Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically Delivered Via Email

June 8, 2023

Administrator
ADARA HOME HEALTH INC
25 1ST AVENUE NE STE 100
BUFFALO, MN 55313

RE: Event ID: 5F546-H1

Dear Administrator:

On March 23, 2023, the Minnesota Department of Health completed a revisit to verify that your facility had achieved and maintained compliance. Based on our visit, we have determined that your facility has achieved substantial compliance with federal regulations and state licensing statutes.

Feel free to contact me with any questions related to this letter.

Sincerely,

Joanne Simon, Compliance Analyst
Minnesota Department of Health
Health Regulation Division
Telephone: 651-201-4161
Email: joanne.simon@state.mn.us

cc: Licensing and Certification File

DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically Delivered Via Email

April 12, 2023

Administrator
ADARA HOME HEALTH INC
25 1ST AVENUE NE STE 100
BUFFALO, MN 55313

RE: Event ID: 5F546-H1

Dear Administrator:
An extended survey was completed at your agency on March 23, 2023 for the purpose of assessing compliance with Federal certification regulations. At the time of survey, the survey team from the Minnesota Department of Health, Health Regulation Division noted one or more deficiencies and found that your agency was not in substantial compliance with the participation requirements. The findings from this survey are documented on the electronically delivered form CMS 2567.

At the time of this survey, it was determined that the following Condition(s) of Participation were found not met:

G 406 42CFR 484.50 Patient Rights
G 510 42CFR 484.55 Comprehensive Assessment of Patients

Since these deficiencies limit your capacity to provide adequate care to patients, you must respond within ten calendar (10) days with your plan of correction. The plan must be specific, realistic, include the date certain for correction of each deficiency and be signed and dated by the administrator or other authorized official of the agency. An acceptable plan of correction must contain the following elements:

The plan of correcting the specific deficiency. The plan should address the processes that led to
the deficiency cited;

- The procedure for implementing the acceptable plan of correction for the specific deficiency cited;

- What correction action(s) will be accomplished for those patients found to have been affected by the deficient practice;
- How you will identify other patients having the potential to be affected by the same deficient practice and what corrective action will be taken;
- What measures will be put into place or what systemic changes you will make to ensure that the deficient practice does not recur;
- The monitoring procedure to ensure that the plan of correction is effective and that the specific deficiency cited remains corrected and/or in compliance with the regulatory requirements, i.e., what quality assurance program will be put into place;
- The title of the person responsible for implementing the acceptable plan of correction; and,
- The date by which the correction will be completed.

If your agency has failed to achieve compliance by the date certain, sanctions including but not limited to fines of up to $10,000.00 per day, may be recommended for imposition to the Centers for Medicare and Medicaid Services (CMS) Regional Office. Informal dispute resolution (IDR) for the cited deficiencies will not delay imposition of any recommended enforcement actions. A change in the seriousness of the noncompliance at the time of the revisit may result in a change in the remedy selected. When this occurs, you will be advised of any change in remedy.

The plan of correction should be directed to:

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

Failure to submit an acceptable written plan of correction of Federal deficiencies within ten calendar days of your receipt of this notice may result in imposition of sanctions, decertification and/or a loss of Federal reimbursement. Additionally, your continued certification is contingent upon corrective action. If, upon a revisit within forty-five (45) days of the survey exit date, correction is not ascertained, we will have no recourse except to recommend to the Centers for Medicare and Medicaid Services Chicago Region V Office that sanctions be imposed.

HOME HEALTH AIDE TRAINING AND/OR COMPETENCY EVALUATION PROHIBITION

Federal Law, as specified in 42 CFR **484.80(f)(3)**, prohibits any home health agency from offering and/or conducting a home health aide training and/or competency evaluation program which, within the previous two years, has been found:

(A) Out of compliance with requirements of 42 CFR **484.80(f)(3);**

(B) To permit an individual that does not meet the definition of “home health aide” as specified in §484.4 to furnish home health aide services (with the exception of licensed health professionals and volunteers);

(C) Has been subject to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of CMS or the State);

(D) Has been assessed a civil monetary penalty of not less than $5,000 as an intermediate sanction;

(E) Has been found to have compliance deficiencies that endanger the health and safety of the HHA’s patients and has had a temporary management appointed to oversee the management of the HHA;

(F) Has had all or part of its Medicare payments suspended; or

(G) Under any Federal or State law within the 2-year period beginning on October 1, 1988--

(1) Has had its participation in the Medicare program terminated;

(2) Has been assessed a penalty of not less than $5,000 for deficiencies in Federal or State standards for HHAs;
(3) Was subject to a suspension of Medicare payments to which it otherwise would have been entitled;
(4) Had operated under a temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA's patients; or
(5) Was closed or had its residents transferred by the State.

Therefore, your facility is precluded from conducting a home health aide training and/or competency evaluation program for a period of two years beginning March 23, 2023.

INFORMAL DISPUTE RESOLUTION

In accordance with 42 CFR 488.745, you have one opportunity to dispute condition-level survey findings warranting a sanction 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:

Home Health Agency 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 a PoC for the cited deficiencies.

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

If you have any questions on this matter, please do not hesitate to call.

Sincerely,

Kamala Fiske-Downing
Minnesota Department of Health

Health Regulation Division
Telephone: (651) 201-4112 Fax: (651) 215-9697
Email: Kamala.Fiske-Downing@state.mn.us

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 248056	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 03/23/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ADARA HOME HEALTH INC	25 1ST AVENUE NE STE 100 , BUFFALO, Minnesota, 55313

(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
G0000	INITIAL COMMENTS On 3/22/23 - 3/23/23 a complaint survey was conducted. This resulted in a partial extended survey at Adara Home Health. The agency was found to have not met the requirements at 42 CFR. Part 484 for Home Health Agencies. The cumulative effects of these findings resulted in the Home Health Agency's inability to ensure provision of quality of care. H#80569456C/96841 and 96810 was substantiated deficiencies were issued at G428. G430, G478, G536, G574, G578, G616, G620, and G706 as a result of the complaint investigation. The Condition of Participation 42 CFR 484.50 Patient Rights at G430 and 42 CFR 484.55 Comprehensive Assessment of Patients at G536 was found not met.	G0000		
G0406	Patient rights CFR(s): 484.50 Condition of participation: Patient rights. The patient and representative (if any), have the right to be informed of the patient's rights in a language and manner the individual understands. The HHA must protect and promote the exercise of these rights. This CONDITION is NOT MET as evidenced by: Based on the number and/or severity of the deficiency cited the Condition of Participation 42 CFR 484.50 Patient Rights at G430 was not met. The agency neglected to conduct psychiatric assessments/evaluations or monitor medical needs as identified in the plan of care for a patient on an antipsychotic and antidepressant medication for 1 of 1 patient (P1) reviewed for necessary care and services. P1 went without Clozaril and Cymbalta medications for approximately 45 days and required hospitalization.	G0406		

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 reverse for further 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.

