DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically delivered
February 2, 2021

Administrator
Mille Lacs Health System
200 North Elm Street
Onamia, MN 56359

RE: CCN: 245127
Cycle Start Date: December 8, 2020

Dear Administrator:

On December 24, 2020, we notified you a remedy was imposed. On January 21, 2021 the Minnesota Department(s) 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 12, 2021.

As authorized by CMS the remedy of:

- Discretionary denial of payment for new Medicare and Medicaid admissions effective January 23, 2021 did not go into effect. (42 CFR 488.417 (b))

In our letter of December 24, 2020, 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 was prohibited from conducting a Nursing Aide Training and/or Competency Evaluation Program (NATCEP) for two years from January 23, 2021 due to denial of payment for new admissions. Since your facility attained substantial compliance on January 12, 2021, the original triggering remedy, denial of payment for new admissions, did not go into effect. Therefore, the NATCEP prohibition is rescinded. However, 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,

Douglas Larson, Enforcement Specialist
Minnesota Department of Health
Licensing and Certification Program

Program Assurance Unit
Health Regulation Division
Telephone: 651-201-4118 Fax: 651-215-9697
Email: doug.larson@state.mn.us

cc: Licensing and Certification File

Electronically delivered
January 14, 2021

Administrator
Mille Lacs Health System
200 North Elm Street
Onamia, MN 56359

RE: CCN: 245127
Cycle Start Date: December 8, 2020

Dear Administrator:

On December 24, 2020, we informed you of imposed enforcement remedies.

On December 28, 2020, the Minnesota Department(s) of Health completed a survey and it has been determined that your facility continues to not to be in substantial compliance. The most serious deficiencies in your facility were found to be widespread deficiencies that constitute no actual harm with potential for more than minimal harm that is not immediate jeopardy (Level F), as evidenced by the electronically attached CMS-2567, whereby corrections are required.

As a result of the survey findings:

- Discretionary Denial of Payment for new Medicare and/or Medicaid Admissions, Federal regulations at 42 CFR § 488.417(a), effective January 23, 2021, will remain in effect.

This Department continues to recommend 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 January 23, 2021. They will also notify the State Medicaid Agency that they must also deny payment for new Medicaid admissions effective January 23, 2021.

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.

As we notified you in our letter of December 24, 2020, 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 is prohibited from conducting Nursing Aide Training and/or Competency Evaluation Programs (NATCEP) for two years from January 23, 2021.

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.

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:

- Optional denial of payment for new Medicare and Medicaid admissions (42 CFR 488.417 (a));

- Per day civil money penalty (42 CFR 488.430 through 488.444).

DEPARTMENT CONTACT

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

Kathleen Lucas, Unit Supervisor
St. Cloud B District Office
Licensing and Certification Program
Health Regulation Division
Minnesota Department of Health
Midtown Square
3333 Division Street, Suite 212

Saint Cloud, Minnesota 56301-4557
Email: kathleen.lucas@state.mn.us
Office: (320) 223-7343 Mobile: (320) 290-1155

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 - Health Regulation Division 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 June 8, 2021 (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

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/ 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,

Douglas Larson, Enforcement Specialist
Minnesota Department of Health
Licensing and Certification Program
Program Assurance Unit
Health Regulation Division
Telephone: 651-201-4118 Fax: 651-215-9697
Email: doug.larson@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
	245127	A. BUILDING _____ B. WING _____	12/28/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MILLE LACS HEALTH SYSTEM	**200 NORTH ELM STREET ONAMIA, MN 56359**

(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
E 000	Initial Comments A COVID-19 Focused Infection Control survey was conducted 12/28/20, at your facility by the Minnesota Department of Health to determine compliance with Emergency Preparedness regulations § 483.73(b)(6). The facility was IN full compliance. Because you are enrolled in ePOC, your signature is not required at the bottom of the first page of the CMS-2567 form. Although no plan of correction is requires, it is required that the facility acknowledge receipt of the electronic documents.	E 000		
F 000	INITIAL COMMENTS A COVID-19 Focused Infection Control survey was conducted 12/28/20 at your facility by the Minnesota Department of Health to determine compliance with §483.80 Infection Control. The facility was NOT in full compliance. Because you are enrolled in ePOC, your signature is not required at the bottom of the first page of the CMS-2567 form The facility's plan of correction (POC) will serve as your allegation of compliance upon the Department's acceptance. Upon receipt of an acceptable electronic POC, an revisit of your facility will be conducted to validate that substantial compliance with the regulations has been attained in accordance with your verification.	F 000		
F 885 SS=F	Reporting-Residents,Representatives&Families CFR(s): 483.80(g)(3)(i)-(iii) §483.80(g) COVID-19 reporting. The facility	F 885		1/12/21

