Electronically Submitted

Administrator
Elim Home
701 First Street
Princeton, MN 55371

RE: CCN: 245494
Cycle Start Date: November 5, 2020

Dear Administrator:

On November 5, 2020, survey was completed at your facility by the Minnesota Department of Health and Public Safety to determine if your facility was in compliance with Federal participation requirements for skilled nursing facilities and/or nursing facilities participating in the Medicare and/or Medicaid programs.

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

REMOVAL OF IMMEDIATE JEOPARDY

On October 29, 2020, the situation of immediate jeopardy to potential health and safety cited at F757 - Drug Regimen Is Free From Unnecessary Drugs was removed.

REMEDIES

As a result of the survey findings and in accordance with survey and certification memo 16-31-NH, this Department is recommending that CMS impose a civil money penalty (42 CFR 488.430 through 488.444). You will receive a formal notice from the CMS RO only if CMS agrees with our recommendation.

SUBSTANDARD QUALITY OF CARE

Your facility's deficiencies with with one or more of the following: §483.10, Residents Rights, §483.12, Freedom from Abuse, Neglect, and Exploitation, §483.15, Quality of Life and §483.25, Quality of Care, 483.40 Behavioral Health Services, §483.45 Pharmacy Services, §483.70 Administration, or §483.80 Infection control has been determined to constitute substandard quality of care as defined at

§488.301. Sections 1819(g)(5)(C) and 1919(g)(5)(C) of the Social Security Act and 42 CFR 488.325(h) require that the attending physician of each resident who was found to have received substandard quality of care, as well as the State board responsible for licensing the facility's administrator, be notified of the substandard quality of care. If you have not already provided the following information, you are required to provide to this agency within ten working days of your receipt of this letter the name and address of the attending physician of each resident found to have received substandard quality of care.

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

Federal law, as specified in the Act at Sections 1819(f)(2)(B) and 1919(f)(2)(B), prohibits approval of nurse assistant training programs offered by, or in, a facility which, within the previous two years, has been subject to an extended or partial extended survey as a result of a finding of substandard quality of care. Therefore, Elim Home is prohibited from offering or conducting a Nurse Assistant Training / Competency Evaluation Programs (NATCEP) or Competency Evaluation Programs for two years effective November 5, 2020. This prohibition remains in effect for the specified period even though substantial compliance is attained. Under Public Law 105-15 (H. R. 968), you may request a waiver of this prohibition if certain criteria are met. Please contact the Nursing Assistant Registry at (800) 397-6124 for specific information regarding a waiver for these programs from this Department.

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 NURSE AIDE TRAINING PROHIBITION

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

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

Department of Health & Human Services
Departmental Appeals Board, MS 6132
Director, Civil Remedies Division

330 Independence Avenue, S.W.
Cohen Building – Room G-644
Washington, D.C. 20201

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

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

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

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

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

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

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

Feel free to contact me if you have questions.

Sincerely,

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

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	245494	A. BUILDING _____ B. WING _____	C 11/05/2020

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F 000	INITIAL COMMENTS On 11/4/20 to 11/5/20, an abbreviated survey was completed at your facility by surveyors from the Minnesota Department of Health (MDH) to conduct a complaint investigation. Elim Home 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: H5494064C; with a deficiency cited at F757. The survey resulted in findings of immediate jeopardy (IJ) and substandard quality of care. An IJ began on 10/16/20, when R1's drawn international normalized ratio (INR; a laboratory test used to determine how long it takes blood to clot) results were not acted upon or addressed to ensure therapeutic dosing of Coumadin (a blood thinning medication) and prevent embolism. The resident developed facial droop, left-sided weakness and was hospitalized for an acute stroke and died several days later as a result. The administrator, director of nursing (DON) and director of SNF clinical services (DCS) were notified of the IJ on 11/4/20, at 4:35 p.m. However, the facility implemented several action(s) prior to the abbreviated survey including auditing all residents on Coumadin to ensure therapeutic dosing and monitoring; revising procedures to ensure nursing and provider staff acted upon received INR results; and, educating staff to ensure knowledge of applicable process changes. As a result, the past non-compliance IJ was removed and the non-compliance corrected as of 10/29/20.	F 000		

