Electronically delivered
September 13, 2019

Administrator
North Shore Health
515 - 5th Avenue West
Grand Marais, MN 55604

RE: Project Number S5384032 and H5384015C

Dear Administrator:

On August 2, 2019, we informed you that the following enforcement remedy was being imposed:

- Discretionary denial of payment for new Medicare and Medicaid admissions effective August 25, 2019. (42 CFR 88.417 (a));

This Department also recommended that CMS impose a civil money penalty. You will receive a formal notice from the CMS RO only if CMS agrees with our recommendation.

- Civil money penalty, (42 CFR 488.430 through 488.444).

This was based on the deficiencies cited by this Department for an abbreviated survey completed on July 17, 2019, and failure to achieve substantial compliance at the recertification survey completed on September 6, 2019. The most serious deficiencies at the time of the revisit were found to be isolated deficiencies that constituted actual harm that was not immediate jeopardy (Level G) whereby corrections were required.

On September 3, 2019 the Minnesota Department of Health completed a PCR to verify that your facility had achieved and maintained compliance with federal certification deficiencies issued pursuant to an recertification survey completed on September 6, 2019. We presumed, based on your plan of correction, that your facility had corrected these deficiencies as of August 9, 2019. Based on our visit, we have determined that your facility has corrected the deficiencies issued pursuant to our abbreviated survey, completed on July 17, 2019, as of August 9, 2019.

As a result of the revisit findings:

- Discretionary denial of payment for new Medicare and Medicaid admissions effective August 25, 2019 is to be rescinded as August 9, 2019. (42 CFR 88.417 (a));

The CMS Region V Office will notify your fiscal intermediary that the denial of payment for new Medicare admissions, effective August 25, 2019, is to be rescinded. They will also notify the State

Medicaid Agency that the denial of payment for all Medicaid admissions, effective August 25, 2019, is to be rescinded.

In our letter of August 2, 2019, we advised you that, in accordance with Federal law, as specified in the Act at Section 1819(f)(2)(B)(iii)(I)(b) and 1919(f)(2)(B)(iii)(I)(b), your facility was prohibited from conducting a Nursing Aide Training and/or Competency Evaluation Program (NATCEP) for two years from August 25, 2019, due to denial of payment for new admissions. Since your facility attained substantial compliance on August 9, 2019, the original triggering remedy, denial of payment for new admissions, did not go into effect. Therefore, the NATCEP prohibition is rescinded.

In addition, this Department recommended to the CMS Region V Office the following actions related to the imposed remedies in their letter of :

- Civil money penalty, (42 CFR 488.430 through 488.444).

The CMS Region V Office will notify you of their determination regarding the imposed remedies, Nursing Aide Training and/or Competency Evaluation Programs (NATCEP) prohibition.

Please note, it is your responsibility to share the information contained in this letter and the results of this visit with the President of your facility's Governing Body.

Feel free to contact me if you have questions.

Sincerely,

Joanne Simon, Enforcement Specialist
Minnesota Department of Health
Licensing and Certification Program
Program Assurance Unit
Health Regulation Division
Telephone: 651-201-4161 Fax: 651-215-9697
Email: joanne.simon@state.mn.us

cc: Licensing and Certification File

Electronically delivered

August 2, 2019

Administrator
North Shore Health
515 - 5th Avenue West
Grand Marais, MN 55604

RE: Project Number H5384015C and S5384032

Survey Cycle Start Date: June 06, 2019.

Dear Administrator:

On June 24, 2019, we informed you that we would recommend enforcement remedies based on the deficiencies cited by this Department for a standard survey, completed on June 6, 2019. This survey found the most serious deficiencies to be isolated deficiencies that constituted no actual harm with potential for more than minimal harm that was not immediate jeopardy (Level D) whereby corrections were required.

On July 17, 2019, an abbreviated standard survey was completed at your facility by the Minnesota Department of Health, to investigate complaint number H5384015C 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.

Based on our visit, we have determined that your facility has not achieved substantial compliance with the deficiencies issued pursuant to our standard survey, completed on June 6, 2019.

At the time of this investigation, we identified the following deficiency:

F 760: Residents Are Free of Significant Med Errors

The most serious deficiencies in your facility were found to be isolated deficiencies that constituted actual harm that was not immediate jeopardy (Level G), as evidenced by the attached CMS-2567, whereby corrections are required.

