Protecting, Maintaining and Improving the Health of All Minnesotans

NOTICE OF REMOVAL OF CONDITIONAL LICENSE

Electronically Delivered

December 17, 2024

Licensee
Comprehensive and Compassionate Care LLC
5298 Sundial Lane
Woodbury, MN 55129

RE: License Number 413541
Health Facility Identification Number (HFID) 39951
Project Number(s) SL39951016

Dear Licensee:

On December 6, 2024, The Minnesota Department of Health (MDH) completed a follow-up survey of your agency to determine correction of orders found on the survey completed August 21, 2024. The follow-up survey found the facility to be in substantial compliance. **Based on these findings, the condition(s) on the license were removed effective December 17, 2024.**

Effective December 12, 2024, MDH is granting your Comprehensive Home Care home care license. Your license effective and expiration dates remain the same as on your provisional license. Your license number is 413541. You will not receive a replacement license certificate until your license is due to renew. If you have not received a letter from us with information regarding renewing your license within 45-days prior to your expiration date, please contact us at (651) 201-5273 or by email at: Health.homecare@state.mn.us.

You are encouraged to retain this document for your records. It is your responsibility to share the information contained in the letter and/or state form with your organization's Governing Body.

If you have any questions, please contact Renee L. Anderson directly at: 651-201-5871.

Sincerely,

Rick Michals

Rick Michals, J.D.
Executive Regional Operations Manager

Minnesota Department of Health
Health Regulation Division

HHH

DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

NOTICE OF TEMPORARY EXTENSION AND CONDITIONAL LICENSE

Electronically Delivered

November 4, 2024

Licensee
Comprehensive and Compassionate Care LLC
5298 Sundial Lane
Woodbury, MN 55129

RE: Temporary Conditional License Number 413541
Health Facility Identification Number (HFID) 39951
Project Number(s) SL39951016

Dear Licensee:

The Minnesota Department of Health (MDH) completed a survey on August 21, 2024, for the purpose of assessing compliance with state licensing statutes. Based on the survey results you were found not to be in substantial compliance with the laws pursuant to Minnesota Statutes, Chapter 144A.

As a result, pursuant to Minn. Stat. § 144A.473, Subd. 3(a), MDH is issuing a 90-day conditional temporary license due to expire on **February 2, 2025**.

STATE CORRECTION ORDERS
The enclosed State Form documents the state correction orders. The Department of Health documents state correction orders using federal software. Tag numbers are assigned to Minnesota state statutes for Home Care Providers. The assigned tag number appears in the far left column entitled "ID Prefix Tag." The state statute number and the corresponding text of the state statute out of compliance are listed in the "Summary Statement of Deficiencies" column. This column also includes the findings that are in violation of the state statute after the statement, "This MN Requirement is not met as evidenced by . . ."

IMPOSITION OF FINES
In accordance with Minn. Stat. § 144A.474, Subd. 11(a), fines and enforcement actions may be imposed based on the level and scope of the violations and may be imposed immediately with no opportunity to correct the violation first as follows:

Level 1: no fines or enforcement.
Level 2: a fine of $500 per violation, in addition to any enforcement mechanism authorized in § 144A.475 for widespread violations;
Level 3: a fine of $3,000 per violation per incident, in addition to any enforcement mechanism authorized in § 144A.475.
Level 4: a fine of $5,000 per incident, in addition to any enforcement mechanism authorized in

§ 144A.475.

In accordance with Minn. Stat. § 144A.474, Subd. 11(a)(5), MDH may impose fine amounts of either $1,000 or $5,000 to temporary licensees who are found to be responsible for maltreatment. MDH may impose a fine of $1,000 for each substantiated maltreatment violation that consists of abuse, neglect, or financial exploitation according to Minn. Stat. § 626.5572. Subd. 2, 9, 17. MDH also may impose a fine of $5,000 for each substantiated maltreatment violation consisting of sexual assault, death, or abuse resulting in serious injury.