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

Electronically Signed

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F 000	Continued From page 1 In addition, an extended survey was conducted on 11/5/20. 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 required for a finding of past non-compliance, it is required the facility acknowledge receipt of the electronic documents.	F 000		
F 757 SS=J	Drug Regimen is Free from Unnecessary Drugs CFR(s): 483.45(d)(1)-(6) §483.45(d) Unnecessary Drugs-General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used- §483.45(d)(1) In excessive dose (including duplicate drug therapy); or §483.45(d)(2) For excessive duration; or §483.45(d)(3) Without adequate monitoring; or §483.45(d)(4) Without adequate indications for its use; or §483.45(d)(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or §483.45(d)(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section. This REQUIREMENT is not met as evidenced by: Based on interview and document review, the facility failed to ensure laboratory results were	F 757	Past noncompliance: no plan of correction required.	

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adequately monitored and acted upon to ensure therapeutic dosing of anticoagulant medication to prevent embolism in 1 of 3 residents (R1) reviewed for unnecessary medication use. These findings constituted an immediate jeopardy (IJ) situation for R1. However, the facility had taken appropriate action(s) to correct the identified non-compliance and, as a result, the findings are being issued as past non-compliance.

The IJ began on 10/16/20, when R1's drawn international normalized ratio (INR; a laboratory test used to determine how long it takes blood to clot) laboratory results were not acted upon by the nursing or provider staff resulting in the omission of therapeutic dosing of anticoagulant medication which contributed to subsequent hospitalization for acute stroke and death. The administrator, director of nursing (DON) and director of SNF clinical services (DCS) were notified of the IJ for R1 on 11/4/20, at 4:35 p.m. However, the facility had implemented several action(s) including auditing other residents on blood thinning medication to ensure therapeutic dosing and appropriate monitoring was in place; revising facility processes to ensure INR laboratory results were promptly identified and acted upon by nursing and/or provider staff; and, implementing verbal and electronic education to ensure staff competency in these processes. As a result, the IJ was removed and the identified non-compliance was corrected as of 10/29/20.

Findings include:

R1's admission Minimum Data Set (MDS), dated 10/15/20, identified R1 had severe cognitive impairment, required extensive assistance with her activities of daily living (ADLs), and have no

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impairment(s) or limitations in upper and lower extremity range of motion (ROM). Further, the MDS identified R1 had atrial fibrillation, heart failure and high blood pressure; and consumed anticoagulant medication for six out of the seven days in the look-back period.

On 11/3/20, at 2:43 p.m. R1's family member (FM)-A was interviewed and explained R1 had lived at the facility's attached assisted living and was generally "pretty healthy" prior to admitting to the nursing home for rehabilitation services after she sustained a fall. R1's intention was then to return back to the assisted living. FM-A stated R1 had a long-standing history of atrial fibrillation (an irregular, often rapid heart rate that commonly causes poor blood flow and increases the risk for clotting and embolism) and, as a result, consumed Coumadin (a blood thinning medication) to reduce her risk of stroke. However, on 10/25/20, the nursing home had contacted her and voiced R1 was demonstrating stroke-like symptoms and FM-A directed them to send R1 to the hospital right away. FM-A stated she met R1 in the emergency room (ED) and the ED physician asked her, "Why did they [the nursing home] stop her Coumadin?" FM-A answered she was not sure, so the physician attempted to contact the nursing home without success. FM-A stated R1 was subsequently diagnosed with "a solid blood clot [stroke]" and left "totally paralyzed," ultimately being placed on comfort cares and returned to the nursing home. Shortly afterwards, FM-A was at the nursing home visiting R1 when the director of nursing (DON) and another female approached her and voiced they "wanted to talk about something." The DON then explained to FM-A there had been "a technical error" and R1 had not received any

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Coumadin for the past several weeks while at the nursing home. FM-A stated the DON voiced the error was the nursing home's fault; however, FM-A then became very upset and demanded they leave R1's room. FM-A stated R1 continued to decline and finally died while at the nursing home. FM-A expressed the entire situation and loss of R1 made her "just furious" and she questioned why the nursing home had abruptly stopped giving R1 the needed medication as "you'd think they [the nursing home] would question it" when someone who was taking Coumadin abruptly stopped. FM-A again voiced being "livid" about the lack of monitoring which contributed to such an error voicing she felt she could have had several more years to enjoy R1, but the nursing home's error resulted in her death. FM-A added, "They killed my [R1]!"

