Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically delivered
February 10, 2023

Administrator
The Estates At Roseville LLC
2727 North Victoria
Roseville, MN 55113

RE: CCN: 245105
Cycle Start Date: January 10, 2023

Dear Administrator:

On January 20, 2023, we notified you a remedy was imposed. On February 7, 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 February 3, 2023.

As authorized by CMS the remedy of:

- Discretionary denial of payment for new Medicare and Medicaid admissions effective February 4, 2023 did not go into effect. (42 CFR 488.417 (b))

However, as we notified you in our letter of January 20, 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 10, 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 10, 2023

Administrator
The Estates At Roseville LLC
2727 North Victoria
Roseville, MN 55113

Re: Reinspection Results
Event ID: 8WSV12

Dear Administrator:

On February 7, 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 26, 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 delivered
February 3, 2023

Administrator
The Estates At Roseville LLC
2727 North Victoria
Roseville, MN 55113

RE: CCN: 245105
Cycle Start Date: January 10, 2023

Dear Administrator:

On January 20, 2023, we informed you of imposed enforcement remedies.

On January 26, 2023, 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 isolated deficiencies that constituted actual harm that was not immediate jeopardy (Level G), 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 February 4, 2023, 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 February 4, 2023. They will also notify the State Medicaid Agency that they must also deny payment for new Medicaid admissions effective February 4, 2023.

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 January 20, 2023, 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 10, 2023.

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" and/or an"E" tag), i.e., the plan of correction should be directed to:

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

PRESUMPTION OF COMPLIANCE - CREDIBLE ALLEGATION OF COMPLIANCE

The facility's ePoC will serve as your allegation of compliance upon the Department's acceptance. In order for your allegation of compliance to be acceptable to the Department, the ePoC must meet the criteria listed in the plan of correction section above. You will be notified by the Minnesota Department of Health - 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 July 10, 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

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.

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,

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
	245105	A. BUILDING _____ B. WING _____	C 01/26/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THE ESTATES AT ROSEVILLE LLC	2727 NORTH VICTORIA ROSEVILLE, MN 55113

(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 1/25/2023-1/26/2023, a standard abbreviated survey was conducted at your facility. Your facility was found to be NOT in compliance with the requirements of 42 CFR 483, Subpart B, Requirments for Long Term Care Facilities. The following complaints were found to be SUBSTANTIATED:H51057596C (MN00090124) with a deficiency cited at F756. The facility's plan of correction (POC) will serve as your allegation of compliance upon the Departments acceptance. Because you are enrolled in ePOC, your signature is not required at the bottom of the first page of the CMS-2567 form. Your electronic submission of the POC will be used as verification of compliance. Upon receipt of an acceptable electronic POC, an onsite revisit of your facility may be conducted to validate that substantial compliance with the regulations has been attained.	F 000		
F 756 SS=G	Drug Regimen Review, Report Irregular, Act On CFR(s): 483.45(c)(1)(2)(4)(5) §483.45(c) Drug Regimen Review. §483.45(c)(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. §483.45(c)(2) This review must include a review of the resident's medical chart. §483.45(c)(4) The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.	F 756		2/3/23

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

Electronically Signed | 02/03/2023

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 756	Continued From page 1 (i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug. (ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified. (iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record. §483.45(c)(5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident. This REQUIREMENT is not met as evidenced by: Based on interview and record review, the facility failed to ensure the consultant pharmacist performed a complete medical record review for prescribed Clozaril an antipsychotic medication for one of one residents (R1) reviewed for antipsychotic medications. The antipsychotic medication required strict monitoring of an absolute neutrophil count and dispensing from the Risk Evaluation and Mitigation Strategy to reorder and administer the medication as prescribed. R1 suffered physical withdrawal symptom and psychosocial decompensation.	F 756	R1 had a complete medical pharmacist record review for prescribed Clozaril antipsychotic. Residents who will be prescribed antipsychotic medications that require strict monitoring of an absolute neutrophil count and dispensing from REMS program had a medical pharmacist record review completed. There are no residents at this time who receive Clozaril at the Estates at Roseville.	