In accordance with Minn. Stat. § 144A.474, Subd. 11(a)(6), when a fine is assessed against a agency for substantiated maltreatment, the commissioner shall not also impose an immediate fine under this chapter for the same circumstance.

MDH may assess fines based on the level and scope of the orders outlined below. The total amount of **potential** fines that may be assessed related to these correction orders is $3,000.00. **MDH is not imposing these fines against your license at this time.**

St - 0 - 0715 - 144a.476, Subd. 2 - Employees, Contractors, And Volunteers - $3,000.00

DOCUMENTATION OF ACTION TO COMPLY
Per Minn. Stat. § 144A.474, Subd. 8(c), the licensee must document actions taken to comply with the correction orders and immediately correct any reissued orders outlined on the state form; however, plans of correction are not required to be submitted for approval. **If corrections are not made, MDH may impose fines as described above and in accordance with Minnesota Statutes Chapter 144A.**

The correction order documentation should include the following:

- Identify how the area(s) of noncompliance was corrected related to the client(s)/employee(s) identified in the correction order.
- Identify how the area(s) of noncompliance was corrected for all of the provider's client(s)/employees that may be affected by the noncompliance.
- Identify what changes to your systems and practices were made to ensure compliance with the specific statute(s).

CORRECTION ORDER RECONSIDERATION PROCESS
In accordance with Minn. Stat. § 144A.474, Subd. 12, you may challenge the correction order issued, including the level and scope, and any fine assessed through the correction order reconsideration process. The request for reconsideration must be in writing and received by the Department of Health within 15 business days of the correction order receipt date.

A state correction order under Minn. Stat. § 144A.44 Subd. 1(14), Free from Maltreatment is associated with a maltreatment determination by the Office of Health Facility Complaints. If maltreatment is substantiated, you will receive a separate letter with the reconsideration process under Minn. Stat. § 626.557.

To submit a reconsideration request, please visit:
https://forms.web.health.state.mn.us/form/HRDAppealsForm

REQUESTING A HEARING
Alternatively, in accordance with Minn. Stat. § 144A.474, Subd. 11 (g), a home care provider that has been assessed a fine under this subdivision has a right to a reconsideration or a hearing under this section and chapter 14. Pursuant to Minn. Stat. § 144A.475, subd 4 and Subd. 7, a request for a hearing must be in writing and received by MDH within 15 calendar days of the correction order receipt date. The request must contain a brief and plain statement describing each matter or issue contested and any new information you believe constitutes a defense or mitigating factor. To submit a hearing request, please visit **https://forms.web.health.state.mn.us/form/HRDAppealsForm**.

To appeal fines via reconsideration, please follow the procedure outlined above. Please note that you may request a reconsideration **or** a hearing, but not both. If you wish to contest tags without fines in a reconsideration and tags with the fines at a hearing, please submit two separate appeals forms at the website listed above.

CONDITIONAL LICENSE ISSUED:
MDH will issue Comprehensive and Compassionate Care LLC a conditional temporary comprehensive home care license for 90 calendar days from the date of this notice. At an unannounced point in time, within the 90 calendar days, MDH will conduct a follow-up survey, as defined in Minn. Stat. § 144A.474, Subd. 2(e). Based on the results of the follow-up survey, MDH will determine if Comprehensive and Compassionate Care LLC is in substantial compliance.

The following conditions apply on the conditional temporary comprehensive license:

a. **Employees, contractors and volunteers:** Comprehensive and Compassionate Care LLC will ensure that Supervision Status Study subjects are under continuous, direct supervision until the study subject is determine eligible, or until the Comprehensive and Compassionate Care LLC is notified by the Department of Human Services (DHS) that the study subject may provide unsupervised services while the background study is being completed.

   i. **Continuous direct supervision definition**: Comprehensive and Compassionate Care LLC will ensure any Supervision Status Study subject is withing sight of or hearing of the agency's supervising individual to the extent that the agency's supervising individual is capable at all times in intervening to protect the health and safely of the persons served by the agency.