R1's care plan, revised 11/1/20, identified R1's care needs while at the nursing home. The section labeled, "Diagnosis," outlined R1 had long-standing atrial fibrillation, listed as her primary diagnosis for admission, and long-term use of anticoagulation therapy. However, the provided copy of the care plan lacked any specific problem statements, goals or intervention(s) pertaining to R1's use of anticoagulation medication(s) despite having these diagnoses recorded; nor any identified interventions or direction on how R1's laboratory monitoring would be monitored and/or completed while she resided at the nursing home.

R1's Interagency Transfer Form, dated 10/8/20, identified R1's past medical history (PMH) included long-term use of anticoagulant therapy, atrial fibrillation and history of ischemic stroke. The form listed R1's medication(s) for discharge

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from the hospital to the nursing home with directions, "Continue these medications ..." The medications included Coumadin with directions, "Take as directed. If you are unsure how to take this medication, talk to your nurse or doctor ... Take 2.5 mg [milligrams] Monday, Wednesday, and Friday and 5 mg all other days." The form identified R1 as being hospitalized for a fall and, " ... will be transferred to TCU [Elim Home Transitional Care Unit] for ongoing physical therapy," with a section labeled, "Follow-Up Appointment Instructions," directing to follow-up with the nursing home physician along with dictation which read, "Have INR rechecked in 7 days [on 10/16/20] for further [Coumadin] dosing." Further, a corresponding (Elim) Physician Order Report, dated 10/9/20, identified handwritten dictation which read, "*Copied from signed hospital MD orders [and] labs per MD/NP recommendations." The order(s) were signed by health unit coordinator (HUC)-A.

R1's subsequent Fairview Health Services laboratory results, dated 10/16/20, identified R1 had the ordered INR drawn and completed. The test identified a reference range (a set of values with upper and lower limits of a lab test based on a group of otherwise healthy people) of 0.86 to 1.14 with no posted units of measurement. R1's test result was recorded as, "3.63," which the test identified as, "Out of Range." There was no visible markings or dictation present on the recorded lab results which identified they had been reviewed by R1's nursing staff or physician.

R1's Medication Administration Record (MAR), dated 10/2020, identified all of R1's provided and consumed medications for the month. R1 was recorded as having been given Coumadin, in

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accordance with the Interagency Transfer Form (dated 10/8/20) directions, from 10/10/20 to 10/15/20. The MAR lacked evidence R1 had been provided any Coumadin after 10/15/20, despite R1 having a history of anticoagulant use and atrial fibrillation.

R1's medical record identified the following additional progress note(s) and hospital records:

On 10/9/20, a progress note identified R1 admitted to the nursing home from the acute care hospital due to a fall with resulted foot sprain. The note read, "Resident plans to do rehabilitation therapy for strengthening and return to prior living situation. Please see chart for past medical Hx [history]."

On 10/13/20, a skilled charting note was recorded which identified R1 had a primary diagnosis of atrial fibrillation and was on Coumadin once-a-day. The note recorded R1 as adjusting well to the nursing home environment and progressing towards her goal(s).

On 10/16/20, a progress note identified it was day seven (7) of R1's admission to the nursing home. A section outlined as, "Clinical Monitoring," read, "[R1] has no recent lab works. Compliant in taking all oral medications."

On 10/20/20, a progress note outlined R1 was afebrile and was progressing towards her goal(s). The note read, "On warfarin [Coumadin] once a day."

On 10/25/20, a progress note identified R1 presented with "stroke symptoms" as she was unable to speak or respond, had facial drooping

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and was unable to move her left arm. R1's eyes were recorded as being unresponsive to light and her blood pressure was recorded as 190/98 mmHg (normal results 90/60 to 120/80 mmHg). The on-call provider was notified along with FM-A. R1 was transported to the hospital via emergency medical service (EMS).