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

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G0406 G0428	Property and person treated with respect CFR(s): 484.50(c)(1) Have his or her property and person treated with respect; This ELEMENT is NOT MET as evidenced by: Based on interview and document review, the agency failed to respect the preference of patients when assigning visit schedules for 3 of 3 patients (P1, P2, and P3) reviewed. P2 attempted to cancel due to post-traumatic stress disorder (PTSD), and P1 and P3 did not participate in their agency visit schedule. P1's Home Health Certification and Plan of Care (POC) dated 1/21/23 to 3/21/23, indicated P1 diagnoses were schizoaffective disorder (a combination of schizophrenia and mood disorders), major depression disorder, bipolar disorder, anxiety disorder, pain, unspecific psychosis, post-traumatic stress disorder, chronic systolic stress disorder, obesity, and type II diabetes. P1's frequency of visits was skilled nursing visits every other week and one as needed (PRN) visit for changes in medical condition. Upon interview on 3/22/23, at 10:43 a.m. P1 stated her next skilled nursing visit was on 3/23/23, however she does not know the time of the visit. P1 stated the times are never consistent the agency calls me the day before and lets me know the time. "It's frustrating not knowing the time, as I can't plan anything else that day." P1 denied having a calendar in her home of the agency's visits. P2's (POC) dated 2/9/23, indicated P2's diagnoses were chronic pain syndrome, polyneuropathy (numbness and weakness of multiple nerves), generalized anxiety disorder, post-traumatic stress disorder and occlusion and stenosis of the left carotid artery. P2's frequency of visits was for weekly skilled nursing. P2's Patient Information Record dated 2/27/23, indicated reason visit was not made was patient	G0406 G0428		

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G0428	Continued from page 2 cancelled at the door. Her needs were met by having a backup of medication set-up. The note did not indicate if P2 was aware of the change of visit from a Thursday to a Monday. P2's Patient Information Record Dated 3/2/23, indicated the reason the visit was not made was because P2 did not answer her door and did not return phone calls. The note did not indicate how P2's needs were met. P2's Patient Information Record dated 3/6/23, indicated a call to the P2 regarding the two missed visits asking P2 if she still wishes to have services from the agency due to two missed visits. The note did not indicate P2's response. P2's Patient Information Record dated 3/9/23, indicated LPN-A contacted P2 on 3/8/23, to set-up a time for the 3/9/23, visit. P2 acknowledged a time. On 3/9/23, LPN-A received a text message from P2 indicating P2 did not want a visit as she was uncomfortable with LPN-A being in her apartment. LPN-A was going to chart visit as a missed due to client refusal. LPN-A received a text message from the home office requesting that writer go to P2's apartment as she was willing to have a visit. Upon arrival LPN-A found P2 to be very agitated and upset saying she does not know why he was there. P2 refused vital signs and assessment. P2 told LPN-A she was going outside and left LPN-A alone in her apartment. LPN-A noticed thirteen of P2's medication bottles were completely empty and P2 had only four other medications on hand. LPN-A filled the medications on hand and ordered the rest of the medication. The medications would not be ready at the pharmacy until 3/14/12. P2 became upset-up again and told LPN-A she would get the medications the following day. LPN-A advised P2 when she did receive all the medications to call the agency. P2's Patient Information Record dated 3/13/23, RN-A notified primary care physician about P2's visit from 3/9/23, increased anxiety and missing medications from the home. The note did not indicate that the agency sent in a male client when client has a history of trauma from a man. P2's Patient Information Record dated 3/15/23, indicated P2's county case manager, called RN-A requesting only a female nurse to do the visits due to	G0428		

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G0428	Continued from page 3 P2's past traumatic experience. Upon interview on 3/22/23, at 1:44 p.m. P2 stated she has weekly nursing visits. P2 stated "Well it's late afternoon and they haven't called me, no one will probably show-up tomorrow." P2 stated she is aware of the day of the week a nurse is coming, but not the time the nurse is arriving, or who the staff is. P2 stated she has left her home because she has not heard from the agency and that has resulted in missed visits. P2 stated the agency called her and asked if she still wanted services because she had missed two visits. P2 stated she was not aware that the agency was switching her 2/27/23, which was a Monday and then the agency attempted to see her on 3/4/23, without notifying P2 of the time for the visit. P2 stated on 3/8/23, she received a call from a "man" at the agency trying to set-up a visit time for 3/9/23. P2 stated she did set-up a time, but later sent licensed practical nurse (LPN)-A a text message saying she was uncomfortable with him coming to visit her. P2 stated she was violently assaulted years ago by a man and she feared being alone with the male staff. On 3/9/23, LPN-A showed-up to visit P2 and she became very anxious, fearful, and got "emotional" with LPN-A. "I was just scared, very scared, they know my history and I refused this visit." P3's POC dated 2/17/23, indicated P3's diagnoses included type II diabetes, with chronic kidney disease, history of falls, unspecified mental disorder, and obesity. P3's frequency of visits was one skilled nursing visit every other week. Upon interview on 3/22/23, at 2:45 p.m. P3 stated he is aware what day of the week, the agency is coming "for the most part", however is never aware of the time of the visit. "A consistent time would be nice; I just don't schedule anything on the day I know they are coming." Upon interview on 3/22/23, at 3:18 p.m. RN-A, clinical supervisor stated that the agency does call the client's the day before the visit to set-up the time. RN-A also stated he was unaware if P2 missed visits due to leaving her home because she did not know the time of the visits. In addition, he stated after a male	G0428		

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G0428	Continued from page 4 nurse was sent to P2's home, P2's county case worker called and reminded the agency of P2's violent past with a male and asked for a female staff member only. RN-A did not believe another male staff member had seen P2 since the complaint. Upon interview on 3/22/23, at 4:12 p.m. RN-C stated she does not know her work schedule until the day before. The agency lets the staff know the schedule and the agency or the nurse reach out to the patient the day before and sets the times. RN-C stated the reason the agency schedules like that is if the agency needs to staff a start of care or something else, then the agency can move the clients around. Upon interview on 3/22/23, at 4:40 p.m. RN-E, regional operations manager, stated the agency has the assigned nursing staff call the patient's the day before the visit, this is because the staff schedules can change from day to day. For the home health aide staff RN-E believed a schedule is sent out to the patients. A facility policy titled Client Notification of Changes in Care/Service dated 6/9/23, indicated under the heading client visit schedule changes. 1. Company personnel will notify the staffing manager/designee where there is a need to significantly alter a client's schedule (i.e., moving a visit from morning to afternoon). 2. When a significant variation of tentative time for visit (i.e., greater than one hour) is anticipated, the staffing manager/designee will immediately notify the client of the change and verify acceptance. 3. Notification to the client will be documented in the client's clinical record. Documentation may include Date and time of the notification, specific schedule changes and the client's response to the schedule change. A facility policy regarding specialized nursing services for PTSD patients was requested, however none was received.	G0428		
G0430	Be free from abuse CFR(s): 484.50(c)(2) Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property;	G0430		