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F 756	Continued From page 2 Findings include: U.S. Food & Drug Administration (FDA) website titled Information on Clozapine, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-clozapine identified Clozapine resources FDA Pharmacy Outreach Presentation dated 8/19/2021, The Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program Modification, Clozapine REMS website, and Clozapine REMS information. The FDA Pharmacy Outreach Presentation identified continued absolute neutrophil count monitoring must be obtained before dispensing from the REMS Dispensing Authorization (RDA). If an RDA is rejected there will be an option to request a Dispense Rationale through the website or contact center. To obtain a Dispense Rationale, the pharmacist must have an ANC that was obtained in the last 30 days within the acceptable range. The pharmacist will need to provide the following to the REMS: Prescriber's NPI number, Blood draw date, ANC value, Dispense Rationales are limited to three per patient per year. Clozapine REMS website titled Pharmacy Materials https://www.newclozapinerems.com/Public/home/ Pharmacy identified guidance titled Clozapine and the Risk of Neutropenia: A Guide for Pharmacists indicated before dispensing Clozapine an absolute neutrophil count (ANC) must be submitted before starting and during Clozapine treatment. The risks to severe neutropenia associated with clozapine can lead to serious infections and death, severe neutropenia is defined as ANC less than 500/?L, "Severe	F 756	Pharmacist received reeducation on Consultant Pharmacist Report Medication Regimen Review. DNS/or Designee will audit monthly for 3 months and as needed of the Pharmacist medication regimen reviews for antipsychotic medications that require strict monitoring of absolute neutrophil count and dispensing from REMS program. Facility will review audit findings at QAPI and adjust audit schedules accordingly to findings. Date of completion: 2/3/2023	

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F 756	Continued From page 3 neutropenia" replaces the previous terms "severe leukopenia," "severe granulocytopenia," and "agranulocytosis". The risk appears greatest during the first 18 weeks of clozapine treatment, the mechanism is not dose dependent. It is unclear if concurrent use of other drugs known to cause neutropenia increases the risk or severity of clozapine-induced neutropenia. If clozapine is used concurrently with a medication(s) known to cause neutropenia: Consider monitoring patients more closely than the treatment guidelines recommend and consult with the treating oncologist in patients receiving concomitant chemotherapy. For a complete discussion of other risks, including other Boxed Warnings, please see the full Prescribing Information available at www.clozapinerems.com. In addition, the guidance indicated patients may transition to less frequent ANC monitoring based on the number of weeks of continuous Clozapine therapy and the patient's ANC's. The role of the pharmacy is to designate an authorized representative in the Clozapine REMS by completing three steps: Step 1: Certify in the Clozapine REMS by: Reviewing Clozapine and the Risk of Neutropenia: A Guide for Pharmacists Successfully complete and submit the Knowledge Assessment for Pharmacies Complete and submit the Inpatient Pharmacy Enrollment Form and/or the Outpatient Pharmacy Enrollment Form Step 2: Ensure training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS requirements using the Clozapine and the Risk of Neutropenia: A Guide for Pharmacists Once a staff is trained on the Clozapine REMS requirements, the authorized representative may invite that staff to become enrolled in the Clozapine REMS. Step 3: Put processes and procedures in place to verify an	F 756		

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F 756	Continued From page 4 available, current ANC is within the acceptable range for patients enrolled but not authorized to receive the drug. Clozapine REMS website titled Prescribers Materials https://www.newclozapinerems.com/Public/home/ Prescriber identified guidance titled Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers instructs providers in an inpatient to submit absolute neutrophil count (ANC) into the REMS program to initiate or continue Clozapine treatment. If another prescriber has previously treated the patient with Clozapine the current prescriber must enroll the patient by completing and submitting the Patient Enrollment Form to the Clozapine REMS (online or by fax) to be able to access the patient's ANC history. R1's discharge orders from the hospital dated 12/16/2022 indicated to continue taking Clozapine 100 milligram (mg) tablet. Instructions were to take 300 mg by mouth at bedtime. Lab results component value date white blood cells (WBC) 7.7 date 9/9/2021 and lab results component value date absolute neutrophil count (ABSNEUTS) 4.3 date 9/9/2021. Minimum Data Set (MDS) assessment, dated 12/22/2022, indicated R1's diagnoses included schizophrenia, depression, diabetes mellitus, alcohol dependence, and admitted to the Estates of Roseville on 12/16/2022 following a left knee arthroplasty. R1's Brief Interview for Mental Status (BIMS) score was 14 of 15, indicating he is cognitively intact. R1's Consultant Pharmacist Medication Regimen	F 756		

