Electronically delivered
December 6, 2019

Administrator
Chris Jensen Health & Rehabilitation Center
2501 Rice Lake Road
Duluth, MN 55811

RE: CCN: 245366
Cycle Start Date: September 18, 2019

Dear Administrator:

On December 5, 2019, we informed you that the following enforcement remedy:

- Discretionary Denial of Payment for new Medicare and/or Medicaid Admissions, Federal regulations at 42 CFR § 488.417(a), effective December 7, 2019, will remain in effect.

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

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

On December 3, 2019, the Minnesota Department of Health completed a Post Certification Revisit to verify that your facility had achieved and maintained compliance with federal certification deficiencies. Based on our visit, we have determined that your facility has not obtained substantial compliance.

The most serious deficiencies in your facility were found to be isolated deficiencies that constitute no actual harm with potential for more than minimal harm that is not immediate jeopardy (Level D), as evidenced by the attached CMS-2567, whereby corrections are required.

As a result of the revisit findings:

- Discretionary Denial of Payment for new Medicare and/or Medicaid Admissions, Federal regulations at 42 CFR § 488.417(a), effective December 7, 2019, will remain in effect.

In addition, this Department continues to recommend to the CMS Region V Office the following actions:

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

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

As we notified you in our letter of December 4, 2019, 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 September 18, 2019.

ELECTRONIC PLAN OF CORRECTION (ePOC)

Within ten (10) calendar days after your receipt of this notice, you must submit an acceptable plan of correction (ePOC) for the deficiencies cited. An acceptable ePOC will serve as your allegation of compliance. Upon receipt of an acceptable ePOC, we will authorize a revisit to your facility to determine if substantial compliance has been achieved. The failure to submit an acceptable ePOC can lead to termination of your Medicare and Medicaid participation (42 CFR 488.456(b)).

To be acceptable, a provider's ePOC must include the following:

- How corrective action will be accomplished for those residents found to have been affected by the deficient practice.
- How the facility will identify other residents having the potential to be affected by the same deficient practice.
- What measures will be put into place, or systemic changes made, to ensure that the deficient practice will not recur.
- How the facility will monitor its corrective actions to ensure that the deficient practice is being corrected and will not recur.
- The date that each deficiency will be corrected.
- An electronic acknowledgement signature and date by an official facility representative.

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

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

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

DEPARTMENT CONTACT

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

Lyla Burkman, Unit Supervisor
Bemidji Survey Team
Licensing and Certification Program
Health Regulation Division
Minnesota Department of Health
705 5th Street Northwest, Suite A
Bemidji, Minnesota 56601-2933
Email: lyla.burkman@state.mn.us
Phone: (218) 308-2104
Fax: (218) 308-2122

PRESUMPTION OF COMPLIANCE - CREDIBLE ALLEGATION OF COMPLIANCE

The facility's ePoC will serve as your allegation of compliance upon the Department's acceptance. In order for your allegation of compliance to be acceptable to the Department, the ePoC must meet the criteria listed in the plan of correction section above. You will be notified by the Minnesota Department of Health, Licensing and Certification Program staff and/or the Department of Public Safety, State Fire Marshal Division staff, if your ePoC for their respective deficiencies (if any) is acceptable.

VERIFICATION OF SUBSTANTIAL COMPLIANCE

Upon receipt of an acceptable ePoC, a Post Certification Revisit (PCR), of your facility will be conducted to validate that substantial compliance with the regulations has been attained in accordance with your verification.

If substantial compliance has been achieved, certification of your facility in the Medicare and/or Medicaid program(s) will be continued and remedies will not be imposed. Compliance is certified as of the latest correction date on the approved ePoC, unless it is determined that either correction actually occurred between the latest correction date on the ePoC and the date of the first revisit, or correction occurred sooner than the latest correction date on the ePoC.

FAILURE TO ACHIEVE SUBSTANTIAL COMPLIANCE BY THE SIXTH MONTH AFTER THE LAST DAY OF THE SURVEY

We will also recommend to the CMS Region V Office and/or the Minnesota Department of Human Services that your provider agreement be terminated by March 18, 2020 (six months after the identification of noncompliance) if your facility does not achieve substantial compliance. This action is mandated by the Social Security Act at Sections 1819(h)(2)(C) and 1919(h)(3)(D) and Federal regulations at 42 CFR Sections 488.412 and 488.456.