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G0430	Continued from page 5 This ELEMENT is NOT MET as evidenced by: Based on interview and document review the agency neglected to conduct psychiatric assessments/evaluations or monitor medical needs as identified in the plan of care for a patient on an antipsychotic and antidepressant medication for 1 of 1 patient (P1) reviewed for necessary care and services. P1 went without Clozaril and Cymbalta medications for approximately 45 days and required hospitalization. U.S. Food and Drug Administration (FDA) website https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019758s084lbl.pdf for Clozaril prescribing information indicated Clozaril is an atypical antipsychotic medication used for the treatment of resistant schizophrenia, reducing suicidal behavior in patients with schizophrenia or schizoaffective disorder. Clozaril is indicated for treatment of patients who fail to respond adequately to standard antipsychotic treatment. Clozaril is a high-risk medication that can cause severe neutropenia, orthostatic hypotension, bradycardia, syncope, seizure, myocarditis, cardiomyopathy, and increased mortality in elderly patients with dementia-related psychosis. The following warnings and precautions include eosinophilia, QT interval prolongation, metabolic changes such as hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain, neuroleptic malignant syndrome, hepatotoxicity, fever, pulmonary embolism, anticholinergic toxicity, and interference with cognitive and motor performance. Clozaril has caused neutropenia leading to serious infection and death. Patients responding to Clozaril should continue maintenance treat of their effective dose beyond the acute episode. Abruptly discontinuing Clozaril is necessary only as a result of moderate to severe neutropenia, a gradually dose reduction should be planned over a period of 1 to 2 weeks. All patients should be carefully monitored for the recurrence of psychotic symptoms and symptoms related to cholinergic rebound such at profuse sweating, headache, nausea, vomiting, and diarrhea. Re-initiation of Clozaril treatment after a patient has discontinued Clozaril for 2 days or more since last dose is to reinitiate with 12.5 mg once or twice daily, if well tolerated the dose may be increased to the previously dose more quickly. Clozaril is only available through a restricted program under a Risk Evaluation and Mitigation Strategies (REMS) program because of the risk of severe neutropenia. Healthcare professionals who prescribe, patients who receive, and pharmacies dispense Clozaril must be enrolled and/or certified in the program. Patient and caregiver counseling information include	G0430		

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G0430	Continued from page 6 the risks and warnings of taking Clozaril, reporting any symptoms to their provider, any potential drug to drug interactions of prescribed or over-the-counter medications. U.S. Food and Drug Administration (FDA) website https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021427s052lbl.pdf for Cymbalta prescribing information indicated Cymbalta is a serotonin and norepinephrine reuptake inhibitor indicated for the treatment of major depressive disorder, generalized anxiety disorder, diabetic peripheral neuropathic pain, fibromyalgia, and chronic musculoskeletal pain. Dosage of Cymbalta was based on the indication for use. Warnings and precautions included Discontinuation Syndrome indicate patients should be monitored for symptoms when discontinuing treatment, a gradual reduction dose rather than abrupt cessation is recommended whenever possible. Additional warnings included hepatotoxicity, orthostatic hypotension, falls, syncope, serotonin syndrome, increased risk of bleeding, sever skin reactions, activation of mania or hypomania, angle-closure glaucoma, seizures, blood pressure increases, inhibitors of CYP1A2 or Thioridazine, hyponatremia, or condition that slow gastric emptying. The medication guide indicated topics on telling your healthcare provider right away of symptoms and feelings listed, what is Cymbalta, who should not take Cymbalta, how should you take it, and what you should avoid while taking Cymbalta, medical conditions to tell your provider, and side effects. P1's Home Health Certification and Plan of Care (POC) dated 1/21/23 to 3/21/23, indicated P1 diagnoses included schizoaffective disorder (a combination of schizophrenia and mood disorders), major depression disorder, bipolar disorder, anxiety disorder, pain, unspecific psychosis, post-traumatic stress disorder, chronic systolic stress disorder, obesity, and type II diabetes. P1's frequency of visits was skilled nursing visits every other week and one as needed (PRN) visit for changes in medical condition. P1's orders of discipline and treatments. 1. Skilled nurse (SN) for instruction/reinforcement of diabetic care to include diet, skin care, administration of insulin, blood glucose testing and diabetic foot care. 2. SN to provide skilled teaching/reinforcement of management of hypertension. 3. SN to review medication profile and reconcile medications as needed, SN may instruct and reinforce medication teaching related to use of medications to treat disease process, SN may fill medication orders/profile bi-weekly. 4. Skilled nurse	G0430		

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G0430	Continued from page 7 for observation/assessment of patient's impaired nutrition related to obesity, instruction patient/caregiver on interventions designed to improve nutritional intake and patient well-being. 5. SN for administration of ability via IM injection every month. 6. SN to perform multifactor fall risk assessment and implement interventions to decrease risk of falls. SN to instruct on home safety, impact of polypharmacy, environmental safety and fall prevention. 7. SN to evaluate and develop plan of care to be countersigned by physician, SN to assess/evaluate co-morbid conditions including schizoaffective disorder and other conditions that present themselves while this episode to identify changes and intervene to minimize complications. 8. SN to observe and assess cardiovascular system to identify changes and intervene to minimize complications. SN to provide skilled teaching related to altered cardiovascular status including pathophysiology, nutrition, medication regimen, and permitted activities. May perform oxygen saturation levels as needed for signs and/or symptoms of possible respiratory complications. 9. SN to provide instructions related to management of congestive heart failure including, but not limited to definition, risk factors, measures to prevent exacerbation, signs/symptoms, and potential complications. 10. SN to monitor plan for current treatment of depression such as effects of medication and/or need for referral for other treatment. 10. All orders disciplines will assess for vulnerability/maltreatment concerns/changes, review the vulnerable/abuse prevention plan, facilitate patient advocacy, notify physician/nurse practitioner and/or refer to MAARC/county common entry point as appropriate for changes/concerns in vulnerability/maltreatment. 11. All ordered disciplines will implement the individual vulnerability/maltreatment/abuse prevention plan, self-management, personal safety, implement pathway, need for skilled care related to fall risk and or behavior and or need for other disciplines. 12. Self-management, medication set-up/management, implement pathways, medication management, assess for medication compliance and alert physician of significant issues/missed doses. Teach patient/caregiver how to set-up medications. Teach medication reminders including alarms. P1's orders in the POC failed to identify any parameters for P1's blood glucose levels, vital signs, weight monitoring, and comorbid conditions related to schizoaffective disorder. The POC failed to identify Clozaril and Cymbalta assessments, lab draws, missed doses, provider notification, and side effects.	G0430		