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F 756	Continued From page 5 Review, completed by Pharmacist (P)-A on 12/22/2022, identified R1 was prescribed two other psychotropic medications and Clozapine instructing the facility staff to monitor for abnormal behaviors and to complete the Abnormal Involuntary Movement Scale (AIMS) assessment every 6 months to assess severity of dyskinesias. R1's medication administration record (MAR) dated December 2022 indicated Clozapine oral tablet, give 300 mg by mouth at bedtime for schizophrenia, start 12/16/2022 at 7:00 p.m., was not administered as prescribed and denoted as a "9" on 12/29/2022, 12/30/2022, and 12/31/2022. According to the MAR's legend, a "9" indicated to read the nursing notes for further details. A progress note written by licensed practical nurse (LPN)-B dated 12/29/2022, stated R1's Clozaril was not administered because the facility was awaiting its arrival from the pharmacy. A progress note written by LPN-A, dated 12/30/2022, stated that an on-call provider was informed that R1 did not receive his clozapine on 12/29/2022, and nursing staff anticipated his clozapine would arrive that evening. LPN-A reported she had contacted the facility's pharmacy, who had requested R1's absolute neutrophil count (ANC). LPN-A indicated an unspecified pharmacy employee had informed her a seven-day supply of Clozapine would be dispensed and delivered to the facility before 12/31/2022. LPN-A then updated an unspecified on-call nurse practitioner and the assistant director of nursing (ADON). R1's provider progress note written by Nurse	F 756		

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F 756	Continued From page 6 Practitioner (NP)-A, dated 12/30/2022 indicated NP-A gave an order for a weekly lab blood draw for a complete blood count (CBC) until R1 was enrolled in the REMS program. An addendum to this progress note, dated 1/3/2023, indicated the REMS enrollment process and prescribing process needed to continue through R1's established psychiatric provider at the Veterans Affairs Medical Center. A progress note written by LPN-C, dated 12/31/2022, stated that R1's clozapine was not in the facility. R1's provider progress note written by NP-B dated 1/1/2023 indicated R1 missed three doses of Clozapine and is going through withdrawal was diaphoretic and chest was hurting, R1 was not in the REMS program. While on the phone with pharmacy, the pharmacy indicated they can dispense Clozapine with an ANC. The provider looked up the hospital ANC that indicated a count of 6.0, the results were faxed to the pharmacy and a seven-day transitional fill was to be dispensed. R1's psychiatrist needs to enroll R1 in the REMS program. A provider progress note addendum by NP-B, dated 1/1/2023 indicated stated that the pharmacy had delivered R1's clozapine and facility staff were given a verbal order to administer R1's 1/1/2023 bedtime clozapine dose as soon as possible. R1's MAR dated January 2023, indicated the facility was assessing the patient every 15-minutes for safety every shift and for any violent or anger outburst related to schizophrenia, due to medication withdrawals along with vital signs every four hours for two days.	F 756		

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THE ESTATES AT ROSEVILLE LLC	2727 NORTH VICTORIA ROSEVILLE, MN 55113