Please note that this notice does not constitute formal notice of imposition of alternative remedies or termination of your provider agreement. Should the Centers for Medicare & Medicaid Services determine that termination or any other remedy is warranted, it will provide you with a separate formal notification of that determination.

APPEAL RIGHTS

If you disagree with this action imposed on your facility, you or your legal representative may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board (DAB). Procedures governing this process are set out in 42 C.F.R. 498.40, et seq. You must file your hearing request electronically by using the Departmental Appeals Board's Electronic Filing System (DAB E-File) at https://dab.efile.hhs.gov no later than sixty (60) days after receiving this letter. Specific instructions on how to file electronically are attached to this notice. A copy of the hearing request shall be submitted electronically to:

Tamika.Brown@cms.hhs.gov

Requests for a hearing submitted by U.S. mail or commercial carrier are no longer accepted as of October 1, 2014, unless you do not have access to a computer or internet service. In those circumstances you may call the Civil Remedies Division to request a waiver from e-filing and provide an explanation as to why you cannot file electronically or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than sixty (60) days after receiving this letter, by mailing to the following address:

Department of Health & Human Services
Departmental Appeals Board, MS 6132
Director, Civil Remedies Division
330 Independence Avenue, S.W.
Cohen Building – Room G-644
Washington, D.C. 20201
(202) 565-9462

A request for a hearing should identify the specific issues, findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. At an appeal hearing, you may be represented by counsel at your own expense. If you have any questions regarding this matter, please contact Tamika Brown, Principal Program Representative by phone at (312) 353-1502 or by e-mail at Tamika.Brown@cms.hhs.gov.

INFORMAL DISPUTE RESOLUTION (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,

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

cc: Licensing and Certification File

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	245366	A. BUILDING _____ B. WING _____	C 12/03/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHRIS JENSEN HEALTH & REHABILITATION CENTER	**2501 RICE LAKE ROAD DULUTH, MN 55811**

(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	F 000		

On 12/2/19 - 12/3/19, an abbreviated standard survey was completed at your facility to conduct a complaint investigation. Your facility was found not to be in compliance with 42 CFR Part 483, Requirements for Long Term Care Facilities.

The following complaints were found to be substantiated without deficiencies cited:

H5366105C
H5366106C
H5366109C
H5366111C
H5366112C
H5366113C
H5366114C
H5366115C
H5366116C

The following complaints were found to be unsubstantiated:

H5366104C
H5366107C
H5366108C
H5366110C

However, as a result of the investigation a deficiency was cited at F760.

The facility's plan of correction (POC) will serve as your allegation of compliance upon the Department's acceptance. Because you are enrolled in ePOC, your signature is not required at the bottom of the first page of the CMS-2567

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Electronically Signed		12/06/2019

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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F 000	Continued From page 1 form. Your electronic submission of the POC will be used as verification of compliance. Upon receipt of an acceptable electronic POC, an on-site revisit of your facility may be conducted to validate that substantial compliance with the regulations has been attained in accordance with your verification.	F 000		
F 760 SS=D	Residents are Free of Significant Med Errors CFR(s): 483.45(f)(2) The facility must ensure that its- §483.45(f)(2) Residents are free of any significant medication errors. This REQUIREMENT is not met as evidenced by: Based on observation, interview and document review, the facility failed to ensure insulin administration was completed without significant medication errors for 1 of 4 residents (R12) observed for insulin administration. Findings include: R12's quarterly Minimum Data Set (MDS) dated 10/15/19, identified R12 as displaying severe cognitive impairment and diagnoses including Alzheimer's dementia and diabetes mellitus. R12's Medication Review Report (physician's orders) dated 9/3/19, directed the staff to administer Lantus SoloStar solution 12 units every 12 hours. On 12/2/19, at 8:51 a.m. registered nurse (RN)-A was observed to prepare R12's lantus insulin. Upon review of the medication cart, RN-A was unable to locate R12's vial of Lantus insulin.	F 760	Submission of this Response and Plan of correction is not a legal admission that a deficiency exists or that this Statement of Deficiency was correctly cited and is also not to be construed as an admission of guilt by the facility, the Executive Director or any employees, agents or other individuals who draft or may be discussed in the response and Plan of correction. In addition, preparation and submission of the Plan of Correction does not constitute an admission or agreement of any kind by the facility of the truth of any facts alleged or the correctness of any conclusion set forth in the allegations. Accordingly, the Facility has prepared and submitted this Plan of Correction prior to the resolution of any appeal which may be filed solely because of the requirements under state and federal law that mandate submission of a Plan of Correction within ten (10) days of the survey as a condition to	12/7/19