   ii. **Direct Contact Services includes:**
      1. Providing face to face care
      2. Training
      3. Supervision
      4. Counseling

5. Consultation
6. Medication assistance

RESULTS OF FOLLOW-UP EVALUATION DURING THE CONDITIONAL TEMPORARY LICENSE PERIOD:
MDH will determine if Comprehensive and Compassionate Care LLC is in substantial compliance based on the results of the follow up survey. MDH will make this determination within the 90-day conditional license period. If MDH determines Comprehensive and Compassionate Care LLC is in substantial compliance on the follow up survey, MDH will remove the conditions from Comprehensive and Compassionate Care LLC ’s temporary comprehensive home care license, and Comprehensive and Compassionate Care LLC will correct violations identified during the survey to come into substantial compliance. If MDH determines Comprehensive and Compassionate Care LLC is not in substantial compliance, MDH may take additional enforcement action against Comprehensive and Compassionate Care LLC, including placement of additional conditions, issuing an extension to the conditional license, or employ any of the enforcement tools listed in Minn. Stat. § 144A.475 up to and including immediate temporary suspension and revocation.

You are encouraged to retain this document for your records. It is your responsibility to share the information contained in the letter and/or state form with your organization’s Governing Body.

If you have any questions, please contact Renee Anderson directly at: 651-201-5871.

Sincerely,

Rick Michals, J.D.
Interim Assistant Division Director

Minnesota Department of Health
Health Regulation Division

HHH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	H39951	A. BUILDING: _____ B. WING _____	08/21/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE AND COMPASSIONATE CAI	5298 SUNDIAL LANE WOODBURY, MN 55129

(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
0 000	Initial Comments ******ATTENTION****** HOME CARE PROVIDER LICENSING CORRECTION ORDER In accordance with Minnesota Statutes, section 144A.43 to 144A.482, this correction order(s) has been issued pursuant to a survey. Determination of whether a violation has been corrected requires compliance with all requirements provided at the Statute number indicated below. When Minnesota Statute contains several items, failure to comply with any of the items will be considered lack of compliance. INITIAL COMMENTS: SL39951016-0 On August 19, 2024 through August 21, 2024, surveyors of this Department's staff, visited this provider and the following correction orders are issued. At the time of the survey, there was one (1) client receiving services under the Comprehensive license. 0715: An immediate correction was issued on August 20, 2024, at a level 3/widespread (I). The immediacy was lifted prior to survey exit; however, the deficiency remains at a level 3/widespread.	0 000	Minnesota Department of Health is documenting the State Licensing Correction Orders using federal software. Tag numbers have been assigned to Minnesota State Statutes for Home Care providers. The assigned tag number appears in the far-left column entitled "ID Prefix Tag." The state Statute number and the corresponding text of the state Statute out of compliance is listed in the "Summary Statement of Deficiencies" column. This column also includes the findings which are in violation of the state requirement after the statement, "This Minnesota requirement is not met as evidenced by." Following the surveyor's findings is 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. The letter in the left column is used for tracking purposes and reflects the scope and level issued pursuant to 144A.474 subd. 11 (b) (1) (2)	
0 715 SS=I	144A.476, Subd. 2 Employees, Contractors, and Volunteers (a) Employees, contractors, and volunteers of a	0 715		

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0 715	Continued From page 1 home care provider are subject to the background study required by section 144.057, and may be disqualified under chapter 245C. Nothing in this section shall be construed to prohibit a home care provider from requiring self-disclosure of criminal conviction information. (b) Termination of an employee in good faith reliance on information or records obtained under paragraph (a) or subdivision 1, regarding a confirmed conviction does not subject the home care provider to civil liability or liability for unemployment benefits. This MN Requirement is not met as evidenced by: Based on interview and record review, the licensee failed to obtain a cleared Minnesota Department of Human Services (DHS) background study clearance prior to providing services for one of four employees (unlicensed personnel (ULP)-C). This resulted in an immediate correction order issued on August 20, 2024. This practice resulted in a level three violation (a violation that harmed a client's health or safety, not including serious injury, impairment, or death, or a violation that has the potential to lead to serious injury, impairment, or death), and was issued at a widespread scope (when problems are pervasive or represent a systemic failure that has affected or has potential to affect a large portion or all of the clients). The findings include: ULP-C was hired on August 8, 2024, to provide direct home care services to clients. C1's record contained documentation that ULP-C	0 715		

