 weeks. Audits will be brought to QAPI for review and further recommendation. Date of Correction: 1/30/2023 Correction will be monitored by: Director of Nursing and/or Designee	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	245218	A. BUILDING _____ B. WING _____	C 01/03/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MAYO CLINIC HEALTH SYSTEM - LAKE CITY	500 WEST GRANT STREET LAKE CITY, MN 55041

(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 760	Continued From page 5 gave order to immediately stop R1's Baclofen (without a taper) and to start Flexeril (muscle relaxer) for better muscle spasm control. New order for Flexeril 10 mg to take 4 times a day. Continue to monitor, notify senior service team provider if symptoms fail to improve or worsen. Physician visit documentation did not identify or mention effectiveness of R1's current dose of baclofen that was inconsistent with hospital discharge orders. R1's progress note, dated 12/15/22, at 3:58 a.m. R1 required repositioning every 30 to 45 minutes. At 4:52 a.m. at 10:25 a.m. hydrocodone administered for pain and discomfort. Vital sign record at 3:01 p.m. B/P was 144/75, HR was 101, and Respirations were 20. At 3:03 p.m. hydrocodone was administered for pain, R1 ' s comfort level was fluctuating throughout the shift. At 6:43 p.m. R1 was having spasms and pain. At 8:20 p.m. R1 administered hydrocodone for pain and muscle spasms. At 10:33 p.m. R1 had been repositioned 5 during the evening shift due to having trouble trying get his legs adjusted so he could lay on his side. R1's progress note dated 12/16/22, at 1:05 a.m. indicated R1 had an unwitnessed fall, found beside his bed on the floor, lying on his right side. Prior to the fall R1 was in bed trying to lower his 70-degree head of bed when his legs began spasming. At 4:20 a.m. R1 continued to have uncontrolled back and arm pain after the fall, with a heart rate of 140. R1 was transferred to the emergency room and returned to the facility at 6:00 a.m. with diagnoses of back contusion. Upon return B/P-203/122 and HR-137. At 7:34 a.m. physician communication was completed to see provider due to increased blood pressure,	F 760		

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F 760	Continued From page 6 hallucinations during the night, uncontrolled back spasms. R1 complained of feeling hot, extreme episodes of anxiety at times, abdominal breathing during times of distress and has a history of autonomic dysreflexia. R1's Consultant Pharmacist's Medication Review, dated 12/16/22 at 11:18 a.m. identified an irregularity of a high dose of baclofen was stopped on 12/14/22, withdrawal has been reported with abrupt discontinuation. Suggested course of action: Discussed with medical director (MD)-A today, recommend taper of baclofen dose to prevent withdrawal (i.e., 20 mg three times a day (TID), then 5 mg TID, then 5 mg twice a day (BID), then 5 mg every day. Implementation timeframe: physician to address as soon as possible (ASAP). R1's Provider visit, dated 12/16/22, indicated R1 was seen for admission visit following a hospital stay from 12/8/22 to 12/12/22 for planned right total reverse shoulder arthroplasty (a surgical procedure to restore the function of a joint). Past medical history includes significant quadriparesis following a motor vehicle accident (MVA), spasticity on baclofen. R1 is reporting ongoing difficulty with muscle spasms and was transitioned from baclofen to Flexeril. Staff have been concerned about increasing anxiety and reported intermittent hallucinations. R1 also reported some visual hallucinations. Consultant pharmacist (CP)-A expressed concern for risk of baclofen withdrawal given recent transition from baclofen to Flexeril. On reviewing vitals, noted that R1 has been running tachycardic and hypertensive. R1 has been quite variable in his blood pressures, but have run typically higher rather than low recently and running particularly	F 760		