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G0430	Continued from page 8 P1's therapeutic level of Clozaril indicated the following lab values. A normal therapeutic range for the use of Clozaril was 350-600 ng/ml. lab level dated 1/3/23 indicated a level of 910 nanograms/milliliter (ng/ml) lab level dated 1/31/23 indicated a level of 952 ng/ml lab level dated 3/7/23, was <25 ng/ml lab level dated 3/16/23 was 101 ng/ml P1's patient information report dated 1/26/23 did not identify any psychiatric assessments, medical monitoring, medication side effects, medication compliance or treatment goals. P1 was instructed to call family or the crisis hotline if she had thoughts of harming herself. P1's medications were set-up from 1/26/23 through 2/8/23 including Clozaril and Cymbalta. P1's patient information report dated 2/9/23 indicated there was no psychiatric assessment or medical monitoring, medication side effects, medication compliance or treatment goals during the visit. P1's medications were set-up from 2/9/23 through 2/23/23, including Clozaril and Cymbalta. P1's patient information report dated 2/12/23 indicated P1 was hearing voices, RN-C re-educated her on the importance of calling the suicide hotline. P1 stated she had a "psych" appointment, uncertain if the appointment was with her psychologist or psychiatrist. RN-C did not conduct a psychiatric assessment nor were additional interventions identified. There was no note of medical monitoring, medication side effects, medication compliance or treatment goals. The note indicated all mediations were set-up, there was not a list and dates of the medications set-up. P1's patient information report dated 2/27/23 P1 was seen on 2/25/23 with a note indicating no changes to the medication regimen, the note did not identify any psychiatric assessments, medical monitoring, medication side effects, medication compliance or treatment goals. The note failed to provide a list of the medications set-up and the dates.	G0430		

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G0430	Continued from page 9 P1's patient information report dated 3/9/23, did not identify any psychiatric assessments, medication side effects, medication compliance or treatment goals during the visit. Medical monitoring was competed. P1's medications were set-up from 3/9/23 through 3/23/23, including Clozaril and Cymbalta. Clinical psychiatry note dated 3/10/23, indicated P1 had an error with medication set-up, missed Cymbalta, Clozaril and Chantix, which was realized 3/9/23. P1's thoughts of suicidal ideation, self-injurious behaviors have worsened. P1 came really close to self-injury on 3/9/23 but did not act on it, she felt like her brain was being shocked and zapped. P1 had increased nightmares, restlessness, more jittery, increased command hallucinations, difficulty with sleep, nausea, diarrhea, urinary urgency, some confusion, and vivid dreams. Daughter-in-law noticed in the past week P1 has been more agitated, anxious, and not sleeping. P1's social worker was at the visit with P1, where concerns of the medication errors were brought up. P1 has been Clozapine and Cymbalta and has been experiencing symptoms of anticholinergic rebound from abrupt discontinuation of Clozapine. P1 had been experiencing discontinuation syndrome from abrupt discontinuation of Cymbalta. P1 has been experiencing significant worsening of command auditory hallucinations to harm or kill herself. Clozapine last dispensed 12/29/22, clozapine level drop from 982 ng/ml to <25 ng/ml and the Cymbalta was last dispensed 1/26/23. P1 reported to psychiatrist that when the error was noted at the nursing visit on 3/9/23, the nurse obtained Clozaril and set-up 450 mg in her med set, which she took 3/9/23. P1 was advised to not take any Clozapine 3/10/23, due to risk with resuming a high dose. Titration dose given. Family aware and is setting-up medications and if family notices any cognitive changes, encouraged them to take P1 to the emergency department. The lack of Clozapine is evidenced in lab work showing a profoundly low level. With an abrupt discontinuation of Cymbalta from 90 mg she was also experiencing antidepressant discontinuation syndrome on top of above-mentioned symptoms which includes feeling jittery, restlessness, feeling of electrical shocks/zaps throughout her body, difficulty sleeping. A psychiatry staff registered nurse (RN), contacted the HHA on 3/10/23, to request a medication administration record or other documentation. The psychiatry staff RN spoke with RN-A who is an agency Clinical Supervisor, several times but outpatient psychiatry did not receive any documentation of what happened or if there was any	G0430		

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G0430	Continued from page 10 attempt to contact the psychiatry office. A home health agency report titled Complaint Report dated 3/13/23, indicated RN-A recorded a complaint on 3/13/23 at 7:30 a.m. regarding P1. The description of the complaint indicated a registered nurse (RN) from P1's mental health provider office called and stated P1's medications were set-up incorrectly. The provider reported P1's Abilify injection was given a week late, Clozaril and Cymbalta was not given as ordered, possibly not set-up for a week or two. P1 was experiencing symptoms and may need to be taken to the emergency department. The home health agency reviewed P1's medication set-up records for the past six weeks and all records show medication were set-up as ordered, except the medication records for the 2/25/23 visit did not have the detailed documentation which RN-A identified a nurse who completed the set-up forgot to create a note, RN-A provided education the nurse. Interventions regarding the complaint included education/retraining to a staff member and follow-up with the provider. An email dated 4/3/23 from P1's psychiatrist indicated she was informed P1 was admitted to a hospital due her psychiatric symptoms that could not be managed safely at home and was related to the "medication error". Upon observation on 3/23/23, at 9:30 a.m. RN-C inquired about P1's sleep pattern, and P1 stated she got three hours of sleep the night before. RN-C failed to look at P1's sleep log or provide any education. P1's weight was 301 lbs. RN-C stated the weight was "up," but could not state what P1's weight should be, only if her weight is up by 2 lbs. in 1 day to take "an extra Lasix." RN-C and P1 both stated P1 will set-up her own "extra Lasix," but does not always take her weight every day. RN-C assessed P1's oxygen saturation rate to be 93%, RN-B did not know what P1's parameters were. RN-C advised P1 to increase her fluid intake to "push out the fluids". P1 stated "I was told by my provider to not drink so much water." RN-C's response was "yeah that is probably right, do what she says." P1's vital signs were 132/72, RN-C was not aware of the specific parameters for P1. RN-C asked P1 If she had any concerns or complaints. P1 stated she was still having sleep problems and suicidal ideation. RN-C asked her if she still has the suicide hotline numbers and provided P1 with the agency after hours number. RN-C did not inquire if P1 had a suicidal plan, and no formal mental health assessment was completed. In addition, P1	G0430		