R1's corresponding (Hospital) Admission History & Physical, dated 10/25/20, identified R1 presented with a history of atrial fibrillation and stroke. R1 was identified as having a long segment occlusion of the right internal carotid artery (ICA) from the neck to the terminus with low attenuation changes in the brain in the right middle carotid artery (MCA) distribution which resulted in "severe deficits" upon presentation. The report continued, " .... presented to the ED [emergency department] tonight due to left sided weakness and aphasia [language disorder sometimes resulted from stroke] that started acutely ... [had] been on warfarin [Coumadin] in the past but this was apparently stopped earlier this week. She was taken to North Memorial by Air Care." A Neurology Consultation, dated 10/25/20, was included which identified R1's symptoms presented suddenly and "have been severe." The report continued, "She had been on Coumadin in the past, but this was discontinued. There was an initial report that she was on Eliquis [an anticoagulant medication], however, it was confirmed that she is not ... In the emergency center, INR was 1.0 ... [CT] showed evidence of a large right MCA acute stroke." A palliative care assessment was recorded which identified R1 was now unable to engage in meaningful conversation and would likely not regain functional use of her upper and lower extremities; so a decision was made to focus on

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F 757	Continued From page 8 comfort-based care. On 10/28/20, a progress note identified R1 returned to the nursing home with " ... Acute ischemic right internal carotid artery stroke." R1 was admitted on hospice care. R1's corresponding Death in Facility MDS, dated 11/1/20, identified R1 expired on 11/1/20. R1's medical record was reviewed and lacked evidence which demonstrated R1's completed INR monitoring (dated 10/16/20) had been reviewed, assessed, acted upon or forwarded to the provider for action and further Coumadin dosing. Further, there were no recorded note(s) which clarified R1's Coumadin consumption despite R1's MAR lacking any evidence of administration after 10/15/20, and subsequent facility's progress note(s) outlining R1 remained on Coumadin. Further, the record lacked indication the abrupt omission of Coumadin from R1's medication regimen had been assessed and acted upon for clarification by the nursing staff despite R1's past medical history being significant for atrial fibrillation and R1 having a documented longstanding use of anticoagulant medication. When interviewed on 11/4/20, at 11:50 a.m. trained medication aide (TMA)-A stated she passed medications, including Coumadin, for the unit R1 resided on and recalled her stay at the nursing home. R1 admitted for rehabilitation and was not on comfort cares when she first came in early October. TMA-A explained she was aware of an incident involving R1's Coumadin happened where the order(s) to continue providing it "didn't transfer somehow" which resulted in R1 not receiving the medication for a period of time. TMA-A stated R1 was a newer resident to the unit	F 757		

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when the incident happened, and voiced typically when someone stopped a high risk medication, like Coumadin, abruptly the staff would question it. TMA-A stated she could not recall if she ever provided R1 any Coumadin throughout her admission and voiced she felt since R1 was new and not a "full time" resident; the staff just didn't question her Coumadin being stopped abruptly like they normally would have. TMA-A stated she was aware R1 had been hospitalized after having a stroke adding R1 "didn't talk anymore" and was "paralyzed" when she returned from the hospital. TMA-A explained, since the incident, they had received some education and added additional step(s) in the facility's MAR system to alert staff passing medications to the presence of anticoagulation medication(s) which would help trigger staff to question if they are not providing it. TMA-A stated some residents used to have these second alerts set-up and some did not adding she was not aware "why some had it and some didn't," however, affirmed all residents taking anticoagulation medication now had them and visually demonstrated these alert(s) to the surveyor for confirmation. TMA-A verified, to her knowledge, R1 did not have this second alert present when the incident happened on 10/16/20.

When interviewed on 11/4/20, at 12:06 p.m. health unit coordinator (HUC)-A verified she had transcribed R1's hospital admission order(s) using the Interagency Transfer Form (see above) upon her admission to the nursing home on 10/9/20. R1 admitted with orders for daily Coumadin which was to continue until the next INR was done and further dosing orders were received. HUC-A stated she counted out the seven (7) days, as directed in the admission orders, and entered the order to stop after the