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F 760	Continued From page 7 high this morning with systolic in the 180's. Because of hypertension, staff were able to obtain supply from a local pharmacy of nifedipine (medication to manage blood pressure) of 10 mg one time. R1 has also had some fluctuations in temperature control, being hot most of the time but cold at other times. R1's blood pressure was noted to be 188/105, pulse 101 and respiratory rate was 24. Physical exam identified R1 was seated in motorized wheelchair, tremor noted that varies in intensity. R1 does express fluctuations in temperature/comfort feelings. Does have some odd comments at times but is able to provide accurate recent history. Mildly anxious but otherwise cooperative during visit. Assessment/Plan Number 1: Autonomic Dysreflexia: Suspect findings here today are consistent with baclofen and potentially autonomic dysreflexia. Note indicated new orders for terazosin (blood pressure medication), baclofen 20 mg three times a day, reduce Flexeril to 5 mg three times a day alternating with baclofen. R1's progress note, dated 12/16/22, at 2:30 p.m. indicated R1 had visual hallucination in morning and afternoon. R1 reported feeling comfortable during the shift, however during bouts of spasms rated pain 10 out 10. At 10:11 p.m. progress note identified R1 required frequent repositioning. R1's progress note dated 12/17/22, at 6:26 a.m. indicated R1 continues to be hallucinating and has been noted to be very restless this shift. R1 stated he thinks his medications are making him "crazy." At 1:19 p.m. R1 was repositioned every 30-45 minutes. At 4:20 p.m. family member reported R1 was not his usual self, was hallucinating, and confused. R1 was sent to	F 760		

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F 760	Continued From page 8 emergency room at 11:00 p.m. and returned to the facility at 11:30 p.m. with order for antibiotics for possible urinary tract infection and instruction to follow-up with primary care provider. R1's progress notes dated 12/18/22, at 10:20 a.m. identified R1 complained of back pain and was agitated. HR-141. R1 was transferred back to the ER for further evaluation. Review on R1's hospitalization records, dated 12/18/22 identified upon arrival to ER, R1 was tachycardia (rapid heartrate), Tachypnea (rapid breathing) and altered mental status. R1 was admitted to medical intensive care unit (MICU) for change in mental status and apnea. Hospital records dated 12/20/22, identified diagnoses of encephalopathy (brain disease that alters brain function) in the setting of baclofen withdrawal. Recommendation to resume R1's prior dose of baclofen, if he continues to have worsening spasticity that is causing pain or difficulty with positioning the baclofen could be increased to maximum daily dosing if it was not already at this level at home. "Baclofen is the primary medication I would recommend treating his spasticity. Botox injections could also be considered. I would not recommend using Flexeril or other muscle spasm medications as the primary treatment for his spasticity. If baclofen is to be stopped again in the future, it should be slowly tapered to avoid dangerous withdrawal." During a phone interview on 12/30/22, at 11:43 a.m. consultant pharmacist (CP)-A stated that R1's baclofen was abruptly discontinued by NP-A on 12/14/22 and should not have been discontinued without a taper. The symptoms of baclofen withdrawal would be similar of opiate	F 760		

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F 760	Continued From page 9 withdrawal and would include symptoms R1 was exhibiting such as increased blood pressure and pulse, hot flashes, hallucinations anxiety, spasticity, and restlessness. During an interview on 12/30/22, at 12:15 p.m. clinical manager (CM)-A stated R1 was admitted on 12/12/22 and was here to rehab from his right shoulder arthroplasty. Also had a diagnosis of a spastic quadriplegic. R1 was having some pretty severe muscle spasms and NP-A saw R1 on 12/14/22 and discontinued his baclofen and started him on Flexeril. CM-A stated that R1 was not tapered off the baclofen and should have been. CM-A stated that R1 was having symptoms to include heat intolerance, severe anxiety, restlessness, hallucinations when the baclofen was discontinued and continued to exhibit them until he was discharged to the ED on 12/18/22. CM-A stated these symptoms would be from the baclofen withdrawal. During a follow-up interview at 2:34 p.m. CM-A stated she did the admission for R1. She did not notice the discrepancy between the discharge summary orders and the signed orders were different. Had she noticed she would have called the provider for clarification. During an interview on 12/30/22, at 2:11 p.m. DON stated, R1's baclofen upon admission on 12/12/22 was not transcribed correctly. R1 was supposed to get a total of 120 mg of baclofen a day in 4 divided doses upon admission and was only receiving 80 mg in 4 divided doses until it was discontinued abruptly by NP-A on 12/14/22. DON stated a taper should have been done and that their consulting pharmacist gave a recommendation on 12/16/22 noting to not stop baclofen without a taper.	F 760		