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

Electronically Signed | 01/15/2021

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 885	Continued From page 1 must— §483.80(g)(3) Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must— (i) Not include personally identifiable information; (ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and (iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other. This REQUIREMENT is not met as evidenced by: Based on interview and document review, the facility failed to notify residents, representatives and families timely of confirmed cases of Coronavirus Disease 2019 (COVID-19) per Center for Medicare & Medicaid Services (CMS) requirements, when five residents tested positive for COVID-19. This deficient practice had the potential to affect all 40 residents, families and representatives at the facility. Findings include: Center for Medicare & Medicaid Services (CMS)	F 885	Corrected on 1/12/21 F885: Failed to notify all residents and family representatives of positive COVID activities in the facility. Potential to affect all 40 residents and family representatives. The facility contacted our electronic medical record company, PCC on 12/29/20 to inquire about their automated phone software to meet the timely notification of all resident families. The PCC software was found to be a viable solution and a plan was set up with PCC	

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F 885	Continued From page 2 Center for Clinical Standards and Quality/Quality, Safety and Oversight Group (CMS QSO) memo 20-29 NH dated 5/6/20, required nursing homes to inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. Review of facility's notification record, indicated the last notification to residents, representatives and families was dated 12/14/20. This notification identified number of new cases in residents and staff, and also indicated mitigation methods taken by the facility to prevent further spread of the COVID-19 virus. Further review of notification, indicated updates within the facility related to indoor visits, essential care visits and vaccinations. On 12/28/20, at 12:46 p.m. family member (FM) -A indicated the facility has notified FM-A previously regarding if there was a new case of COVID-19 in either a resident or staff. However, FM-A indicated that she had not received a notification regarding any new positive cases after the most recent routine weekly testing that was completed on 12/21/20. On 12/28/20, at 2:25 p.m. director of nursing (DON) indicated most recent notification to residents, representatives and families was on 12/14/20. DON indicated the medical director will always call the positive family members and update them on the positive test results, and will at times call all family members in the facility regarding the new positive cases. Further, DON	F 885	to install on 1/4/21. All family representative phone numbers within the system were validated. A letter was sent out on 12/30/20 informing families that we were exploring this notification system and again on 1/8/21 with progress on the automated notification system. The software installation was completed on 1/5/21. Due to a few minor glitches in the system the roll out was delayed. On 1/12/21, the DON, received web ex training on the notification system and a test of the system was completed on the same day, a printed receipt of all those notified was completed. On 1/15/21 a letter was sent informing families that the system is in place. On 1/5/21 the Outbreak investigation policy was updated to include notification of resident representatives as soon as possible or no later than 5pm the next calendar day. Also on 1/5/21 a new policy: Notification to Residents & Family Representatives of COVID Activity was put into practice. Audits 1/12/21: The DON or designee will conduct an audit when the facility has active COVID cases or surveillance monitoring shows that there are three residents or staff that have new onset of respiratory symptoms within 72 hours of each other to ensure that all families were notified by 5pm the following day. A printed receipt of all those notified will be kept and brought forward to the QAPI Committee.	

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F 885	Continued From page 3	F 885		

indicated a discussion is usually had with the administrator; infection preventionist (IP) and herself if a notification needs to go out to residents, representatives and families regarding the change in cases. DON also indicated care coordinator (CC)-A and CC-B will divide all residents and call their family members to notify them of new positive cases in the facility. Further, DON indicated activities department continues to call family members to update them regarding the outbreak status and activities and visitor restrictions in place at that time. In addition, DON confirmed five new positive cases of COVID-19 "should prompt a phone call and if you can't reach a bunch of people then a letter will go out too." DON also confirmed only families that were affected by a positive loved one were updated regarding their test results, and there were no other phone calls made or letters sent to residents, representatives or families after the most recent routine testing that occurred on 12/21/20, which resulted in five new positive residents.

On 12/28/20, at 4:24 pm administrator indicated the facility was still considered to be in a COVID-19 outbreak status therefore did not warrant a call to update residents, representative and families. Administrator also indicated that families know the facility is in an outbreak and the families speak with the care coordinators on the units and also speak with the medical director daily, but the facility is not documenting that information in the resident records or keeping a log. Further, administrator confirmed residents, representatives and families were not informed after the most recent routine testing that was completed on 12/21/20, which resulted in five new positive residents and the facility does not

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F 885	Continued From page 4 have a policy regarding notifying residents, representatives and families. Facility policy titled Outbreak Investigation, revised 9/3/20, indicated "appropriate notifications to the Medical Director, Administrator, all departments, attending physicians, state and local agencies, and resident representatives will take place as soon as possible after the outbreak has been identified." Further review of policy, indicated "outbreak monitoring and reporting will continue until the outbreak has resolved. Control measure may include on confirmed resident, unit isolation or quarantine measure for the entire facility." Facility lacked information regarding informing residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other, per guidance by CMS.	F 885		