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(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 757	Continued From page 10 10/15/20 dose which was in accordance with Cassia (the corporate oversight) policy to reduce the risk of double-dosing R1 after the INR was drawn on 10/16/20. HUC-A explained when an INR was drawn and completed, the results were sent to a provider inbox along with the facility's EMR (electronic medical record) where they get uploaded and the provider would then write "new orders" for a resident's Coumadin dosing. HUC-A verified R1's ordered INR was drawn, as directed, on 10/16/20, and the results were received by the facility on the same day; however, she was unaware if the results had been sent or communicated to the provider for further orders adding, "I don't know." HUC-A expressed the unit "team leads" were responsible to ensure all received lab results, including INRs, were addressed and acted upon; however, in R1's incident, the provider never reviewed the results so no new Coumadin dosing orders were written. This resulted in the medication essentially being discontinued and R1 receiving no anticoagulation therapy from 10/15/20 through her hospitalization on 10/25/20 (10 days). HUC-A stated the facility learned of the incident and immediately started to conduct audits of other residents to ensure they all had the needed anticoagulation in place. The facility then revised their process for INR laboratory monitoring to include printing out hard copies of the INRs and providing them directly to the team lead(s) for review and action, before they are uploaded back into the EMR system. HUC-A stated she felt this was a better system than what was in place previously to help ensure laboratory results were not missed in the future. When interviewed on 11/4/20, at 1:03 p.m. licensed practical nurse (LPN)-B explained the process used by the facility to ensure laboratory	F 757		

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monitoring was completed. The ordered lab(s) were placed on a calendar to be tracked and drawn; the results then would be followed up on by the team lead or provider. LPN-B voiced they felt the provider whom ordered the laboratory monitoring was ultimately responsible to ensure they were addressed, but added nursing should also be checking to ensure action on them "as a courtesy." LPN-B stated they were aware an incident had occurred involving R1 and her Coumadin where there had been "no follow up" on R1's drawn INR which caused no further Coumadin dosing orders to be written. LPN-B expressed they were not exactly sure what had caused the error; however, recalled the team lead "was not here" when the incident happened and the results had somehow been sent to the original Hospitalist who ordered the Coumadin, and not the nursing home provider, which may have contributed to the error. However, since the incident happened, all ordered laboratory monitoring, including INRs, were being printed and provided to each units' team lead who now is responsible to sign and date every single lab to ensure it's acted upon and addressed. The lab(s) were then scanned back into the EMR. LPN-B stated the lack of Coumadin dosing for R1 "probably" could have been avoided, in hindsight, and the new systems in place should prevent future similar errors.

On 11/4/20, at 1:37 p.m. team lead registered nurse (RN)-A and team lead licensed practical nurse (LPN)-C were interviewed. R1 admitted in early October 2020, and her goals were for restorative therapies and to then return to her prior living arrangements. R1's admission orders directed to take Coumadin on a daily basis with an INR draw being ordered for 10/16/20, so as a

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result, R1's ordered Coumadin was stopped on 10/15/20, in accordance with Cassia's policy, to prevent duplication of doses. The INR was then drawn, as ordered, on 10/16/20, and the results were sent to the hospital provider along with being placed in the nursing home's "resident message" queue in the EMR system. RN-A and LPN-C verified R1's results were available to the nursing home despite being sent to the hospital provider; however, added follow-up on the laboratory results "got missed" and no further Coumadin dosing orders were written or provided as "nobody addressed it" as the results were received on the afternoon of 10/16/20, and left in the queue until the HUC returned after the weekend. The HUC then saw the results and thought they had already been acted upon, so they moved them from the queue to R1's formal EMR, despite them never being sent to the provider for dosing orders. LPN-C voiced the error was "kind of a fluke" she felt; however, they had reached out to the medical director who was working with IT (information technology) to resolve any issues on the hospital's end which could have contributed to the wrong provider being notified of the laboratory results. They felt several factors, including any potential IT issues with the hospital system, contributed to missed laboratory results including an ongoing rotation of pool nurses who likely would not have known to check various places for the laboratory results, and several of the team leads were "extremely new." LPN-C and RN-A both voiced the lack of laboratory result monitoring and subsequent error was "absolutely" avoidable if someone would have checked the EMR system timely and added, "We own it." LPN-C explained they learned of the error after R1 had been hospitalized for the stroke as the hospital had sent some paperwork which

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indicated R1's Coumadin had been "discontinued for unknown reason" so they immediately investigated and identified the error. This resulted in immediate action to audit other residents and then to fix the issues which they felt contributed to it. This included revision of the process for INR monitoring by having the HUC staff members print out hard copies of each INR and provide them directly to the team lead(s) for action and follow-up. They also began immediate education on this process to the direct care staff which continued to this day on a shift-to-shift basis until everyone was educated. LPN-C voiced the whole incident and ultimate death of R1 was a "sad situation all the way around" and expressed it was important to ensure completed laboratory monitoring results are addressed and acted upon as "labs are ordered for a reason" and INR monitoring was needed to ensure anticoagulation medications are working properly and to reduce the risk of blood clots which could lead to a stroke "and death" as a result.