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F 760	Continued From page 10 During a phone interview on 12/30/22, at 5:24 p.m. medical director (MD)-A stated he was aware of R1's transcription error regarding baclofen and verified R1 was initially receiving 40 mg less baclofen per day initially than when he was in the hospital until it was abruptly discontinued on 12/14/22. MD-A stated, the baclofen should not have been discontinued without a taper and that the CP-A made him aware of this on 12/16/22. MD-A stated, the symptoms R1 was exhibiting were most likely from baclofen withdrawal leading to autonomic dysreflexia. The immediate jeopardy that began on 12/14/22, was removed on 1/1/23, when it was verified, the facility implemented the following: -reviewed policies and procedures for transcribing medications upon admission and educated staff on these policies -educate staff and providers on medications that require tapers and withdrawal symptoms -review and revise policy for change in condition and acceptable parameters for vital signs and educated staff on these policies Facility policy titled, "Medication Error Management Policy," revised 5/17, Procedure: 1. All medication errors must be reported immediately upon identification of error occurring, complete the medication error report fully and give to nursing supervisor or director of nursing (DON). 2. Resident's MD/NP needs to be notified: the immediacy of the notification is dependent on the category of error, harm/lack of harm to the resident and time of day; notification of timing will be determined by the nursing supervisor or DON. 3. Initiate any orders received by the MD. 6. Root cause analysis is to be completed for all	F 760		

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F 760	Continued From page 11 medication errors. 8. DON reviews all medication reports, is responsible for determining notification of error to the Medical Director and intervention, if any, regarding the individual employee or medication systems/procedures re-education and/or disciplinary measures are to be implemented as outlined below based on the type of error and prescribed educational and/or counseling intervention. Significant error: an error that resulted in the need for treatment or intervention and caused temporary resident discomfort; an error occurred that resulted in hospitalization. Significant Medication Error with change in condition and hospitalization: if a nurse/TMA has one error in this category, a root cause an analysis of error will be completed in 3 days. An investigation suspension until completion of an internal review and the root cause analysis may be imposed.	F 760		

Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically delivered
January 19, 2023

Administrator
Mayo Clinic Health System - Lake City
500 West Grant Street
Lake City, MN 55041

Re: State Nursing Home Licensing Orders
Event ID: E9K411

Dear Administrator:

The above facility was surveyed on December 29, 2022 through January 3, 2023 for the purpose of assessing compliance with Minnesota Department of Health Nursing Home Rules and Statutes. At the time of the survey, the survey team from the Minnesota Department of Health - Health Regulation Division noted one or more violations of these rules or statutes that are issued in accordance with Minn. Stat. § 144.653 and/or Minn. Stat. § 144A.10. If, upon reinspection, it is found that the deficiency or deficiencies cited herein are not corrected, a civil fine for each deficiency not corrected shall be assessed in accordance with a schedule of fines promulgated by rule and/or statute of the Minnesota Department of Health.

To assist in complying with the correction order(s), a "suggested method of correction" has been added. This provision is being suggested as one method that you can follow to correct the cited deficiency. Please remember that this provision is only a suggestion and you are not required to follow it. Failure to follow the suggested method will not result in the issuance of a penalty assessment. You are reminded, however, that regardless of the method used, correction of the order within the established time frame is required. The "suggested method of correction" is for your information and assistance only.

You have agreed to participate in the electronic receipt of State licensure orders consistent with the Minnesota Department of Health Informational Bulletin 14-01, available at https://www.health.state.mn.us/facilities/regulation/infobulletins/ib04_8.html. The State licensing orders are delineated on the Minnesota Department of Health State Form and are being delivered to you electronically. The Minnesota Department of Health is documenting the State Licensing Correction Orders using federal software. Tag numbers have been assigned to Minnesota state statutes/rules for Nursing Homes.

The assigned tag number appears in the far left column entitled "ID Prefix Tag." The state statute/rule number and the corresponding text of the state statute/rule out of compliance is listed in the "Summary Statement of Deficiencies" column and replaces the "To Comply" portion of the correction order. This column also includes the findings that are in violation of the state statute or rule after the statement, "This MN Requirement is not met as evidenced by." Following the surveyors findings are the Suggested Method of Correction and the Time Period For Correction.