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0 715	Continued From page 2 assisted C1 with showering and dressing on August 17, 2024. ULP-C's employee record did not contain evidence of a cleared background study on the DHS Net Study 2.0 Roster. On August 20, 2024, at 12:00 p.m., Owner/Director (O/D)-A stated that he had completed his own background study through Net Study 2.0, but had only checked Bureau of Criminal Apprehension results for all other employees. On August 20, 2024, at 12:48 p.m., the Net Study 2.0 roster was reviewed and confirmed ULP-C was not listed on the Net Study 2.0 roster for this provider. The licensee's undated Background Checks policy indicated employees will not have direct contact until the provider has obtained the results of the criminal history record information and verified employability. Supervision defined in NETStudy 2.0 System User Manual Updated July 7, 2023, page 53: Supervision Status Study subjects must be under continuous, direct supervision until the study subject is determined eligible of until the entity is notified by DHS that the study subject may provide unsupervised services while the background study is being completed. The supervision status is shown in the "Supervision Required" column for convenience. However, programs are instructed to rely on background study notices for supervision status and other background study determination information. Continuous Direct Supervision defined in	0 715		

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0 715	Continued From page 3 NETStudy 2.0 System User Manual Updated July 7, 2023, page 7: Continuous, Direct Supervision - An individual is within sight or hearing of the program's supervising individual to the extent that the program's supervising individual is capable at all times of intervening to protect the health and safety of the persons served by the program. Direct Contact Services - Providing face-to-face care, training, supervision, counseling, consultation, or medication assistance to persons served by the entity. No further information was provided. TIME PERIOD FOR CORRECTION: Immediate Immediacy was removed as confirmed by supervisor review on August 21, 2024, however, noncompliance remains at a scope and level of three, widespread (I).	0 715		
0 815 SS=D	144A.479, Subd. 7 Employee Records The home care provider must maintain current records of each paid employee, regularly scheduled volunteers providing home care services, and of each individual contractor providing home care services. The records must include the following information: (1) evidence of current professional licensure, registration, or certification, if licensure, registration, or certification is required by this statute or other rules; (2) records of orientation, required annual training and infection control training, and competency evaluations; (3) current job description, including qualifications, responsibilities, and identification of staff providing supervision;	0 815		

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0 815	Continued From page 4 (4) documentation of annual performance reviews which identify areas of improvement needed and training needs; (5) for individuals providing home care services, verification that any health screenings required by infection control programs established under section 144A.4798 have taken place and the dates of those screenings; and (6) documentation of the background study as required under section 144.057. Each employee record must be retained for at least three years after a paid employee, home care volunteer, or contractor ceases to be employed by or under contract with the home care provider. If a home care provider ceases operation, employee records must be maintained for three years. This MN Requirement is not met as evidenced by: Based on interview and record review, the licensee failed to ensure the employee record included the required content, including records of competency evaluations and a job description, for one of four employees (unlicensed personnel (ULP)-C). This practice resulted in a level two violation (a violation that did not harm a client's health or safety but had the potential to have harmed a client's health or safety, but was not likely to cause serious injury, impairment, or death), and was issued at a widespread scope (when problems are pervasive or represent a systemic failure that has affected or has potential to affect a large portion or all of the clients). The findings include: The findings include:	0 815		