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G0430	Continued from page 11 stated, she still gets so anxious she cannot settle her legs down. RN-C's response was "that is tough, I am sorry for what you have been going through." Upon interview on 3/22/23, 9:36 a.m. P1 stated “my agency messed up my meds.” She stated she was not certain how long she had been without her medications but stated it “gets confusing” as sometimes she has three different medication boxes set-up in her home as the home as the agency comes out every other week. She stated she started to unravel, but could not figure out why, her legs were shaking, her mind was racing and was “being careless,” she did not care if she lived, she had many ideas of how to harm herself. P1 reported 2-3 hours of sleep a night, she joined a health club and reported she had diarrhea for a week. Her daughter-in-law locked up her medications and all the knives in the house. When her son and daughter-in-law, who live with her, went to work on their overnight shifts, family member (FM-A) had P1 stay with her father so she would always have supervision. P1 was in contact with her psychologist during this time and called the crisis line multiple times. P1 stated she has always been compliant in taking her medications because they have kept her stable. She did question that it appeared she had less medications but did not think any of it and did not have a detailed medication list to follow. P1 stated, I do not know if I can trust the agency, my daughter-in-law has really stepped up and fixed the problem. The agency did not come out and perform a visit when they heard that my Clozaril level had a significant drop. P1 stated that some of the agency nurses come in and just set-up her medications, other nurses take her vital signs, some inquire about her weight, some check her legs and feet and other do not. “I don’t know what they are supposed to be doing.” P1 does not recall an exact date a post-it note was left on her medication box. She stated some nurses leave her a note of what to fill, others just tell her pick-up her medications and place them in the boxes. P1 denied any education on medication set-up from the HHA. Upon interview on 3/22/23, at 11:33 a.m., a pharmacist stated P1’s last refill of Clozaril was 12/30/23, she had a lab draw on 1/30/23, but no refill request. Her next Clozaril dose was filled 3/15/23 with a titration order. “She went most of February and half of March without Clozaril.” “Her Cymbalta was last filled on 1/26/23, so I am assuming she has missed doses of that as well.”	G0430		

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G0430	Continued from page 12 Upon interview on 3/22/23, at 2:10 p.m., the agency Registered Nurse (RN)-B stated that she completed a visit on 1/26/22, this was her last visit with P1 as the agency was changing branches. RN-B stated P1 receives services for her mental health. The agency performs medication set-up, weight monitoring, psychiatric assessments, physical assessments including diabetic education. The agency also administers P1's monthly Abilify medication injections. Upon interview on 3/22/23, at 3:30 p.m., RN-D stated she only saw P1 once and during the visit she was to assess P1's cognition, medication compliance and medication reconciliation. RN-D stated she was not aware of the side-effects of P1's medications, however the agency software program has the education staff should be looking at with any questions for medications, she denied using this resource for P1. RN-D stated she did not go through any formal assessment questions when seeing P1. RN-D stated she measured P1 vital signs and P1 was alert and oriented, she denied any other assessments. Upon interview on 3/22/23 at 4:12 p.m. RN-C for P1's visits the nurse set-up medications and reorders them, they also give her a monthly Abilify medication injection. RN-C stated she follows the plan of care, "it should tell us in the plan what to do." RN-C stated if the agency was supposed to do anything with Clozaril lab levels it should be on the care plan, and she did not recall hearing of any lab values needed. Upon interview on 3/23/23, at 10:55 a.m. P1's psychologist stated P1 notified her on 3/9/23, that her HHA nurse realized she had not been getting her Clozaril in her past medication set-ups. The psychologist stated P1 first reported she was feeling "off" on 2/27/23. On 3/1/23, P1 was reporting no sleep for days, increased auditory hallucinations, suicidal ideation and thoughts of self-harm, no plan, but definite thought of method, psychomotor agitation, racing thoughts and increased self-directed energy. The psychologist stated he has worked with P1 for 16 months and this was the first time I have seen any symptoms. On 3/9/23, P1 was reporting her brain felt like a static globe and felt electric shocks, but her body felt tired. P1 was instructed to go to the emergency room. P1 had a psychiatry appointment the following day.	G0430		

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G0430	Continued from page 13 Upon interview on 3/23/23, at 3:01 p.m. LPN-A stated on 3/9/23, he completed a visit on P1. He stated this was the first time he had seen her, so he was not familiar with her medications. LPN-A stated he does systems check of all the clients upon each visit and assesses the client's cognition. He could not recall any specific assessments or interventions for P1. Upon interview on 3/23/23, at 3:16 p.m. RN-A stated after he received a call from P1's psychiatrist on 3/13/23 [SIC] that P1's Clozaril level was profoundly low and has not been dispensed since 12/29/22 [SIC], it was likely P1 has not been receiving Clozaril since late January. RN-A stated he was not aware that there was a concern P1 was not receiving her prescribed Cymbalta. RN-A was not aware of any assessment the nursing staff is doing for P1's schizoaffective disorder and Clozaril use. RN-A was not aware that Clozaril required a lab level and did not have knowledge about the REM program. Upon interview on 3/23/23, at 3:53 p.m. RN-F stated she was told by RN-A that there was a concern of possible missed medication. RN-F stated her expectations were if a medication could not be filled the agency nurse should notify the provider, call the pharmacy, follow-up with the patient, and do an as needed nursing visit if needed. RN-F stated missing Clozaril is a significant medication error. RN-F was not aware P1 was not receiving her prescribed Cymbalta. RN-F stated her expectation of the staff is that the care plan is followed at each visit and each patient should have parameters set for them to progress towards their goals and so the nurses can education to achieve the goals. The agency policy titled Vulnerability Reporting indicated neglect means the failure or omission by a caregiver to supply a vulnerable adult with care or services including but not limited to food, clothing, shelter, healthcare, or supervision which is reasonable and necessary to obtain or maintain the vulnerable adults physical or mental health or safety, considering he physical and mental capacity or dysfunction of the vulnerable adult. An agency policy titled Medication Error, dated 5/10/21 indicated an Unusual Occurrence Report is to be completed for all medication errors. Information gathered regarding medication errors will be tracked and analyzed as part of the company's performance	G0430		

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G0430	Continued from page 14 improvement plan. A medication error was defined as missing a scheduled administration of a medication or any reason, e.g., staffing difficulties, equipment, supplies. A significant medication error was defined any error that requires or results in the following, discontinuing a medication or modifying dose, treatment with a prescribed medication and cognitive deterioration or impairment. If the error is one of omission, follow the corrected medication schedule after discussing with the physician and pharmacist as appropriate. Document the events of the error objectively in the client's clinical record. An agency policy titled Medication management dated 6/8/22, indicated a clinically significant medication issues would be omissions, dosage errors and impairment or decline in a patient's mental or physical condition. An agency policy titled Initial Assessment/Certification dated 4/8/21, indicated the assessment facilitates the identification and prioritization of the patient needs, goals, and plan of care.	G0430		
G0478	Investigate complaints made by patient CFR(s): 484.50(e)(1)(i) (i) Investigate complaints made by a patient, the patient's representative (if any), and the patient's caregivers and family, including, but not limited to, the following topics: This ELEMENT is NOT MET as evidenced by: Based on interviews and document review, the facility failed to thoroughly investigate a complaint made to the home health care agency for 2 of 3 patients (P1, and P2) reviewed. The agency was informed of a medication error for P1 on 3/10/23, began an investigation on 3/13/23, and did not complete a thorough investigation. The agency did not contact P1 until a routine assessment on 3/21/23. In addition, the agency failed to do any investigation on a complaint reported from a county case worker for P2. P1's Home Health Certification and Plan of Care (POC) dated 1/21/23 to 3/21/23, indicated P1 diagnoses included schizoaffective disorder (a combination of schizophrenia and mood disorders), major depression disorder, bipolar disorder, anxiety disorder, pain, unspecific psychosis, post-traumatic stress disorder,	G0478		