PLEASE DISREGARD THE HEADING OF THE FOURTH COLUMN WHICH STATES, "PROVIDER'S PLAN OF CORRECTION." THIS APPLIES TO FEDERAL DEFICIENCIES ONLY. THIS WILL APPEAR ON EACH PAGE.

THERE IS NO REQUIREMENT TO SUBMIT A PLAN OF CORRECTION FOR VIOLATIONS OF MINNESOTA STATE STATUTES/RULES.

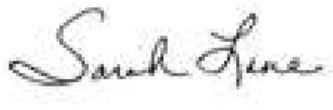
Although no plan of correction is necessary for State Statutes/Rules, please enter the word "corrected" in the box available for text. You must then indicate in the electronic State licensure process, under the heading completion date, the date your orders will be corrected prior to electronically submitting to the Minnesota Department of Health. We urge you to review these orders carefully, item by item, and if you find that any of the orders are not in accordance with your understanding at the time of the exit conference following the survey, you should immediately contact:

Lisa Krebs, Rapid Response
Licensing and Certification Program
Health Regulation Division
Minnesota Department of Health
Rochester District Office
18 Woodlake Drive, Rochester MN, 55904
Email: Lisa.Krebs@state.mn.us
Office (507) 206-2728

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.

Please feel free to call me with any questions.

Sincerely,



Sarah Lane, Compliance Analyst
Federal Enforcement | Health Regulation Division
Minnesota Department of Health
P.O. Box 64900
Saint Paul, MN 55164-0900
Telephone: 651-201-4308 Fax: 651-215-9697
Email: sarah.lane@state.mn.us

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	00770	A. BUILDING: _____ B. WING _____	C 01/03/2023

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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 12/29/22, 12/30/22 and 1/3/23, a complaint survey was conducted at your facility by surveyors from the Minnesota Department of Health (MDH). Your facility was found NOT in compliance with the MN State Licensure. Please indicate in your electronic plan of correction you have reviewed these orders and identify the date	2 000		

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2 000	Continued From page 1 when they will be completed. The following complaint was found to be SUBSTANTIATED: H52187060C (MN89707), with a licensing order issued at 1545. The following complaints were found to be UNSUBSTANTIATED: H52186682C (MN89351) and H52186687C (MN89364). The Minnesota Department of Health is documenting the State Licensing Correction Orders using Federal software. Tag numbers have been assigned to Minnesota state statutes/rules for Nursing Homes. The assigned tag number appears in the far-left column entitled "ID Prefix Tag." The state statute/rule out of compliance is listed in the "Summary Statement of Deficiencies" column and replaces the "To Comply" portion of the correction order. This column also includes the findings which are in violation of the state statute after the statement, "This Rule is not met as evidence by." Following the surveyor ' s findings are the Suggested Method of Correction and Time Period for Correction. You have agreed to participate in the electronic receipt of State licensure orders consistent with the Minnesota Department of Health Informational Bulletin 14-01, available at <https://www.health.state.mn.us/facilities/regulation/infobulletins/ib14_1.html> The State licensing orders are delineated on the attached Minnesota Department of Health orders being submitted to you electronically. Although no plan of correction is necessary for State Statutes/Rules, please enter the word "CORRECTED" in the box available for text. You must then indicate in the electronic State licensure process, under the heading completion date, the date your orders will be corrected prior to electronically submitting to the Minnesota Department of Health. The facility	2 000		

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2 000	Continued From page 2 is enrolled in ePOC and therefore a signature is not required at the bottom of the first page of state form. PLEASE DISREGARD THE HEADING OF THE FOURTH COLUMN WHICH STATES, "PROVIDER'S PLAN OF CORRECTION." THIS APPLIES TO FEDERAL DEFICIENCIES ONLY. THIS WILL APPEAR ON EACH PAGE.	2 000		
21545	MN Rule 4658.1320 A.B.C Medication Errors A nursing home must ensure that: A. Its medication error rate is less than five percent as described in the Interpretive Guidelines for Code of Federal Regulations, title 42, section 483.25 (m), found in Appendix P of the State Operations Manual, Guidance to Surveyors for Long-Term Care Facilities, which is incorporated by reference in part 4658.1315. For purposes of this part, a medication error means: (1) a discrepancy between what was prescribed and what medications are actually administered to residents in the nursing home; or (2) the administration of expired medications. B. It is free of any significant medication error. A significant medication error is: (1) an error which causes the resident discomfort or jeopardizes the resident's health or safety; or (2) medication from a category that usually requires the medication in the resident's blood to be titrated to a specific blood level and a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. All medications are administered as prescribed. An incident report or medication error report must be filed for any medication error	21545		1/30/23