As a result of our finding that your facility is not in substantial compliance, this Department is recommending the following remedy. 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 Medicaid admissions effective August 25, 2019. (42 CFR 88.417 (a));

This Department is also recommending that CMS impose a civil money penalty. You will receive a formal notice from the CMS RO only if CMS agrees with our recommendation.

- Civil money penalty, (42 CFR 488.430 through 488.444).

The CMS Region V Office will notify your Medicare Administrative Contractor (MAC) that the denial of payment for new admissions is effective August 25, 2019, (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 25, 2019, (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.

Please note, it is your responsibility to share the information contained in this letter and the results of this visit with the President of your facility's Governing Body.

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 $10,483; 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 August 25, 2019. This prohibition is not subject to appeal. Further, this prohibition may be rescinded at a later date if your facility achieves substantial compliance prior to the effective date of denial of payment for new admissions. If this prohibition is not rescinded, 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.

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.

The state agency may, in lieu of a revisit, determine correction and compliance by accepting the facility's ePoC if the ePoC is reasonable, addresses the problem and provides evidence that the corrective action has occurred.

If an acceptable ePoC is not received within 10 calendar days from the receipt of this letter, we will recommend to the CMS Region V Office that one or more of the following remedies be imposed:

- Civil money penalty (42 CFR 488.430 through 488.444).

Failure to submit an acceptable ePoC could also result in the termination of your facility's Medicare and/or Medicaid agreement (488.456(b)).

DEPARTMENT CONTACT

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

Teresa Ament, Unit Supervisor
Duluth Survey Team
Licensing and Certification Program
Health Regulation Division
Minnesota Department of Health
Duluth Technology Village
11 East Superior Street, Suite 290

Duluth, Minnesota 55802-2007
Email: teresa.ament@state.mn.us
Phone: (218) 302-6151
Fax: (218) 723-2359

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 the 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 THIRD OR SIXTH MONTH AFTER THE LAST DAY OF THE SURVEY

If substantial compliance with the regulations is not verified by September 6, 2019 (three months after the identification of noncompliance), the CMS Region V Office must deny payment for new admissions as mandated by the Social Security Act (the Act) at Sections 1819(h)(2)(D) and 1919(h)(2)(C) and Federal regulations at 42 CFR Section 488.417(b).

In addition, if substantial compliance with the regulations is not verified by December 6, 2019 (six months after the identification of noncompliance) your provider agreement will be terminated. 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

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:

Tamika.Brown@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 Tamika Brown, Principal Program Representative by phone at (312) 353-1502 or by e-mail at Tamika.Brown@cms.hhs.gov.

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 electronic 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,

Joanne Simon, Enforcement Specialist
Minnesota Department of Health
Licensing and Certification Program
Program Assurance Unit
Health Regulation Division
Telephone: 651-201-4161 Fax: 651-215-9697
Email: joanne.simon@state.mn.us

cc: Licensing and Certification File

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	245384	A. BUILDING _____ B. WING _____	C 07/17/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTH SHORE HEALTH	**515 - 5TH AVENUE WEST GRAND MARAIS, MN 55604**

(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 7/16 to 7/17/19, an abbreviated survey was completed at your facility to conduct a complaint investigation. Your facility was found not to be in compliance with 42 CFR Part 483, Requirements for Long Term Care Facilities. The following complaint was found to be substantiated: H5384015C, deficiency issued at F760. The facility's plan of correction (POC) will serve as your allegation of compliance upon the Department's 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 on-site revisit of your facility may be conducted to validate that substantial compliance with the regulations has been attained in accordance with your verification.	F 000		
F 760 SS=G	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 ensure that 1 of 3 residents (R1) was free of significant medication errors when staff failed to administer R1's torsemide (a diuretic medication, used for removing excess sodium and water from the body) for seven days.	F 760	F760 Preparation, submission and implementation of this Plan of Correction does not constitute an admission of, or agreement with, the facts and conclusions set forth in the statement of deficiencies.	8/9/19