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G0478	Continued from page 15 chronic systolic stress disorder, obesity, and type II diabetes. P1's frequency of visits was skilled nursing visits every other week and one as needed (PRN) visit for changes in medical condition. P1's orders of discipline and treatments. 1. Skilled nurse (SN) for instruction/reinforcement of diabetic care to include diet, skin care, administration of insulin, blood glucose testing and diabetic foot care. 2. SN to provide skilled teaching/reinforcement of management of hypertension. 3. SN to review medication profile and reconcile medications as needed, SN may instruct and reinforce medication teaching related to use of medications to treat disease process, SN may fill medication orders/profile bi-weekly. 4. Skilled nurse for observation/assessment of patient's impaired nutrition related to obesity, instruction patient/caregiver on interventions designed to improve nutritional intake and patient well-being. 5. SN for administration of ability via IM injection every month. 6. SN to perform multifactor fall risk assessment and implement interventions to decrease risk of falls. SN to instruct on home safety, impact of polypharmacy, environmental safety and fall prevention. 7. SN to evaluate and develop plan of care to be countersigned by physician, SN to assess/evaluate co-morbid conditions including schizoaffective disorder and other conditions that present themselves while this episode to identify changes and intervene to minimize complications. 8. SN to observe and assess cardiovascular system to identify changes and intervene to minimize complications. SN to provide skilled teaching related to altered cardiovascular status including pathophysiology, nutrition, medication regimen, and permitted activities. May perform oxygen saturation levels as needed for signs and/or symptoms of possible respiratory complications. 9. SN to provide instructions related to management of congestive heart failure including, but not limited to definition, risk factors, measures to prevent exacerbation, signs/symptoms, and potential complications. 10. SN to monitor plan for current treatment of depression such as effects of medication and/or need for referral for other treatment. 10. All orders disciplines will assess for vulnerability/maltreatment concerns/changes, review the vulnerable/abuse prevention plan, facilitate patient advocacy, notify physician/nurse practitioner and/or refer to MAARC/county common entry point as appropriate for changes/concerns in vulnerability/maltreatment. 11. All ordered disciplines will implement the individual vulnerability/maltreatment/abuse prevention plan, self-management, personal safety, implement pathway, need for skilled care related to fall risk and or behavior and or need for other disciplines. 12.	G0478		

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G0478	Continued from page 16 Self-management, medication set-up/management, implement pathways, medication management, assess for medication compliance and alert physician of significant issues/missed doses. Teach patient/caregiver how to set-up medications. Teach medication reminders including alarms. Clinical psychiatry note dated 3/10/23, indicated P1 had an error with medication set-up, missed Cymbalta, Clozaril and Chantix, which was realized 3/9/23. P1's thoughts of suicidal ideation, self-injurious behaviors have worsened. P1 came really close to self-injury on 3/9/23 but did not act on it, she felt like her brain was being shocked and zapped. P1 had increased nightmares, restlessness, more jittery, increased command hallucinations, difficulty with sleep, nausea, diarrhea, urinary urgency, some confusion, and vivid dreams. Daughter-in-law noticed in the past week P1 has been more agitated, anxious, and not sleeping. P1’s social worker was at the visit with P1, where concerns of the medication errors were brought up. P1 has been Clozapine and Cymbalta and has been experiencing symptoms of anticholinergic rebound from abrupt discontinuation of Clozapine. P1 had been experiencing discontinuation syndrome from abrupt discontinuation of Cymbalta. P1 has been experiencing significant worsening of command auditory hallucinations to harm or kill herself. Clozapine last dispensed 12/29/22, clozapine level drop from 982 ng/ml to <25 ng/ml and the Cymbalta was last dispensed 1/26/23. P1 reported to psychiatrist that when the error was noted at the nursing visit on 3/9/23, the nurse obtained Clozaril and set-up 450 mg in her med set, which she took 3/9/23. P1 was advised to not take any Clozapine 3/10/23, due to risk with resuming a high dose. Titration dose given. Family aware and is setting-up medications and if family notices any cognitive changes, encouraged them to take P1 to the emergency department. The lack of Clozapine is evidenced in lab work showing a profoundly low level. With an abrupt discontinuation of Cymbalta from 90 mg she was also experiencing antidepressant discontinuation syndrome on top of above-mentioned symptoms which includes feeling jittery, restlessness, feeling of electrical shocks/zaps throughout her body, difficulty sleeping. A psychiatry staff registered nurse (RN), contacted the HHA on 3/10/23, to request a medication administration record or other documentation. The psychiatry staff RN spoke with RN-A who is an agency Clinical Supervisor, several times but outpatient psychiatry did not receive any documentation of what happened or if there was any attempt to contact the psychiatry office.	G0478		

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G0478	Continued from page 17 A home health agency report titled Complaint Report dated 3/13/23, indicated RN-A recorded a complaint on 3/13/23 at 7:30 a.m. regarding P1. The description of the complaint indicated a registered nurse (RN) from P1's mental health provider office called and stated P1's medications were set-up incorrectly. The provider reported P1's Abilify injection was given a week late, Clozaril and Cymbalta was not given as ordered, possibly not set-up for a week or two. P1 was experiencing symptoms and may need to be taken to the emergency department. The home health agency reviewed P1's medication set-up records for the past six weeks and all records show medication were set-up as ordered, except the medication records for the 2/25/23 visit did not have the detailed documentation which RN-A identified a nurse who completed the set-up forgot to create a note, RN-A provided education the nurse. Interventions regarding the complaint included education/retraining to a staff member and follow-up with the provider. Upon interview on 3/22/23, at 10:43 a.m. P1 stated the agency did not reach out to her following the allegations. The agency did not call or provide a visit to until 3/21/23, which was a recertification visit. Upon interview on 3/22/23, at 3:18 p.m. RN-A stated receiving a call from the providers office. RN-A stated following the call he reviewed P1's visit notes and did not see that any medications were missed. However, 2/25/23, RN-D did not document correctly. RN-A made a call to RN-D and RN-D confirmed all the medications were set-up on 2/25/23. RN-A denied reaching out to the P1, denied reaching out to the pharmacy. RN-A stated he was not aware that Clozaril required a lab draw, was a significant medication and could not be filled until lab work was completed. Upon interview on 3/23/23, at 3:53 p.m. RN-F, Director of Clinical Programs, stated she was aware there were allegations of "possibly missed set-up medications." She stated she believed the allegations were taken care of until the state agency (SA) came onsite to investigate. RN-F was starting her own investigation of the allegations. P2's (POC) dated 2/9/23, indicated R2's diagnoses included chronic pain syndrome, polyneuropathy (numbness and weakness of multiple nerves), generalized	G0478		