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21545	Continued From page 3 that occurs. Any significant medication errors or resident reactions must be reported to the physician or the physician's designee and the resident or the resident's legal guardian or designated representative and an explanation must be made in the resident's clinical record. C. All medications are administered as prescribed. An incident report or medication error report must be filed for any medication error that occurs. Any significant medication errors or resident reactions must be reported to the physician or the physician's designee and the resident or the resident's legal guardian or designated representative and an explanation must be made in the resident's clinical record. This MN Requirement is not met as evidenced by: Based on interview and document review the facility failed to accurately transcribe order for baclofen (medication used to treat muscles spasms) upon admission, identify withdrawal symptoms, and tapered baclofen according to manufacturer's recommendations for 1 of 3 residents (R1) who received baclofen. R1 had significant withdrawal symptoms resulting in hospitalization . The facility failure resulted in an immediate jeopardy (IJ) for R1. The IJ began on 12/14/22, when nurse practitioner (NP)-A abruptly discontinued R1's baclofen resulting in R1 having significant withdrawal symptoms was sent to the emergency department (ED) on 12/18/22 and admitted to the ICU where R1 remained hospitalized. The administrator and the director of nursing (DON) were notified of the IJ on 12/30/22, at 4:30 p.m. The IJ was removed on 1/1/23, but	21545	CORRECTED	

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21545	Continued From page 4 non-compliance remained at the lower scope and severity of level D, which indicated no actual harm with potential for more than minimal harm that is not immediate jeopardy. Findings include: The manufacturer's package insert for baclofen included: Warnings and Precautions * Abrupt discontinuation of baclofen has resulted in serious adverse reactions including death; therefore, reduce the dosage slowly when baclofen is discontinued. 5.1 Adverse Reactions from Abrupt Withdrawal Abrupt discontinuation of baclofen, regardless of the cause, has resulted in adverse reactions that include hallucinations, seizures, high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to Rhabdomyolysis, multiple organ-system failure, and death. Therefore, reduce the dosage slowly when OZOBAX (baclofen) is discontinued, unless the clinical situation justifies a rapid withdrawal. R1's admission record copied on 12/29/22 identified R1 was admitted to the facility on 12/12/22, with diagnoses that included: pain due to internal orthopedic quadriplegia (paralysis of all 4 limbs), chronic pain syndrome, and autonomic dysreflexia (a potential life-threatening medical emergency where an abnormal overreaction of the involuntary nervous system to stimulation resulting in excessive sweating, a change in heart rate and high blood pressure, fever anxiety, and goosebumps with flushed skin above the level of the spinal cord injury). R1's hospital After Visit Summary (AVS) indicated	21545		

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21545	Continued From page 5 R1 received baclofen 40 milligrams (mg) on 12/12/22, at 12:10 p.m. R1's hospital Discharge Summary Brief Overview dated, 12/12/22, under section Medication List at Discharge as of 1:22 p.m included the order: Baclofen 20 mg tablet patient taking differently: (he) takes 20 mg by mouth in the morning, 40 mg at 11:00 a.m., 20 mg at 5:00 p.m., and 40 mg at bed time. The start date of this dosage was 11/8/22, over a month ago. Hospital records did not identify how long R1 had been taking baclofen medication. R1's facility physician order dated 12/12/22 for baclofen upon admission to the NH was inconsistent with the discharging physician order. The order transcribed into R1's record was baclofen 20 mg four times a day, which was 40 mg less than the hospital discharge summary identified. R1's care plan dated 12/12/22, identified R1 had chronic pain and right shoulder surgical pain. R1 required scheduled Baclofen for muscle spasms in his back. Interventions included to administer medications for pain as ordered and monitor response. Further directed staff to evaluate the effectiveness of the pain interventions, review for compliance, alleviating of symptoms, dosing schedules and satisfaction with results, impact on functional ability and on cognition. R1's medication administration record (MAR) for December 2022, indicated R1's baclofen was administered on 12/12/22, 20 mg at 4:00 p.m. and again at 8:00 p.m. Baclofen was given 20 mg four times a day from 12/12/22 and discontinued on 12/14/22 with the last dose given at 4:00 p.m.	21545		