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

Electronically Signed | 08/07/2019

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 760	Continued From page 1 R1 sustained harm, a decline in condition with wheezing and edema, and required hospitalization. Findings include: R1's Interagency Referral Form printed 7/2/19, indicated R1 had diagnoses that included hypertension, cellulitis, and hyperkalemia (excess potassium in the blood). R1's quarterly Minimum Data Set (MDS) assessment dated 6/10/19, also indicated R1 had a diagnosis of hypertension. R1's physician orders dated 7/2/19, included: Torsemide 20 milligrams (mg) by mouth daily (used to reduce extra fluid (edema) in the body). R1's Medication Adminstration Record (MAR) indicated R1 was prescribed 20 mg of Torsemide to start on 7/3/19. However, review of the resident's MAR indicated R1 did not receive the prescribed Torsemide 20 mg from 7/2-7/9/19. R1's care plan printed 7/14/19, identified a need for clinical monitoring of R1's hypertension while using Torsemide and Metoprolol (a beta-blocking drug related to propranolol, used to treat hypertension and angina). R1's hospital admission notes dated 7/9/19, indicated R1 had been readmitted to the facility on 7/2/19, with an order for Torsemide 20 mg daily. The note included: "Unfortunately" this did not occur, and the medication was "unknowingly held" and likely contributed to R1's decline in the week he was at the facility. Further, the admission note indicated the "critical" medication	F 760	This Plan of Correction is prepared and/or executed as a means to continuously improve the quality of care, to comply with all applicable state and federal regulatory requirements and constitutes the facility's allegation of compliance. The facility policy Admission-Readmission was reviewed and updated on August 7, 2019 and now addresses medication orders on readmission. The facility policy Medication/Treatment Orders and Transcription was reviewed and updated on August 7, 2109 and now addresses acknowledging medications on the electronic Medication Administration Record and Medications on HOLD. The policy Admission Process for Pre-planned Admissions was created and will be completed by August 9, 2019 and states that Bed Hold status will be removed by 0630 on the day of readmission. On July 10, 2019 the facility reinstituted a process of a 24 hour check of all new orders. The Night nurse has been reviewing these new orders nightly and signs and dates the orders as checked. Trained Medication Aides were educated at their August 6, 2019 staff meeting regarding the need to verify every medication with a HOLD status with Charge Nurse. Charge Nurses were educated at their	

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F 760	Continued From page 2 not having been given was discovered at the time of R1's hospitalization. R1's Hospital Discharge Summary dated 7/10/19, indicated R1 had returned to the nursing home from a previous hospitalization (6/25/19 to 7/2/19) more debilitated than his baseline. The discharge summary also indicated a medication error from the readmission to the nursing home 7/2/19, led to R1's Torsemide not being given for a week, which likely contributed to R1's decline. During interview on 7/16/19 at 1:50 p.m., registered nurse (RN)-B verified although R1 had orders for Torsemide 20 mg following hospitalization which was not administered following hospital return 7/2/19. RN-B stated R1 was rehospitalized 7/9/19, and died on 7/10/19. On 7/16/19 at 2:30 p.m., the director of nursing (DON) stated R1 became ill with a fever, chills, and a change in mentation on 6/25/19, and went to the emergency room (ER) at the local hospital. Lab work indicated R1 had an infection, and the family had requested it be treated locally. However during the ER visit, R1's condition deteriorated. R1's family decided to send R1 to a tertiary hospital in Duluth for "one more chance" at life. The DON stated R1 was re-admitted to the nursing home on 7/2/19, but there had never been a definitive source of the infection identified. The DON also stated when R1 returned to the facility he was on oxygen, was short of breath, and was fatigued. The DON continued to state R1 was not feeling well during the early morning of 7/9/19, and had a low blood sugar that did not improve with food, and he had a slight wheeze. The DON stated a nurse's note indicated a little later that morning of 7/9/19, R1 had sounded	F 760	August 7, 2019 staff meetings regarding the need to question physicians about medications on HOLD if an end date of the HOLD is not identified. Meditech, the facility electronic resident care software, has reviewed the error. In addition to replicating the software action to determine the how the medication was placed in HOLD status in an effort to refine processes, Meditech has been directed to develop a process so that orders cannot be placed prior to the Bed Hold being released. Physicians were reminded at their July 17, 2019 Medical Staff meeting to not enter orders for a resident who is on Bed Hold. They are to wait until the resident has been electronically readmitted to the facility before entering orders on admission day. They were informed that the process for Medical Records will be to electronically readmit the resident at 0630 on the day of re-admission. During the July 17, 2019 Medical Staff meeting, the use of medications on HOLD in the Care Center was discussed at length. If a medication is placed on HOLD, the Physicians were asked to designate an end date to limit the time a medication is on HOLD. Without an end date for the HOLD, Nursing staff have been directed to contact the Physician daily for clarification. The Director of Nursing or Designee will monitor medications placed on HOLD to	