When interviewed on 11/4/20, at 2:08 p.m. nurse practitioner (NP)-A verified R1 had admitted to the nursing home for rehabilitation and was planning to return to her assisted living upon discharge. NP-A explained she was normally the person who managed residents' INR results, and subsequent dosing orders, and proceeded to recall R1's incident. R1 was to have an ordered INR drawn and completed on 10/16/20, but "for whatever reason" the results did not get sent to her inbox to be addressed which caused no further dosing orders to be written. This lead to "about a week later" when R11 was then hospitalized for a stroke. NP-A verified R1's Coumadin was never intentionally discontinued at the nursing home as R1 was considered "high

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risk" for stroke given her cardiac issues and history of previous stroke. NP-A and the nursing home first learned of the missed laboratory results and subsequent Coumadin dosing when they received paperwork from the hospital prior to her return which directed R1's Coumadin had been discontinued for some "unknown reason" which lead them to investigate. NP-A voiced a series of events may have contributed to the lack of laboratory result monitoring, including the lack of provider presence within the facility for the past weeks due to the COVID-19 pandemic restrictions and R1 being a new patient to the nursing home. However, NP-A acknowledged the nursing home and herself were responsible to ensure all laboratory monitoring gets acted upon and addressed, and expressed if the nursing home had contacted her about the results with no subsequent orders she "would have addressed it." NP-A continued and voiced her "heart just dropped" when she learned the Coumadin was never re-dosed and ordered for R1 after the 10/16/20 INR results were posted. NP-A reiterated R1 was "at very high risk" for subsequent stroke given her medical history and the lack of Coumadin, while possibly not preventing a stroke in it's entirety, likely contributed to the severity of the stroke and R1's subsequent death given "how long she went without it." Further, NP-A voiced since the incident happened, the nursing home had taken quick action to identify and correct contributing issues including revising their laboratory monitoring process and having the medical director work with Fairview and IT to get a better notification system implemented when laboratory results get posted.

On 11/4/20, at 2:52 p.m. the director of nursing

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(DON) and administrator were interviewed. The DON verified the incident happened as outlined by RN-A and LPN-C and expressed the drawn INR results had been sent to the wrong provider, in addition to the nursing home, which resulted in them not being acted upon or addressed and caused no further Coumadin orders to be written for R1 after 10/16/20. The DON stated the facility learned of the missed results, and subsequent lack of Coumadin dosing, when the hospital sent back information for R1's re-admission to the nursing home which identified R1's Coumadin had been stopped for an unknown reason. They immediately started to investigate the situation and develop ways to prevent recurrence which included auditing other residents with current anticoagulation orders to ensure therapeutic dosing; working with Fairview IT to develop a separate "Elim Pool" for all laboratory results to be directed into from the laboratory; revising their in-house process to include printing out hard copies of INR order(s) to ensure they are witnessed and acted upon by the team lead(s). The DON voiced education on all these items had already began and remained in progress through verbal and electronic methods. Further, the DON expressed she did not feel the incident was avoidable "in this situation," however, added the entire situation, including R1's stroke and subsequent death, was "really unfortunate" and a "terrible circumstance."

A provided undated Verification of Investigation (VOI) outlined the facility's completed investigation into the incident involving R1 and the missed INR results. The detail listed outlined, "INR ordered on 10/16. INR drawn. [NP-A] did not write follow up orders to continue anticoagulation therapy. 10/25: [R1's] assessment showed signs

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of stroke. Verbal orders obtained to send resident to hospital ... confirmed to have CVA s/p [status post] tPA [thrombolytic therapy; used to breakdown blood clots] 10/25/20. Resident returning to Elim, from hospital 10/28/20." A series of interviews were listed which included HUC-A, RN-A, NP-A and the medical director and the incident was reviewed in detail. The conclusion outlined, "Cassia policy was reviewed and verified to be followed by Elim Staff. This was a misfortunate [sic] event that happened due to unforeseeable circumstances. Plan and processes put into place within hours to prevent similar events from happening again." These included, but were not limited to, a review of the Coumadin & INR policies; having team lead and medical record staff member(s) review the applicable policies; updating NP-A and R1's primary care physician on the incident; having INR results printed and provided directly to the team lead(s) for action and orders prior to being scanned back into the EMR; and, medical record staff members printing a EMR report of the whole facility' lab draws on given lab day(s) to ensure NP action and follow-up.