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21545	Continued From page 6 R1's progress note dated 12/13/22, at 4:39 a.m. indicated R1 was so uncomfortable in bed; wanted to lay flat but complains of shortness of breath (SOB), hydrocodone (narcotic pain med) given for comfort. R1 had been repositioned over 5 times this shift. -At 7:00 a.m. R1 was asking for his medications and refused to put the head of the bed (HOB) up because R1 stated that he gets back spasms. Blood pressure (B/P) 210/111 (normal is 120/80). -At 2:59 p.m. indicated R1 was in pain and had spasms most of the day. B/P was 178/96, heart rate (HR) 78 (normal heart rate 60-100), respirations at 24 (normal 12-16). -At 5:35 p.m. R1 was given ibuprofen (medication to treat pain, fever, and inflammation) and the follow up pain scale was a 6/10, still having back pain and muscle spasms. R1 stated, could not wait until 7:00 p.m. to get scheduled meds. -At 7:20 p.m. R1's HOB lowered per request due to being uncomfortable and muscle spasms while raised. R1's monitoring sheet, dated 12/14/22 indicated R1's had frequent spasms to the extent of causing him to start falling out of bed and required repositioning to prevent falls. R1's progress note dated 12/14/22, at 1:38 p.m. indicated R1 had requested a different bed because of spasms caused his legs to come out of the bed. Vital sign records at 2:33 p.m. BP was 166/86, HR-88, and respirations were 18. At 2:59 p.m. progress note indicated R1 had been calling out for assistance every 1.5 hours if not more frequently for positioning because of the spasms. R1's physician visit dated 12/14/22, indicated R1 was seen by nurse practitioner (NP)-A for muscle spasms in R1's legs. The note identified NP-A	21545		

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21545	Continued From page 7 gave order to immediately stop R1's Baclofen (without a taper) and to start Flexeril (muscle relaxer) for better muscle spasm control. New order for Flexeril 10 mg to take 4 times a day. Continue to monitor, notify senior service team provider if symptoms fail to improve or worsen. Physician visit documentation did not identify or mention effectiveness of R1's current dose of baclofen that was inconsistent with hospital discharge orders. R1's progress note, dated 12/15/22, at 3:58 a.m. R1 required repositioning every 30 to 45 minutes. At 4:52 a.m. at 10:25 a.m. hydrocodone administered for pain and discomfort. Vital sign record at 3:01 p.m. B/P was 144/75, HR was 101, and Respirations were 20. At 3:03 p.m. hydrocodone was administered for pain, R1 ' s comfort level was fluctuating throughout the shift. At 6:43 p.m. R1 was having spasms and pain. At 8:20 p.m. R1 administered hydrocodone for pain and muscle spasms. At 10:33 p.m. R1 had been repositioned 5 during the evening shift due to having trouble trying get his legs adjusted so he could lay on his side. R1's progress note dated 12/16/22, at 1:05 a.m. indicated R1 had an unwitnessed fall, found beside his bed on the floor, lying on his right side. Prior to the fall R1 was in bed trying to lower his 70-degree head of bed when his legs began spasming. At 4:20 a.m. R1 continued to have uncontrolled back and arm pain after the fall, with a heart rate of 140. R1 was transferred to the emergency room and returned to the facility at 6:00 a.m. with diagnoses of back contusion. Upon return B/P-203/122 and HR-137. At 7:34 a.m. physician communication was completed to see provider due to increased blood pressure, hallucinations during the night, uncontrolled back	21545		