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F 760	Continued From page 3 "wheezy and gurgly" and all lung fields sounded very wet (fluid in lungs, a sign of respiratory distress). The DON stated R1 had not gotten relief from use of a nebulizer so his son was called, and he agreed to a local hospitalization at 6:45 a.m. Upon medication reconciliation at the time of the resident's 7/9/19 hospitalization, it was discovered the Torsemide had not been administered after R1's 7/2/19, readmission from the hospital. The DON stated R1 was given a dose of Torsemide and was diuresed 1 liter (excessive urination indicated fluid leaving the body). The DON stated they had traced the origin of the medication error to the fact that R1's primary care physician (MD)-C entered R1's re-admission orders prior to facility medical record staff ending R1's bed hold status. The computer system put all R1's medications on hold after the physician entered the orders. The DON indicated staff noticed within about 10 minutes that all R1's orders were put on hold. The pharmacist (P)-A immediately went in and manually re-entered all of R1's medication orders, including the Torsemide 20 mg. Next, P-A dispensed the medications, and delivered them to R1's locked pass through medication drawer. According to the DON, at some point after the manual re-entry of the Torsemide to the orders (which was the only order that was new/increased), it had continued to appear as "on hold" in the facility's electronic medical record system. The DON stated the evening nurse RN-A, had acknowledged R1's medications but had not noticed the Torsemide was in an "on hold"status. The DON further stated while RN-A had "missed" that the medication was documented as on hold, upon follow up with RN-A, RN-A was able to demonstrate the correct procedure for acknowledging medication orders.	F 760	ensure there is an end date to the HOLD status weekly for the first four weeks. If medications on HOLD meet the requirements then the monitor will continue monthly for six months and quarterly for six months. If, after the first four weeks the requirements are not met, the monitoring will continue weekly for the next six months and quarterly for the remaining six months. The results of this monitor will be reported to Quality Improvement/Peer Review Committee quarterly for one year. The Pharmacists will monitor the reasons scheduled medications are documented as non-administered weekly for three months. The reasons include 48 pre-built options such as patient refusal, various side effects, and medication not available. If, after the first three months, the Pharmacists identify trends and patterns in the non-administered medications, the monitor will continue weekly for another three months. If there are no patterns and trends, the monitor will be completed monthly for three months. The Pharmacist will discontinue the monitor when no area of concern has been identified. The results of this monitor will be reported to Quality Improvement/Peer Review Committee. The Revenue Cycle/Health Information Manager or Designee will monitor all readmissions for six months for the removal of bed hold status by 0630 on the day of readmission. If, after the first six months the requirements are not met, the	

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F 760	Continued From page 4 The DON also stated licensed practical nurse (LPN)-A had documented on 7/3/19, that R1's torsemide was "on hold" in the computer system, and LPN-A had taken the medication out of R1's medication drawer and put it in the overflow bin. According to the DON, LPN-A had not questioned the hold, nor had she discussed it with anyone. The DON confirmed that R1 had not received any Torsemide while at the facility between 7/2 and 7/9/19 and stated immediately upon awareness of the medication error, the facility had worked to determine what had happened and how to prevent any re-occurrences. The DON stated they are re-instituting a system check where the overnight nurse checks medical orders to ensure accuracy. On 7/17/19, at 9:00 a.m. P-A stated she manually went in and "edited, and resumed" each and every medication order the physican had ordered for R1, about 30 medications. P-A stated she processed all of R1's medications, labeled them,and took them to R1's locked medication drawer. P-A stated after she re-entered all the medications by hand, there was another area that showed the torsemide was on hold, but she didn't see that. P-A stated she had re-entered all medications so she had fixed the computer issue. P-A also stated the evening nurse incorrectly acknowledged the medication, which had the torsemide listed as on hold. On 7/17/19, at 9:30 a.m. in a telephone interview, physician (MD)-A stated the Torsemide medication error was one of multiple factors affecting R1's re-hospitalization. MD-A stated R1 was already a very ill person, and was septic and near death when he'd first transferred to the hospital 6/25/19. MD-A stated R1 certainly had a	F 760	monitoring will continue for the next six months. The results of this monitor will be reported to Quality Improvement/Peer Review Committee quarterly for one year.	