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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
G0478	Continued from page 18 anxiety disorder, post-traumatic stress disorder and occlusion and stenosis of the left carotid artery. R2's frequency of visits was for weekly skilled nursing. 1. SN to evaluate and develop plan of care to be countersigned by physician, SN to assess/evaluate co-morbid conditions including schizoaffective disorder and other conditions that present themselves while this episode to identify changes and intervene to minimize complications. 2. SN to perform multifactor fall risk assessment and implement interventions to decrease risk of falls. 3. Skilled nursing to perform observe and assess patient with generalized depression. Assess need for medication, medication changes, and potential need for referral to provide counseling and assistance with managing depression. 4. All orders disciplines will assess for vulnerability/maltreatment concerns/changes, review the vulnerable/abuse prevention plan, facilitate patient advocacy, notify physician/nurse practitioner and/or refer to MAARC/county common entry point as appropriate for changes/concerns in vulnerability/maltreatment. 5. Self-management, medication set-up/management, implement pathways, medication management, assess for medication compliance and alert physician of significant issues/missed doses. 6. Skilled assessment to evaluate patient for maladaptive, aggressive, noncompliant, self-harming, and/or abusive behaviors. Assess medication treatment compliance, need for medication changes, and potential need for referral to a provider for counseling/assistance with managing behaviors. Provide skilled teaching to promote personal safety, reduce maladaptive behaviors and improve daily health practices. Report to significant concerns in behaviors to physician or nurse practitioner for interventions. 7. SN to review medication profile and reconcile medications as needed, SN may instruct and reinforce medication teaching related to use of medications to treat disease process, SN may fill medication orders/profile every Thursday. 8. SN to monitor plan for current treatment of depression such as effects of medication and/or need for referral for other treatment. 9. SN to provide/instruct regarding interventions to monitor and mitigate pain. 10. Licensed professional to report vital signs falling outside the following established parameters. Temp <95>101, pulse <50>100, respirations <12>29, systolic blood pressure <85>100, diastolic blood pressure <50>90. R2's Patient Information Record dated 3/15/23, indicated R2's county case manager, called RN-A requesting only a female nurse to do the visits due to R2's past drama.	G0478		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 248056	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 03/23/2023

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G0478	Continued from page 19 Upon interview on 3/22/23, at 1:44 p.m. P2 stated on 3/9/23, LPN-A showed-up to visit P2 and she became very anxious, fearful, and got “emotional” with LPN-A. “I was just scared, very scared, they know my history and I refused this visit.” Upon interview on 3/22/23, At 3:18 p.m. RN-A, stated he did receive a complaint from R2’s county case manager about not allowing male nurses to visit P2 due to the post-traumatic stress disorder related to the violent past with a male perpetrator. RN-A denied awareness of P2’s diagnosis. RN-A stated he did not fill out a complaint report, update staff, reach out to P2 or update the visit schedule to include only female staff. Upon interview on 3/23/23, at 3:53 p.m. RN-F stated she was unaware of any complaints regarding P2, however stated there should have been an incident written up and investigated. A facility policy titled Client Incident, Accident, Injury, or Unusual Occurrence dated 4/17/18 indicated the supervisor should review the Unusual Occurrence Report and determine the factors which contributed to the occurrence and complete the required documentation. The completed Unusual Occurrence Report should be submitted to the Branch General Manger for review and investigation if necessary.	G0478		
G0510	Comprehensive Assessment of Patients CFR(s): 484.55 Condition of participation: Comprehensive assessment of patients. Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. This CONDITION is NOT MET as evidenced by: The Condition of Participation 42 CFR 484.55 Comprehensive Assessment of Patients at G536 was found not met. The agency failed to identify the potential	G0510		

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G0510	Continued from page 20 adverse effects with the drug therapy Clozaril, an antipsychotic medication, and Cymbalta, an antidepressant for 1 of 1 patient (P1) reviewed for medication. P1's Clozaril medication was not ordered, set-up, and reconciled as prescribed. P1 went without Clozaril for approximately 45 days, psychiatrically decompensated, and was hospitalized. In addition, P1 went without Cymbalta for approximately 45 days.	G0510		
G0536	A review of all current medications CFR(s): 484.55(c)(5) A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy. This ELEMENT is NOT MET as evidenced by: Based on interview and document review the agency failed to identify the potential adverse effects with the drug therapy Clozaril, an antipsychotic medication, and Cymbalta, an antidepressant for 1 of 1 patient (P1) reviewed for medication. P1's Clozaril medication was not ordered, set-up, and reconciled as prescribed. P1 went without Clozaril for approximately 45 days, psychiatrically decompensated, and was hospitalized. In addition, P1 went without Cymbalta for approximately 45 days. U.S. Food and Drug Administration (FDA) website https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019758s084lbl.pdf for Clozaril prescribing information indicated Clozaril is an atypical antipsychotic medication used for the treatment of resistant schizophrenia, reducing suicidal behavior in patients with schizophrenia or schizoaffective disorder. Clozaril is indicated for treatment of patients who fail to respond adequately to standard antipsychotic treatment. Doses start at 12.5 mg once or twice daily and to use caution with titration increasing to total daily dosage in increments of 25 milligrams (mg) to 50 mg if well tolerated with a maximum daily dose of 900 mg. Clozaril is a high risk medication that can cause severe neutropenia, orthostatic hypotension, bradycardia, syncope, seizure, myocarditis, cardiomyopathy, and increased mortality in elderly patients with dementia-related psychosis. The following warnings and precautions include eosinophilia, QT interval prolongation, metabolic changes such as hyperglycemia, diabetes mellitus,	G0536		