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21545	Continued From page 8 spasms. R1 complained of feeling hot, extreme episodes of anxiety at times, abdominal breathing during times of distress and has a history of autonomic dysreflexia. R1's Consultant Pharmacist's Medication Review, dated 12/16/22 at 11:18 a.m. identified an irregularity of a high dose of baclofen was stopped on 12/14/22, withdrawal has been reported with abrupt discontinuation. Suggested course of action: Discussed with medical director (MD)-A today, recommend taper of baclofen dose to prevent withdrawal (i.e., 20 mg three times a day (TID), then 5 mg TID, then 5 mg twice a day (BID), then 5 mg every day. Implementation timeframe: physician to address as soon as possible (ASAP). R1's Provider visit, dated 12/16/22, indicated R1 was seen for admission visit following a hospital stay from 12/8/22 to 12/12/22 for planned right total reverse shoulder arthroplasty (a surgical procedure to restore the function of a joint). Past medical history includes significant quadriparesis following a motor vehicle accident (MVA), spasticity on baclofen. R1 is reporting ongoing difficulty with muscle spasms and was transitioned from baclofen to Flexeril. Staff have been concerned about increasing anxiety and reported intermittent hallucinations. R1 also reported some visual hallucinations. Consultant pharmacist (CP)-A expressed concern for risk of baclofen withdrawal given recent transition from baclofen to Flexeril. On reviewing vitals, noted that R1 has been running tachycardic and hypertensive. R1 has been quite variable in his blood pressures, but have run typically higher rather than low recently and running particularly high this morning with systolic in the 180's. Because of hypertension, staff were able to	21545		

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21545	Continued From page 9 obtain supply from a local pharmacy of nifedipine (medication to manage blood pressure) of 10 mg one time. R1 has also had some fluctuations in temperature control, being hot most of the time but cold at other times. R1's blood pressure was noted to be 188/105, pulse 101 and respiratory rate was 24. Physical exam identified R1 was seated in motorized wheelchair, tremor noted that varies in intensity. R1 does express fluctuations in temperature/comfort feelings. Does have some odd comments at times but is able to provide accurate recent history. Mildly anxious but otherwise cooperative during visit. Assessment/Plan Number 1: Autonomic Dysreflexia: Suspect findings here today are consistent with baclofen and potentially autonomic dysreflexia. Note indicated new orders for terazosin (blood pressure medication), baclofen 20 mg three times a day, reduce Flexeril to 5 mg three times a day alternating with baclofen. R1's progress note, dated 12/16/22, at 2:30 p.m. indicated R1 had visual hallucination in morning and afternoon. R1 reported feeling comfortable during the shift, however during bouts of spasms rated pain 10 out 10. At 10:11 p.m. progress note identified R1 required frequent repositioning. R1's progress note dated 12/17/22, at 6:26 a.m. indicated R1 continues to be hallucinating and has been noted to be very restless this shift. R1 stated he thinks his medications are making him "crazy." At 1:19 p.m. R1 was repositioned every 30-45 minutes. At 4:20 p.m. family member reported R1 was not his usual self, was hallucinating, and confused. R1 was sent to emergency room at 11:00 p.m. and returned to the facility at 11:30 p.m. with order for antibiotics for possible urinary tract infection and instruction	21545		

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21545	Continued From page 10 to follow-up with primary care provider. R1's progress notes dated 12/18/22, at 10:20 a.m. identified R1 complained of back pain and was agitated. HR-141. R1 was transferred back to the ER for further evaluation. Review on R1's hospitalization records, dated 12/18/22 identified upon arrival to ER, R1 was tachycardia (rapid heartrate), Tachypnea (rapid breathing) and altered mental status. R1 was admitted to medical intensive care unit (MICU) for change in mental status and apnea. Hospital records dated 12/20/22, identified diagnoses of encephalopathy (brain disease that alters brain function) in the setting of baclofen withdrawal. Recommendation to resume R1's prior dose of baclofen, if he continues to have worsening spasticity that is causing pain or difficulty with positioning the baclofen could be increased to maximum daily dosing if it was not already at this level at home. "Baclofen is the primary medication I would recommend treating his spasticity. Botox injections could also be considered. I would not recommend using Flexeril or other muscle spasm medications as the primary treatment for his spasticity. If baclofen is to be stopped again in the future, it should be slowly tapered to avoid dangerous withdrawal." During a phone interview on 12/30/22, at 11:43 a.m. consultant pharmacist (CP)-A stated that R1's baclofen was abruptly discontinued by NP-A on 12/14/22 and should not have been discontinued without a taper. The symptoms of baclofen withdrawal would be similar of opiate withdrawal and would include symptoms R1 was exhibiting such as increased blood pressure and pulse, hot flashes, hallucinations anxiety, spasticity, and restlessness.	21545		