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F 760	Continued From page 5	F 760		

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On 7/17/19, at 11:00 a.m. LPN-A stated she had not questioned the Torsemide hold in R1's electronic medical record. However, stated she had later noticed the Torsemide in R1's medication drawer, and had personally removed it and put it in the overflow area of the medication room. LPN-A stated she done this based on past practice and the processes she had used in the past. LPN-A stated she did not question what she had done because the medication was listed on hold, so she'd removed it from the drawer.

On 7/17/19, at 11:21 a.m. RN-A stated she got called in to fix the hold status, as she does computer work for the facility. RN-A stated the software functioned as it was designed; a resident was out on a bed hold, and so the medications that the physician entered were put on "hold." However, when a resident was coming back to a long term care facility, it would be helpful to have orders entered before the resident came in the front door. RN-A stated the physician was doing his part in preparing for R1's return to the facility. RN-A stated facility staff noticed all the medications got put in "hold" status and had it fixed within the hour however, the Torsemide order had not responded the same way as it was a new order (20 mg instead of the 10 mg originally ordered). RN-A stated in April 2019, the facility began a new process in their electronic medical record that puts a resident on a bed hold or leave of absence (LOA). This was done at other facilities that use this same computer

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	245384	A. BUILDING _____ B. WING _____	C 07/17/2019

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On 7/17/19, at 3:30 p.m. in a telephone interview, RN-A stated acknowledging an order means to compare the printed medication list to the electronic medical record order. RN-A stated she was "rather new" and had been sick. RN-A stated she shouldn't have been at work and had not identified the order read "hold." RN-A stated she was used to looking at the hard copy from the hospital, not a print out from the pharmacy, and she was not comfortable with the system used at this facility.

The facility's Leave of Absence Process (for residents) dated 4/5/19, indicated the admission department was to end the bed hold, and notify the physician to review and update resident orders.

The facility's Admission-Readmission policy updated 8/9/18, lacked direction about how to address orders that were on "hold."

DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically Delivered

August 2, 2019

Administrator
North Shore Health
515 - 5th Avenue West
Grand Marais, MN 55604

Re: State Nursing Home Licensing Orders - Complaint Number H5384015C

Dear Administrator:

A complaint investigation was completed on August 17, 2019. At the time of the investigation, the investigator assessed compliance with Minnesota Department of Health Nursing Home Rules. The investigator from the Minnesota Department of Health, Office of Health Facility Complaints, noted one or more violations of these rules. These state licensing orders are issued in accordance with Minnesota Statute section 144.653 and/or Minnesota Statute Section 144A.10. If, upon reinspection, it is found that the violations 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 of the Minnesota Department of Health.

To assist in complying with the licensing 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 violation. 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 violation within the established time frame is required. The “suggested method of correction” is for your information and assistance only.

The State licensing orders are delineated on the Minnesota Department of Health order form. The Minnesota Department of Health is documenting the state licensing 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 after the statement, "This Rule is not met as evidenced by." Following investigator's 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.

When all licensing orders are corrected, the form should be signed and returned electronically to:

Teresa Ament, Unit Supervisor
Duluth Survey Team
Licensing and Certification Program
Health Regulation Division
Minnesota Department of Health
Duluth Technology Village
11 East Superior Street, Suite 290
Duluth, Minnesota 55802-2007
Email: teresa.ament@state.mn.us
Phone: (218) 302-6151
Fax: (218) 723-2359

You may request a hearing on any assessments that result from non-compliance with these licensing orders by providing a written request to the Department within 15 days of receipt of a notice of assessment for non-compliance.

Please note it is your responsibility to share the information contained in this letter and the results of this visit with the President of your facility's Governing Body.

Sincerely,

Joanne Simon, Enforcement Specialist
Minnesota Department of Health
Licensing and Certification Program
Program Assurance Unit
Health Regulation Division
Telephone: 651-201-4161 Fax: 651-215-9697
Email: joanne.simon@state.mn.us

cc: Licensing and Certification File

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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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 7/16/17 to 7/17/19, surveyors of this Department's staff visited the above provider and conducted a complaint investigation to investigate complaint #H5384015C. As a result the following correction orders are issued. You have agreed to participate in the electronic	2 000		

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2 000	Continued From page 1 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	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 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	21545		8/7/19