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F 756	Continued From page 7 A facility form titled "Medication Error Reporting Form," dated 1/1/2023 and completed by LPN-A, indicated that R1 suffered negative physical outcomes due to the not receiving his scheduled Clozapine on 12/29/2022, 12/30/2022, and 12/31/2022. A progress note written by LPN-C, dated 1/1/2023 indicated she began 15-minute safety checks on R1 at the instruction of an unspecified nurse manager. A progress note written by LPN-C, dated 1/1/2023 indicated R1 was experiencing withdrawal symptoms, including diaphoresis and hypertension. LPN-C reported R1 had told her he felt safe. LPN-C did not document further psychological assessment of R1. A progress note written by LPN-C, dated 1/1/2023, stated that R1's bedtime clozapine dose was administered at 1:28 p.m. During an interview with R1 on 1/25/2023 at 11:28 a.m., R1 stated when he was not receiving his Clozapine, he experienced uncomfortable withdrawal symptoms and thoughts of self-harm. R1 reported sweating profusely and feeling physically weak, preventing him from completing his physical therapy exercises. R1 stated his visual and auditory hallucinations worsened, he felt emotionally unstable, and he experienced disembodied voices instructing him to hurt himself and others. During an interview with the DON on 1/25/2023 at 2:50 p.m., she stated she was contacted by LPN-A on 12/31/2022 and informed of the Clozapine omission on 12/29/2022 and	F 756		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	245105	A. BUILDING _____ B. WING _____	C 01/26/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THE ESTATES AT ROSEVILLE LLC	2727 NORTH VICTORIA ROSEVILLE, MN 55113

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F 756	Continued From page 8 12/30/2022. The DON stated the pharmacy intended to have the medication delivered to the facility on the evening 12/31/2022, however the Clozapine arrived on 1/1/2023. The she stated nursing staff are not expected to know which medications require ongoing labs. She indicated that any medications requiring ongoing lab monitoring would be notated in a resident's electronic medication administration record (EMAR). The DON stated it is the responsibility of the pharmacist during the monthly medication regimen review to notate which medications require ongoing monitoring for nursing staff. She expects the consultant pharmacist to note these medications in the EMAR and then report their findings to as part of the Medication Regimen Review. During an interview with LPN-A on 1/26/23 at 9:30 a.m., LPN-A stated on 12/30/2022 she noticed an order for CBC with differential had not been completed for R1. LPN-A reported she called the pharmacy to report the missed CBC order, who informed her that a 7-day supply of Clozapine would be dispensed that evening. LPN-A stated she then spoke with the on-call provider to communicate the issue and receive orders for a CBC with differential for R1 after the holiday weekend. During an interview with the pharmacist (P)-A on 1/26/2023 at 2:02 p.m., she stated Clozapine required regular ANC monitoring to administer safely. She stated that it is industry standard to review ANC levels during a Medication Regimen review. P-A stated she reviewed R1's electronic medical record, including his orders and hospital discharge paperwork, and did not see any ongoing orders to monitor R1's ANC. She stated	F 756		

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F 756	Continued From page 9 she did not include the need for ANC monitoring in her Medication Regimen Review because the hospital obtained an ANC prior to R1's discharge and the facility's pharmacy was supplying his clozapine without issue. P-A stated it was R1's primary care provider or psychiatrist's responsibility to determine ongoing labs for ANC monitoring. A facility policy titled "Medication Regimen Review," dated August 2019, indicated that the consulting pharmacist is required to complete a thorough review of the resident's medical record to identify clinical irregularities. Any lapses in care or monitoring regarding the resident's medications are to be reported to the Director of Nursing.	F 756		

Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically delivered
February 3, 2023

Administrator
The Estates At Roseville LLC
2727 North Victoria
Roseville, MN 55113

Re: State Nursing Home Licensing Orders
Event ID: 8WSV11

Dear Administrator:

The above facility was surveyed on January 25, 2023 through January 26, 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:

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

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

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
	00497	A. BUILDING: _____ B. WING _____	C 01/26/2023

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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 1/25/2023-1/26/2023, 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 when they will be completed.	2 000		

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

Electronically Signed | 02/03/23

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2 000	Continued From page 1 The following complaint was found to be SUBSTANTIATED: H51057596C (MN00090124) with a licensing order issued at 1530. 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 is enrolled in ePOC and therefore a signature is	2 000		