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F 760	Continued From page 2 RN-A entered the medication room and returned with a vial of insulin he obtained from the emergency medication kit (E-Kit). The vial was half full, was not equipped with a manufacture seal, and had a hand written date of 12/2/19, on the side of the bottle indicating when the bottle had been opened. -At 9:00 a.m. RN-A drew up 12 units of insulin in a syringe and stated he was ready to administer the insulin. -At 9:02 a.m. when asked, RN-A confirmed the vial of insulin did not have a manufacture's seal on it when he removed it from the emergency kit and stated he had written the 12/2/19, date to the side of the vial moments prior when he had removed it from the E-Kit. RN-A stated he did not know when the manufacturer's seal had been removed from the vial and confirmed half of the medication had been previously removed indicating the insulin vial had previously been accessed/used. RN-A stated he was unable to identify when it had been opened and verified the insulin was only good for 28 days after opening. RN-A stated he would have to find a different vial of insulin to use for R12, and left the unit. -At 9:06 a.m. RN-A returned to the unit with a second vial of Lantus insulin from an adjoining nursing unit's E-Kit. The vial was dated 11/4/19. RN-A withdrew 12 units of insulin and walked to R12's room. Upon entering the room, the surveyor stopped RN-A and asked how long the insulin he was about to administer was good for before expiration. RN-A returned to the nurse's desk and checked the facility nursing medication book. RN-A confirmed the medication was good for 28 days and verified the vial had been opened	F 760	participate in Title 18 and Title 19 programs. This Plan of Correction is submitted as the facility's credible allegation of compliance. F760-Significant Medication Errors: R12's individual Lantus insulin pen was delivered from the pharmacy on 12/2/19 at 4pm. This insulin had been ordered prior, but delivery was delayed due to blizzard conditions in the area. R12's insulin was dated when opened and she is receiving her scheduled insulin doses as ordered. Other residents who have orders for insulin are receiving insulin from vials or pens that are not expired and are accurately dated when opened. All medication carts and insulin e-kits were checked on 12/6/19 to ensure that all opened vials or pens are properly dated when opened. The Insulin Storage Policy which was not requested during the survey, was reviewed and does contain direction regarding marking the date on insulin when it is open, and prior to drawing insulin to look at the date opened. Licensed nurses have been re-educated on facility expectation to write date opened on the label when they open a new vial or pen of insulin; and to look at the date the vial or pen was opened each time prior to drawing insulin.	

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F 760	Continued From page 3 for 29 days ago. -At 9:17 a.m. RN-A called the pharmacy and requested insulin to be delivered for R12. RN-A stated the medication would take about 45 minutes to arrive at the facility. -At 12:30 p.m. RN-A stated R12's physician had been contacted and notified R12 had not received the morning insulin. RN-A stated R12's physician had ordered the medication to be administered when it arrived at the facility. -At 3:50 p.m. the director of nurses (DON) stated whomever opened a new bottle of insulin by removing the manufacture seal, was to write a date on it indicating when it was opened. If the bottle did not have a manufacture seal, and did not have a date on it, the medication was not to be used. -At 4:15 p.m. RN-A confirmed the manufacturer's seal was missing from the first vial of insulin, and that he had written the 12/2/19, date on the bottle when he removed the opened vial from the E-kit, but did not know when it had originally been opened. The Sanofi-Aventis U.S. LLC (Lantus manufacture) package insert dated 7/2015, indicated Lantus vials are to be thrown away after 28 days. The Insulin Administration policy dated 4/1/08, directed the staff how to administer insulin, however it did not direct the staff as to how to properly date the bottle when it was opened. The policy did not address when insulin would be expired.	F 760	Insulin Administration Observational Audits will be conducted 3 x week for 4 weeks, then will be reviewed by QAPI for recommendation and further direction. These audits will include observing the nurse checking for date opened, and if open and undated - insulin is discarded; and observing the nurse when opening a new vial or pen that the date is recorded as the open date. Audits of the med carts and the Insulin e-kits will be conducted weekly for 4 weeks to monitor for compliance. The results of these audits will be reviewed by QAPI for recommendation and further direction.	