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21545	Continued From page 2 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 ensure that 1 of 3 residents (R1) was free of significant medication errors when staff failed to administer R1's torsemide (a diuretic medication, used for removing excess sodium and water from the body) for seven days. R1 sustained harm, a decline in condition with wheezing and edema, and required hospitalization. Findings include: R1's Interagency Referral Form printed 7/2/19, indicated R1 had diagnoses that included hypertension, cellulitis, and hyperkalemia (excess potassium in the blood). R1's quarterly Minimum Data Set (MDS) assessment dated 6/10/19, also indicated R1 had a diagnosis of hypertension. R1's physician orders dated 7/2/19, included: Torsemide 20 milligrams (mg) by mouth daily (used to reduce extra fluid (edema) in the body).	21545	Complete	

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R1's Medication Adminstration Record (MAR) indicated R1 was prescribed 20 mg of Torsemide to start on 7/3/19. However, review of the resident's MAR indicated R1 did not receive the prescribed Torsemide 20 mg from 7/2-7/9/19.

R1's care plan printed 7/14/19, identified a need for clinical monitoring of R1's hypertension while using Torsemide and Metoprolol (a beta-blocking drug related to propranolol, used to treat hypertension and angina).

R1's hospital admission notes dated 7/9/19, indicated R1 had been readmitted to the facility on 7/2/19, with an order for Torsemide 20 mg daily. The note included: "Unfortunately" this did not occur, and the medication was "unknowingly held" and likely contributed to R1's decline in the week he was at the facility. Further, the admission note indicated the "critical" medication not having been given was discovered at the time of R1's hospitalization.

R1's Hospital Discharge Summary dated 7/10/19, indicated R1 had returned to the nursing home from a previous hospitalization (6/25/19 to 7/2/19) more debilitated than his baseline. The discharge summary also indicated a medication error from the readmission to the nursing home 7/2/19, led to R1's Torsemide not being given for a week, which likely contributed to R1's decline.

During interview on 7/16/19 at 1:50 p.m., registered nurse (RN)-B verified although R1 had orders for Torsemide 20 mg following hospitalization which was not administered following hospital return 7/2/19. RN-B stated R1 was rehospitalized 7/9/19, and died on 7/10/19.

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21545	Continued From page 4 On 7/16/19 at 2:30 p.m., the director of nursing (DON) stated R1 became ill with a fever, chills, and a change in mentation on 6/25/19, and went to the emergency room (ER) at the local hospital. Lab work indicated R1 had an infection, and the family had requested it be treated locally. However during the ER visit, R1's condition deteriorated. R1's family decided to send R1 to a tertiary hospital in Duluth for "one more chance" at life. The DON stated R1 was re-admitted to the nursing home on 7/2/19, but there had never been a definitive source of the infection identified. The DON also stated when R1 returned to the facility he was on oxygen, was short of breath, and was fatigued. The DON continued to state R1 was not feeling well during the early morning of 7/9/19, and had a low blood sugar that did not improve with food, and he had a slight wheeze. The DON stated a nurse's note indicated a little later that morning of 7/9/19, R1 had sounded "wheezy and gurgly" and all lung fields sounded very wet (fluid in lungs, a sign of respiratory distress). The DON stated R1 had not gotten relief from use of a nebulizer so his son was called, and he agreed to a local hospitalization at 6:45 a.m. Upon medication reconciliation at the time of the resident's 7/9/19 hospitalization, it was discovered the Torsemide had not been administered after R1's 7/2/19, readmission from the hospital. The DON stated R1 was given a dose of Torsemide and was diuresed 1 liter (excessive urination indicated fluid leaving the body). The DON stated they had traced the origin of the medication error to the fact that R1's primary care physician (MD)-C entered R1's re-admission orders prior to facility medical record staff ending R1's bed hold status. The computer system put all R1's medications on hold after the physician entered the orders. The DON indicated staff noticed within about 10 minutes	21545		

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that all R1's orders were put on hold. The pharmacist (P)-A immediately went in and manually re-entered all of R1's medication orders, including the Torsemide 20 mg. Next, P-A dispensed the medications, and delivered them to R1's locked pass through medication drawer. According to the DON, at some point after the manual re-entry of the Torsemide to the orders (which was the only order that was new/increased), it had continued to appear as "on hold" in the facility's electronic medical record system. The DON stated the evening nurse RN-A, had acknowledged R1's medications but had not noticed the Torsemide was in an "on hold"status. The DON further stated while RN-A had "missed" that the medication was documented as on hold, upon follow up with RN-A, RN-A was able to demonstrate the correct procedure for acknowledging medication orders. The DON also stated licensed practical nurse (LPN)-A had documented on 7/3/19, that R1's torsemide was "on hold" in the computer system, and LPN-A had taken the medication out of R1's medication drawer and put it in the overflow bin. According to the DON, LPN-A had not questioned the hold, nor had she discussed it with anyone. The DON confirmed that R1 had not received any Torsemide while at the facility between 7/2 and 7/9/19 and stated immediately upon awareness of the medication error, the facility had worked to determine what had happened and how to prevent any re-occurrences. The DON stated they are re-instituting a system check where the overnight nurse checks medical orders to ensure accuracy.