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2 000	Continued From page 2 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		
21530	MN Rule 4658.1310 A.B.C Drug Regimen Review A. The drug regimen of each resident must be reviewed at least monthly by a pharmacist currently licensed by the Board of Pharmacy. This review must be done in accordance with Appendix N of the State Operations Manual, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care, published by the Department of Health and Human Services, Health Care Financing Administration, April 1992. This standard is incorporated by reference. It is available through the Minitex interlibrary loan system. It is not subject to frequent change. B. The pharmacist must report any irregularities to the director of nursing services and the attending physician, and these reports must be acted upon by the time of the next physician visit, or sooner, if indicated by the pharmacist. For purposes of this part, "acted upon" means the acceptance or rejection of the report and the signing or initialing by the director of nursing services and the attending physician. C. If the attending physician does not concur with the pharmacist's recommendation, or does not provide adequate justification, and the pharmacist believes the resident's quality of life is being adversely affected, the pharmacist must refer the matter to the medical director for review if the medical director is not the attending	21530		2/3/23

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21530	Continued From page 3 physician. If the medical director determines that the attending physician does not have adequate justification for the order and if the attending physician does not change the order, the matter must be referred for review to the quality assessment and assurance committee required by part 4658.0070. If the attending physician is the medical director, the consulting pharmacist must refer the matter directly to the quality assessment and assurance committee. This MN Requirement is not met as evidenced by: Based on interview and record review, the facility failed to ensure the consultant pharmacist performed a complete medical record review for prescribed Clozaril an antipsychotic medication for one of one residents (R1) reviewed for antipsychotic medications. The antipsychotic medication required strict monitoring of an absolute neutrophil count and dispensing from the Risk Evaluation and Mitigation Strategy to reorder and administer the medication as prescribed. R1 suffered physical withdrawal symptom and psychosocial decompensation. Findings include: U.S. Food & Drug Administration (FDA) website titled Information on Clozapine, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-clozapine identified Clozapine resources FDA Pharmacy Outreach Presentation dated 8/19/2021, The Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program Modification, Clozapine REMS website, and Clozapine REMS information. The FDA Pharmacy Outreach Presentation identified continued absolute	21530	Corrected	

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21530	Continued From page 4 neutrophil count monitoring must be obtained before dispensing from the REMS Dispensing Authorization (RDA). If an RDA is rejected there will be an option to request a Dispense Rationale through the website or contact center. To obtain a Dispense Rationale, the pharmacist must have an ANC that was obtained in the last 30 days within the acceptable range. The pharmacist will need to provide the following to the REMS: Prescriber's NPI number, Blood draw date, ANC value, Dispense Rationales are limited to three per patient per year. Clozapine REMS website titled Pharmacy Materials https://www.newclozapinerems.com/Public/home/ Pharmacy identified guidance titled Clozapine and the Risk of Neutropenia: A Guide for Pharmacists indicated before dispensing Clozapine an absolute neutrophil count (ANC) must be submitted before starting and during Clozapine treatment. The risks to severe neutropenia associated with clozapine can lead to serious infections and death, severe neutropenia is defined as ANC less than 500/?L, "Severe neutropenia" replaces the previous terms "severe leukopenia," "severe granulocytopenia," and "agranulocytosis". The risk appears greatest during the first 18 weeks of clozapine treatment, the mechanism is not dose dependent. It is unclear if concurrent use of other drugs known to cause neutropenia increases the risk or severity of clozapine-induced neutropenia. If clozapine is used concurrently with a medication(s) known to cause neutropenia: Consider monitoring patients more closely than the treatment guidelines recommend and consult with the treating oncologist in patients receiving concomitant chemotherapy. For a complete discussion of other risks, including other Boxed Warnings,	21530		

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21530	Continued From page 5 please see the full Prescribing Information available at www.clozapinerems.com. In addition, the guidance indicated patients may transition to less frequent ANC monitoring based on the number of weeks of continuous Clozapine therapy and the patient's ANC's. The role of the pharmacy is to designate an authorized representative in the Clozapine REMS by completing three steps: Step 1: Certify in the Clozapine REMS by: Reviewing Clozapine and the Risk of Neutropenia: A Guide for Pharmacists Successfully complete and submit the Knowledge Assessment for Pharmacies Complete and submit the Inpatient Pharmacy Enrollment Form and/or the Outpatient Pharmacy Enrollment Form Step 2: Ensure training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS requirements using the Clozapine and the Risk of Neutropenia: A Guide for Pharmacists Once a staff is trained on the Clozapine REMS requirements, the authorized representative may invite that staff to become enrolled in the Clozapine REMS. Step 3: Put processes and procedures in place to verify an available, current ANC is within the acceptable range for patients enrolled but not authorized to receive the drug. Clozapine REMS website titled Prescribers Materials https://www.newclozapinerems.com/Public/home/ Prescriber identified guidance titled Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers instructs providers in an inpatient to submit absolute neutrophil count (ANC) into the REMS program to initiate or continue Clozapine treatment. If another prescriber has previously treated the patient with Clozapine the current prescriber must enroll the patient by completing and submitting the Patient	21530		