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DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically delivered
December 6, 2019

Administrator
Chris Jensen Health & Rehabilitation Center
2501 Rice Lake Road
Duluth, MN 55811

Re: State Nursing Home Licensing Orders
Event ID: TLW411

Dear Administrator:

The above facility was surveyed on December 2, 2019 through December 3, 2019 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:

Lyla Burkman, Unit Supervisor
Bemidji Survey Team
Licensing and Certification Program
Health Regulation Division
Minnesota Department of Health
705 5th Street Northwest, Suite A
Bemidji, Minnesota 56601-2933
Email: lyla.burkman@state.mn.us
Phone: (218) 308-2104
Fax: (218) 308-2122

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

Please feel free to call me with any questions.

Sincerely,

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

cc: Licensing and Certification File

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	00598	A. BUILDING: _____ B. WING _____	C 12/03/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHRIS JENSEN HEALTH & REHABILITATION C	2501 RICE LAKE ROAD DULUTH, MN 55811

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2 000	Initial Comments *****ATTENTION****** NH LICENSING CORRECTION ORDER In accordance with Minnesota Statute, section 144A.10, this correction order has been issued pursuant to a survey. If, upon reinspection, it is found that the deficiency or deficiencies cited herein are not corrected, a fine for each violation not corrected shall be assessed in accordance with a schedule of fines promulgated by rule of the Minnesota Department of Health. Determination of whether a violation has been corrected requires compliance with all requirements of the rule provided at the tag number and MN Rule number indicated below. When a rule contains several items, failure to comply with any of the items will be considered lack of compliance. Lack of compliance upon re-inspection with any item of multi-part rule will result in the assessment of a fine even if the item that was violated during the initial inspection was corrected. You may request a hearing on any assessments that may result from non-compliance with these orders provided that a written request is made to the Department within 15 days of receipt of a notice of assessment for non-compliance. INITIAL COMMENTS: On 12/2/19 - 12/3/19, an abbreviated survey was conducted to determine compliance of state licensure. Your facility was found not to be in compliance with the MN state licensure. The following complaints were found to be	2 000	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.	

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2 000	Continued From page 1 substantiated without licensing orders issued: H5366105C H5366106C H5366109C H5366111C H5366112C H5366113C H5366114C H5366115C H5366116C The following complaints were found to be unsubstantiated: H5366104C H5366107C H5366108C H5366110C However, as a result of the investigation a licensing order was cited at 4658.1320 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	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 which are in violation of the state statute after the statement, "This Rule 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.	
21545	MN Rule 4658.1320 A.B.C Medication Errors A nursing home must ensure that: A. Its medication error rate is less than five percent as described in the Interpretive Guidelines for Code of Federal Regulations, title 42, section 483.25 (m), found in Appendix P of the State Operations Manual, Guidance to	21545		12/7/19

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	00598	A. BUILDING: _____ B. WING _____	C 12/03/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHRIS JENSEN HEALTH & REHABILITATION C	2501 RICE LAKE ROAD DULUTH, MN 55811

(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) COMPLETE DATE
21545	Continued From page 2	21545		

Surveyors for Long-Term Care Facilities, which is incorporated by reference in part 4658.1315. For purposes of this part, a medication error means:

(1) a discrepancy between what was prescribed and what medications are actually administered to residents in the nursing home; or

(2) the administration of expired medications.

B. It is free of any significant medication error. A significant medication error is:

(1) an error which causes the resident discomfort or jeopardizes the resident's health or safety; or

(2) medication from a category that usually requires the medication in the resident's blood to be titrated to a specific blood level and a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. All medications are administered as prescribed. An incident report or medication error report must be filed for any medication error that occurs. Any significant medication errors or resident reactions must be reported to the physician or the physician's designee and the resident or the resident's legal guardian or designated representative and an explanation must be made in the resident's clinical record.