On 7/17/19, at 9:00 a.m. P-A stated she manually went in and "edited, and resumed" each and every medication order the physican had ordered for R1, about 30 medications. P-A stated she

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processed all of R1's medications, labeled them,and took them to R1's locked medication drawer. P-A stated after she re-entered all the medications by hand, there was another area that showed the torsemide was on hold, but she didn't see that. P-A stated she had re-entered all medications so she had fixed the computer issue. P-A also stated the evening nurse incorrectly acknowledged the medication, which had the torsemide listed as on hold.

On 7/17/19, at 9:30 a.m. in a telephone interview, physician (MD)-A stated the Torsemide medication error was one of multiple factors affecting R1's re-hospitalization. MD-A stated R1 was already a very ill person, and was septic and near death when he'd first transferred to the hospital 6/25/19. MD-A stated R1 certainly had a condition the Torsemide would have helped to treat. MD-A also stated R1 would have succumbed within a week or so regardless of the Torsemide due to multiple advancing health issues.

On 7/17/19, at 11:00 a.m. LPN-A stated she had not questioned the Torsemide hold in R1's electronic medical record. However, stated she had later noticed the Torsemide in R1's medication drawer, and had personally removed it and put it in the overflow area of the medication room. LPN-A stated she done this based on past practice and the processes she had used in the past. LPN-A stated she did not question what she had done because the medication was listed on hold, so she'd removed it from the drawer.

On 7/17/19, at 11:21 a.m. RN-A stated she got called in to fix the hold status, as she does computer work for the facility. RN-A stated the software functioned as it was designed; a

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21545	Continued From page 7 resident was out on a bed hold, and so the medications that the physician entered were put on "hold." However, when a resident was coming back to a long term care facility, it would be helpful to have orders entered before the resident came in the front door. RN-A stated the physician was doing his part in preparing for R1's return to the facility. RN-A stated facility staff noticed all the medications got put in "hold" status and had it fixed within the hour however, the Torsemide order had not responded the same way as it was a new order (20 mg instead of the 10 mg originally ordered). RN-A stated in April 2019, the facility began a new process in their electronic medical record that puts a resident on a bed hold or leave of absence (LOA). This was done at other facilities that use this same computer system, but had not been done at this facility before. In the process, Step 1 was for the Admission Department to end the bed hold/LOA, and Step 2 was for the physician to review orders, restore ones that would continue, and begin new orders. RN-A stated since this new process began, two residents had returned from LOA. The process went fine for the first resident, as the bed hold was removed prior to the physician entering orders. However for R1, the physican was entering orders prior to the removal of the bed hold, so the holds were put in place. RN-A again stated because the Torsemide was a new/increased order (not just a restored order), the computer system placed it on hold again, after the original catch and fix by the facility. On 7/17/19, at 3:30 p.m. in a telephone interview, RN-A stated acknowledging an order means to compare the printed medication list to the electronic medical record order. RN-A stated she was "rather new" and had been sick. RN-A stated she shouldn't have been at work and had not	21545		

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identified the order read "hold." RN-A stated she was used to looking at the hard copy from the hospital, not a print out from the pharmacy, and she was not comfortable with the system used at this facility.

The facility's Leave of Absence Process (for residents) dated 4/5/19, indicated the admission department was to end the bed hold, and notify the physician to review and update resident orders.

The facility's Admission-Readmission policy updated 8/9/18, lacked direction about how to address orders that were on "hold."

SUGGESTED METHOD OF CORRECTION: The director of nursing (DON) and/or designee could review the facility polices in regards to medication orders upon re-admssion. The DON and/or designee could educate staff on checking accuracy of medications that are on hold.. The DON or designee could routinely monitor to ensure medication safety checks in computer are implemented.

TIME PERIOD FOR CORRECTION: Twenty-One (21) days.