When interviewed on 11/5/20, at 9:45 a.m. the consulting pharmacist (CP)-A stated methods of INR monitoring, and subsequent dosing of Coumadin, vary "a little bit from facility to facility." CP-A explained the facility typically stopped the dosing just prior to an INR draw, and the results were then sent to the provider for subsequent dosing to be ordered; however, CP-A stated he was unaware "what their process was at that point" to ensure completed results were addressed and acted upon. CP-A voiced he was aware of the error and missed INR results for R1 and stated he did feel "some process

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improvements" came as a result of the error. CP-A explained, typically, after someone is off Coumadin a repeat INR is done within "a day or two" to help determine subsequent dosing needs. The "standard goal" of Coumadin therapy was to keep an INR "between two [2.00] and three [3.00]" to reduce the risk of clotting and stroke; and someone off Coumadin could fall below that therapeutic range within "four and seven days." CP-A voiced "anything under two [2.00]" would "increase the risk of clotting" in someone with atrial fibrillation.

A provided Cassia Coumadin and INR Procedure policy, reviewed 2/25/20, identified the "licensed nurse" was responsible for it's implementation. The policy directed several steps to ensure all Coumadin and INR order(s) were transcribed and followed which included:

- Residents taking Coumadin would have "Resident take Coumadin" placed in their administration notes on the electronic Medication Administration Record (eMAR);

- Residents would have an order for every evening which directed the nurse to ensure a current Coumadin order was in place;

- HUC or nurse to transcribe order into computer by deleting any Coumadin orders that are no longer current and adding the new order for Coumadin;

- Coumadin orders are scheduled to be administered on the evening shift;

- HUC or nurse will add INR to EMR lab order. INR will be entered as an AM order;

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F 757	Continued From page 18 - Nurse checking / verifying order will follow the above steps to assure their done; - Each change of shift, it will be the responsibility of each nurse to check that INRs have been obtained for the day; - Night shift runs the lab-due report which will indicate who is due for an INR; and, - When an INR has been obtained, physician has been contacted and new order has been obtained, the results will be documented in the INR order under the task in the EMR. The past non-compliance IJ which began on 10/16/20, was removed prior to the abbreviated survey due to multiple action(s) taken by the facility to correct the identified non-compliance. These actions included beginning a root cause analysis of the incident, auditing other residents currently taking anticoagulation medication to ensure therapeutic dosing and developing and implementing several stop-gap actions to reduce the risk of recurrence to R1 or others. A series of other residents with current orders for anticoagulation therapy were reviewed which identified these action(s) had been successfully implemented; and provided education roster(s) identified education to persons involved with laboratory monitoring at the nursing home had been conducted. As a result, the IJ was removed and non-compliance corrected as of 10/29/20.	F 757		

DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically delivered
November 28, 2020

Administrator
Elim Home
701 First Street
Princeton, MN 55371

Re: Event ID: 9LBG11

Dear Administrator:

The above facility survey was completed on November 5, 2020 for the purpose of assessing compliance with Minnesota Department of Health Nursing Home Rules. At the time of the survey, the survey team from the Minnesota Department of Health - Health Regulation Division noted no violations of these rules promulgated under Minnesota Stat. section 144.653 and/or Minnesota Stat. Section 144A.10.

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

Please feel free to call me with any questions.

Sincerely,

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

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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 11/4/20 to 11/5/20, an abbreviated survey was conducted to determine compliance of state licensure. Elim Home was found to be in compliance with the Minnesota (MN) state licensure. The following complaint was found to be	2 000		

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2 000	Continued From page 1 substantiated: H5494064C: however, no correction orders were issued due to actions implemented by the facility prior to the abbreviated survey. The facility is enrolled in ePOC and therefore a signature is not required at the bottom of the first page of state form. Although no plan of correction is required, it is required that the facility acknowledge receipt of the electronic documents.	2 000		