C. All medications are administered as prescribed. An incident report or medication error report must be filed for any medication error that occurs. Any significant medication errors or resident reactions must be reported to the physician or the physician's designee and the resident or the resident's legal guardian or designated representative and an explanation must be made in the resident's clinical record.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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21545	Continued From page 3 This MN Requirement is not met as evidenced by: Based on observation, interview and document review, the facility failed to ensure insulin administration was completed without significant medication errors for 1 of 4 residents (R12) observed for insulin administration. Findings include: R12's quarterly Minimum Data Set (MDS) dated 10/15/19, identified R12 as displaying severe cognitive impairment and diagnoses including Alzheimer's dementia and diabetes mellitus. R12's Medication Review Report (physician's orders) dated 9/3/19, directed the staff to administer Lantus SoloStar solution 12 units every 12 hours. On 12/2/19, at 8:51 a.m. registered nurse (RN)-A was observed to prepare R12's lantus insulin. Upon review of the medication cart, RN-A was unable to locate R12's vial of Lantus insulin. RN-A entered the medication room and returned with a vial of insulin he obtained from the emergency medication kit (E-Kit). The vial was half full, was not equipped with a manufacture seal, and had a hand written date of 12/2/19, on the side of the bottle indicating when the bottle had been opened. -At 9:00 a.m. RN-A drew up 12 units of insulin in a syringe and stated he was ready to administer the insulin. -At 9:02 a.m. when asked, RN-A confirmed the vial of insulin did not have a manufacture's seal on it when he removed it from the emergency kit and stated he had written the 12/2/19, date to the	21545	corrected	

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21545	Continued From page 4	21545		

side of the vial moments prior when he had removed it from the E-Kit. RN-A stated he did not know when the manufacturer's seal had been removed from the vial and confirmed half of the medication had been previously removed indicating the insulin vial had previously been accessed/used. RN-A stated he was unable to identify when it had been opened and verified the insulin was only good for 28 days after opening. RN-A stated he would have to find a different vial of insulin to use for R12, and left the unit.

-At 9:06 a.m. RN-A returned to the unit with a second vial of Lantus insulin from an adjoining nursing unit's E-Kit. The vial was dated 11/4/19. RN-A withdrew 12 units of insulin and walked to R12's room. Upon entering the room, the surveyor stopped RN-A and asked how long the insulin he was about to administer was good for before expiration. RN-A returned to the nurse's desk and checked the facility nursing medication book. RN-A confirmed the medication was good for 28 days and verified the vial had been opened for 29 days ago.

-At 9:17 a.m. RN-A called the pharmacy and requested insulin to be delivered for R12. RN-A stated the medication would take about 45 minutes to arrive at the facility.

-At 12:30 p.m. RN-A stated R12's physician had been contacted and notified R12 had not received the morning insulin. RN-A stated R12's physician had ordered the medication to be administered when it arrived at the facility.

-At 3:50 p.m. the director of nurses (DON) stated whomever opened a new bottle of insulin by removing the manufacture seal, was to write a date on it indicating when it was opened. If the

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21545	Continued From page 5 bottle did not have a manufacture seal, and did not have a date on it, the medication was not to be used. -At 4:15 p.m. RN-A confirmed the manufacturer's seal was missing from the first vial of insulin, and that he had written the 12/2/19, date on the bottle when he removed the opened vial from the E-kit, but did not know when it had originally been opened. The Sanofi-Aventis U.S. LLC (Lantus manufacture) package insert dated 7/2015, indicated Lantus vials are to be thrown away after 28 days. The Insulin Administration policy dated 4/1/08, directed the staff how to administer insulin, however it did not direct the staff as to how to properly date the bottle when it was opened. The policy did not address when insulin would be expired. SUGGESTED METHOD OF CORRECTION: The administrator, director of nursing (DON) and consulting pharmacist could review and revise policies and procedures for insulin administration. Nursing staff could be educated as necessary to the importance of properly administrating medications. The DON or designee, along with the pharmacist, could conduct audits on a regular basis to ensure compliance. TIME PERIOD FOR CORRECTION: Twenty one (21) days.	21545		