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21530	Continued From page 6 Enrollment Form to the Clozapine REMS (online or by fax) to be able to access the patient's ANC history. R1's discharge orders from the hospital dated 12/16/2022 indicated to continue taking Clozapine 100 milligram (mg) tablet. Instructions were to take 300 mg by mouth at bedtime. Lab results component value date white blood cells (WBC) 7.7 date 9/9/2021 and lab results component value date absolute neutrophil count (ABSNEUTS) 4.3 date 9/9/2021. Minimum Data Set (MDS) assessment, dated 12/22/2022, indicated R1's diagnoses included schizophrenia, depression, diabetes mellitus, alcohol dependence, and admitted to the Estates of Roseville on 12/16/2022 following a left knee arthroplasty. R1's Brief Interview for Mental Status (BIMS) score was 14 of 15, indicating he is cognitively intact. R1's Consultant Pharmacist Medication Regimen Review, completed by Pharmacist (P)-A on 12/22/2022, identified R1 was prescribed two other psychotropic medications and Clozapine instructing the facility staff to monitor for abnormal behaviors and to complete the Abnormal Involuntary Movement Scale (AIMS) assessment every 6 months to assess severity of dyskinesias. R1's medication administration record (MAR) dated December 2022 indicated Clozapine oral tablet, give 300 mg by mouth at bedtime for schizophrenia, start 12/16/2022 at 7:00 p.m., was not administered as prescribed and denoted as a "9" on 12/29/2022, 12/30/2022, and 12/31/2022. According to the MAR's legend, a "9" indicated to read the nursing notes for further details.	21530		

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21530	Continued From page 7 A progress note written by licensed practical nurse (LPN)-B dated 12/29/2022, stated R1's Clozaril was not administered because the facility was awaiting its arrival from the pharmacy. A progress note written by LPN-A, dated 12/30/2022, stated that an on-call provider was informed that R1 did not receive his clozapine on 12/29/2022, and nursing staff anticipated his clozapine would arrive that evening. LPN-A reported she had contacted the facility's pharmacy, who had requested R1's absolute neutrophil count (ANC). LPN-A indicated an unspecified pharmacy employee had informed her a seven-day supply of Clozapine would be dispensed and delivered to the facility before 12/31/2022. LPN-A then updated an unspecified on-call nurse practitioner and the assistant director of nursing (ADON). R1's provider progress note written by Nurse Practitioner (NP)-A, dated 12/30/2022 indicated NP-A gave an order for a weekly lab blood draw for a complete blood count (CBC) until R1 was enrolled in the REMS program. An addendum to this progress note, dated 1/3/2023, indicated the REMS enrollment process and prescribing process needed to continue through R1's established psychiatric provider at the Veterans Affairs Medical Center. A progress note written by LPN-C, dated 12/31/2022, stated that R1's clozapine was not in the facility. R1's provider progress note written by NP-B dated 1/1/2023 indicated R1 missed three doses of Clozapine and is going through withdrawal was diaphoretic and chest was hurting, R1 was not in	21530		