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21545	Continued From page 11 During an interview on 12/30/22, at 12:15 p.m. clinical manager (CM)-A stated R1 was admitted on 12/12/22 and was here to rehab from his right shoulder arthroplasty. Also had a diagnosis of a spastic quadriplegic. R1 was having some pretty severe muscle spasms and NP-A saw R1 on 12/14/22 and discontinued his baclofen and started him on Flexeril. CM-A stated that R1 was not tapered off the baclofen and should have been. CM-A stated that R1 was having symptoms to include heat intolerance, severe anxiety, restlessness, hallucinations when the baclofen was discontinued and continued to exhibit them until he was discharged to the ED on 12/18/22. CM-A stated these symptoms would be from the baclofen withdrawal. During a follow-up interview at 2:34 p.m. CM-A stated she did the admission for R1. She did not notice the discrepancy between the discharge summary orders and the signed orders were different. Had she noticed she would have called the provider for clarification. During an interview on 12/30/22, at 2:11 p.m. DON stated, R1's baclofen upon admission on 12/12/22 was not transcribed correctly. R1 was supposed to get a total of 120 mg of baclofen a day in 4 divided doses upon admission and was only receiving 80 mg in 4 divided doses until it was discontinued abruptly by NP-A on 12/14/22. DON stated a taper should have been done and that their consulting pharmacist gave a recommendation on 12/16/22 noting to not stop baclofen without a taper. During a phone interview on 12/30/22, at 5:24 p.m. medical director (MD)-A stated he was aware of R1's transcription error regarding baclofen and verified R1 was initially receiving 40 mg less baclofen per day initially than when he	21545		

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21545	Continued From page 12 was in the hospital until it was abruptly discontinued on 12/14/22. MD-A stated, the baclofen should not have been discontinued without a taper and that the CP-A made him aware of this on 12/16/22. MD-A stated, the symptoms R1 was exhibiting were most likely from baclofen withdrawal leading to autonomic dysreflexia. The immediate jeopardy that began on 12/14/22, was removed on 1/1/23, when it was verified, the facility implemented the following: -reviewed policies and procedures for transcribing medications upon admission and educated staff on these policies -educate staff and providers on medications that require tapers and withdrawal symptoms -review and revise policy for change in condition and acceptable parameters for vital signs and educated staff on these policies Facility policy titled, "Medication Error Management Policy," revised 5/17, Procedure: 1. All medication errors must be reported immediately upon identification of error occurring, complete the medication error report fully and give to nursing supervisor or director of nursing (DON). 2. Resident's MD/NP needs to be notified: the immediacy of the notification is dependent on the category of error, harm/lack of harm to the resident and time of day; notification of timing will be determined by the nursing supervisor or DON. 3. Initiate any orders received by the MD. 6. Root cause analysis is to be completed for all medication errors. 8. DON reviews all medication reports, is responsible for determining notification of error to the Medical Director and intervention, if any, regarding the individual employee or medication systems/procedures re-education and/or disciplinary measures are to be	21545		

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21545	Continued From page 13 implemented as outlined below based on the type of error and prescribed educational and/or counseling intervention. Significant error: an error that resulted in the need for treatment or intervention and caused temporary resident discomfort; an error occurred that resulted in hospitalization. Significant Medication Error with change in condition and hospitalization: if a nurse/TMA has one error in this category, a root cause an analysis of error will be completed in 3 days. An investigation suspension until completion of an internal review and the root cause analysis may be imposed. SUGGESTED METHOD OF CORRECTION: The director of nursing (DON) or designee could review and revise policies and procedures for transcription medication errors. The director of nursing or designee could develop a system to educate staff and develop a monitoring system to ensure medication were correctly administered. The quality assurance committee could monitor these measures to ensure compliance. TIME PERIOD FOR CORRECTION: Twenty One (21) days	21545		