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0 815	Continued From page 5 ULP-C was hired on August 8, 2024 to provide direct home care services to the licensee's client. ULP-C's employee record lacked documented evidence of competency evaluations and a current job description, including qualifications, responsibilities, and identification of staff providing supervision. On August 21, 2024, at 3:20 p.m., Owner/Director (O/D)-A verified ULP-C's personnel file lacked documentation of competency evaluations and a current job description. O/D-A stated that he believed ULP-C had completed all the required competency evaluations, but those evaluations were not specifically documented and retained. O/D-A also stated that he thought he gave ULP-C a job description, but he could not locate it. The licensee's undated Evaluation Process policy indicated competency evaluations must be performed by a registered nurse and the competency evaluations kept in the employees personnel file. The licensee's undated Personnel Job Descriptions policy indicated the licensee will establish job descriptions for each job classification, and the employee will sign the job description upon hire. No further information was provided. TIME PERIOD FOR CORRECTION: Twenty-one (21) days	0 815		
01245 SS=F	144A.4798, Subd. 1 TB Infection Control (a) A home care provider must establish and	01245		

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01245	Continued From page 6 maintain a comprehensive tuberculosis infection control program according to the most current tuberculosis infection control guidelines issued by the United States Centers for Disease Control and Prevention (CDC), Division of Tuberculosis Elimination, as published in the CDC's Morbidity and Mortality Weekly Report. This program must include a tuberculosis infection control plan that covers all paid and unpaid employees, contractors, students, and volunteers. The commissioner shall provide technical assistance regarding implementation of the guidelines. (b) The home care provider must maintain written evidence of compliance with this subdivision. This MN Requirement is not met as evidenced by: Based on interview and record review, the licensee failed to establish and maintain a tuberculosis (TB) prevention and control program based on the most current guidelines issued by the centers for Disease Control and Prevention (CDC) to include completion of a facility risk assessment. and employee screening with a two-step tuberculin skin test (TST) or single TB blood test for two of four employees (registered nurse (RN)-B, unlicensed personnel (ULP)-C). This practice resulted in a level two violation (a violation that did not harm a client's health or safety but had the potential to have harmed a client's health or safety, but was not likely to cause serious injury, impairment, or death), and was issued at a widespread scope (when problems are pervasive or represent a systemic failure that has affected or has potential to affect a large portion or all of the clients). The findings include:	01245		

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01245	Continued From page 7 During the entrance conference, on August 19, 2024, at 3:30 p.m., the surveyor requested the licensee's TB facility risk assessment. Owner/Director (O/D)-A stated that he did not have this assessment and he was not aware of the TB facility risk assessment requirement. RN-B was hired August 8, 2024, and provided direct cares and services to licensee's clients. RN-B's employee record record lacked evidence of TB history and symptom screen. RN-B's record included documentation of a QuantiFERON-TB Gold Plus blood test completed August 29, 2023, that identified a negative result. RN-B's baseline QuantiFERON-TB Gold Plus blood test was completed greater than 90 days before hire. ULP-C was hired August 8, 2024, and provided direct cares and services to licensee's clients. ULP-C's employee record lacked evidence of TB history and symptom screen, and and a two-step TST or single TB blood test. On August 21, 2024, at 3:20 p.m., O/D-A stated he thought that ULP-C and RN-B had completed TB history, symptom screens, and QuantiFERON-TB Gold Plus blood tests, but he could not locate all the documents. O/D-A also stated that he was not aware of requirement for employee baseline TB testing to be completed within 90 days before hire. The Minnesota Department of Health (MDH) guidelines, Regulations for Tuberculosis Control in Minnesota Health Care Settings, dated July 2013, and based on CDC guidelines, indicated a TB infection control program should include a facility TB risk assessment. The guidelines also	01245		

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01245	Continued From page 8 indicated an employee may begin working with patients after a negative TB history and symptom screen (no symptoms of active TB disease) and a negative IGRA (serum blood test) or TST (first step) dated within 90 days before hire. The second TST may be performed after the HCW (health care worker) starts working with patients. Baseline TB screening should be documented in the employee's record. The licensee's Tuberculosis Exposure Control Plan, dated June 2024, indicated an initial TB risk assessment be completed annually and baseline TB screening would be required for all employees. No further information was provided. TIME PERIOD FOR CORRECTION: Twenty-one (21) days	01245		