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21530	Continued From page 8 the REMS program. While on the phone with pharmacy, the pharmacy indicated they can dispense Clozapine with an ANC. The provider looked up the hospital ANC that indicated a count of 6.0, the results were faxed to the pharmacy and a seven-day transitional fill was to be dispensed. R1's psychiatrist needs to enroll R1 in the REMS program. A provider progress note addendum by NP-B, dated 1/1/2023 indicated stated that the pharmacy had delivered R1's clozapine and facility staff were given a verbal order to administer R1's 1/1/2023 bedtime clozapine dose as soon as possible. R1's MAR dated January 2023, indicated the facility was assessing the patient every 15-minutes for safety every shift and for any violent or anger outburst related to schizophrenia, due to medication withdrawals along with vital signs every four hours for two days. A facility form titled "Medication Error Reporting Form," dated 1/1/2023 and completed by LPN-A, indicated that R1 suffered negative physical outcomes due to the not receiving his scheduled Clozapine on 12/29/2022, 12/30/2022, and 12/31/2022. A progress note written by LPN-C, dated 1/1/2023 indicated she began 15-minute safety checks on R1 at the instruction of an unspecified nurse manager. A progress note written by LPN-C, dated 1/1/2023 indicated R1 was experiencing withdrawal symptoms, including diaphoresis and hypertension. LPN-C reported R1 had told her he felt safe. LPN-C did not document further psychological assessment of R1.	21530		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	00497	A. BUILDING: _____ B. WING _____	C 01/26/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THE ESTATES AT ROSEVILLE LLC	2727 NORTH VICTORIA ROSEVILLE, MN 55113

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21530	Continued From page 9 A progress note written by LPN-C, dated 1/1/2023, stated that R1's bedtime clozapine dose was administered at 1:28 p.m. During an interview with R1 on 1/25/2023 at 11:28 a.m., R1 stated when he was not receiving his Clozapine, he experienced uncomfortable withdrawal symptoms and thoughts of self-harm. R1 reported sweating profusely and feeling physically weak, preventing him from completing his physical therapy exercises. R1 stated his visual and auditory hallucinations worsened, he felt emotionally unstable, and he experienced disembodied voices instructing him to hurt himself and others. During an interview with the DON on 1/25/2023 at 2:50 p.m., she stated she was contacted by LPN-A on 12/31/2022 and informed of the Clozapine omission on 12/29/2022 and 12/30/2022. The DON stated the pharmacy intended to have the medication delivered to the facility on the evening 12/31/2022, however the Clozapine arrived on 1/1/2023. The she stated nursing staff are not expected to know which medications require ongoing labs. She indicated that any medications requiring ongoing lab monitoring would be notated in a resident's electronic medication administration record (EMAR). The DON stated it is the responsibility of the pharmacist during the monthly medication regimen review to notate which medications require ongoing monitoring for nursing staff. She expects the consultant pharmacist to note these medications in the EMAR and then report their findings to as part of the Medication Regimen Review. During an interview with LPN-A on 1/26/23 at 9:30	21530		

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21530	Continued From page 10 a.m., LPN-A stated on 12/30/2022 she noticed an order for CBC with differential had not been completed for R1. LPN-A reported she called the pharmacy to report the missed CBC order, who informed her that a 7-day supply of Clozapine would be dispensed that evening. LPN-A stated she then spoke with the on-call provider to communicate the issue and receive orders for a CBC with differential for R1 after the holiday weekend. During an interview with the pharmacist (P)-A on 1/26/2023 at 2:02 p.m., she stated Clozapine required regular ANC monitoring to administer safely. She stated that it is industry standard to review ANC levels during a Medication Regimen review. P-A stated she reviewed R1's electronic medical record, including his orders and hospital discharge paperwork, and did not see any ongoing orders to monitor R1's ANC. She stated she did not include the need for ANC monitoring in her Medication Regimen Review because the hospital obtained an ANC prior to R1's discharge and the facility's pharmacy was supplying his clozapine without issue. P-A stated it was R1's primary care provider or psychiatrist's responsibility to determine ongoing labs for ANC monitoring. A facility policy titled "Medication Regimen Review," dated August 2019, indicated that the consulting pharmacist is required to complete a thorough review of the resident's medical record to identify clinical irregularities. Any lapses in care or monitoring regarding the resident's medications are to be reported to the Director of Nursing. SUGGESTED METHOD OF CORRECTION: The Director of Nursing or designated person to	21530		

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21530	Continued From page 11 determine how the deficiency occurred, review policies and procedures, revise as necessary, educated staff on revisions, and monitor to ensure compliance. TIME PERIOD FOR CORRECTION: Twenty-One (21) days.	21530		