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G0536	Continued from page 21 dyslipidemia, and weight gain, neuroleptic malignant syndrome, hepatotoxicity, fever, pulmonary embolism, anticholinergic toxicity, and interference with cognitive and motor performance. Clozaril has caused neutropenia leading to serious infection and death when a patients absolute neutrophil count (ANC) is less than 500 microliters (ul). Prior to initiating treatment, a patient's ANC baseline must be at least 1500 ul. During treatment, patients must have regular ANC monitoring. Patients are to immediately report symptoms consistent with severe neutropenia or infection, e.g., fever, weakness, lethargy, or sore throat. Patients responding to Clozaril should continue maintenance treat of their effective dose beyond the acute episode. Abruptly discontinuing Clozaril is necessary only as a result of moderate to severe neutropenia, a gradually dose reduction should be planned over a period of 1 to 2 weeks with additional ANC monitoring and all patients should be carefully monitored for the recurrence of psychotic symptoms and symptoms related to cholinergic rebound such at profuse sweating, headache, nausea, vomiting, and diarrhea. Re-initiation of Clozaril treatment after a patient has discontinued Clozaril for 2 days or more since last dose is to reinitiate with 12.5 mg once or twice daily, if well tolerated the dose may be increased to the previously dose more quickly. Clozaril is only available through a restricted program under a Risk Evaluation and Mitigation Strategies (REMS) program because of the risk of severe neutropenia. Healthcare professionals who prescribe, patients who receive, and pharmacies dispense Clozaril must be enrolled and/or certified in the program. Patient and caregiver counseling information include the risks and warnings of taking Clozaril, reporting any symptoms to their provider, any potential drug to drug interactions of prescribed or over-the-counter medications. U.S. Food and Drug Administration (FDA) website https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021427s052lbl.pdf for Cymbalta prescribing information indicated Cymbalta is a serotonin and norepinephrine reuptake inhibitor indicated for the treatment of major depressive disorder, generalized anxiety disorder, diabetic peripheral neuropathic pain, fibromyalgia, and chronic musculoskeletal pain. Dosage of Cymbalta was based on the indication for use. Warnings and precautions included Discontinuation Syndrome indicate patients should be monitored for symptoms when discontinuing treatment, a gradual reduction dose rather than abrupt cessation is recommended whenever possible. Additional warnings included hepatotoxicity, orthostatic hypotension,	G0536		

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G0536	Continued from page 22 falls, syncope, serotonin syndrome, increased risk of bleeding, sever skin reactions, activation of mania or hypomania, angle-closure glaucoma, seizures, blood pressure increases, inhibitors of CYP1A2 or Thioridazine, hyponatremia, or condition that slow gastric emptying. The medication guide indicated topics on telling your healthcare provider right away of symptoms and feelings listed, what is Cymbalta, who should not take Cymbalta, how should you take it, and what you should avoid while taking Cymbalta, medical conditions to tell your provider, and side effects. P1's Home Health Certification and Plan of Care (POC) dated 1/21/23, indicated P1 diagnoses included schizoaffective disorder (a combination of schizophrenia and mood disorders), major depression disorder, bipolar disorder, anxiety disorder, pain, unspecific psychosis, post-traumatic stress disorder, chronic systolic stress disorder, obesity, and type II diabetes. P1's frequency of visits was skilled nursing visits every other week and one as needed (PRN) visit for changes in medical condition. P1's orders of discipline and treatments. 1. Skilled nurse (SN) for instruction/reinforcement of diabetic care to include diet, skin care, administration of insulin, blood glucose testing and diabetic foot care. 2. SN to provide skilled teaching/reinforcement of management of hypertension. 3. SN to review medication profile and reconcile medications as needed, SN may instruct and reinforce medication teaching related to use of medications to treat disease process, SN may fill medication orders/profile bi-weekly. 4. Skilled nurse for observation/assessment of patient's impaired nutrition related to obesity, instruction patient/caregiver on interventions designed to improve nutritional intake and patient well-being. 5. SN for administration of ability via IM injection every month. 6. SN to perform multifactor fall risk assessment and implement interventions to decrease risk of falls. SN to instruct on home safety, impact of polypharmacy, environmental safety and fall prevention. 7. SN to evaluate and develop plan of care to be countersigned by physician, SN to assess/evaluate co-morbid conditions including schizoaffective disorder and other conditions that present themselves while this episode to identify changes and intervene to minimize complications. 8. SN to observe and assess cardiovascular system to identify changes and intervene to minimize complications. SN to provide skilled teaching related to altered cardiovascular status including pathophysiology, nutrition, medication regimen, and permitted activities. May perform oxygen saturation levels as needed for signs and/or symptoms	G0536		

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G0536	Continued from page 23 of possible respiratory complications. 9. SN to provide instructions related to management of congestive heart failure including, but not limited to definition, risk factors, measures to prevent exacerbation, signs/symptoms, and potential complications. 10. SN to monitor plan for current treatment of depression such as effects of medication and/or need for referral for other treatment. 10. All orders disciplines will assess for vulnerability/maltreatment concerns/changes, review the vulnerable/abuse prevention plan, facilitate patient advocacy, notify physician/nurse practitioner and/or refer to MAARC/county common entry point as appropriate for changes/concerns in vulnerability/maltreatment. 11. All ordered disciplines will implement the individual vulnerability/maltreatment/abuse prevention plan, self-management, personal safety, implement pathway, need for skilled care related to fall risk and or behavior and or need for other disciplines. 12. Self-management, medication set-up/management, implement pathways, medication management, assess for medication compliance and alert physician of significant issues/missed doses. Teach patient/caregiver how to set-up medications. Teach medication reminders including alarms. P1’s treatment orders failed to identify any parameters for P1’s blood glucose levels, vital signs, and weight monitoring. In addition, the POC failed to identify Clozaril assessments, lab draws, missed doses, provider notification, and side effects. P1’s therapeutic level of Clozaril indicated the following lab values. A normal therapeutic range for the use of Clozaril was 350-600 ng/ml. lab level dated 1/3/23 indicated a level of 910 nanograms/milliliter (ng/ml) lab level dated 1/31/23 indicated a level of 952 ng/ml lab level dated 3/7/23, was <25 ng/ml lab level dated 3/16/23 was 101 ng/ml P1’s patient information report dated 1/26/23, indicated all P1’s medications were set-up from 1/26/23 through 2/8/23, including Clozaril and Cymbalta. The note did not indicate any refills were ordered or P1 was short of any medications or instructions given to P1 to picking and fill medications on her own.	G0536		

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G0536	Continued from page 24 P1's patient information report dated 2/9/23, indicated all P1's medications were set-up from 2/9/23 – 2/23/23, including Clozaril and Cymbalta. The note indicated Clozaril, duloxetine and ropinirole were called into pharmacy for a refill. The note failed to indicate any instructions given to P1 regarding the medications called into pharmacy. P1's patient information report dated 2/27/23, indicated P1 was seen on 2/25/23 with a narrative note indicating no changes to the medication regimen. The note failed to provide a list of the medications set-up and the dates. P1's patient information report dated 3/9/23, indicated all P1's medications set-up from 3-9-23 through 3/23/23, including Clozaril and Cymbalta. Refills ordered were Clozaril, Cymbalta, gabapentin, and celecoxib. The note failed indicate licensed practical nurse (LPN)-A could not find P1's Clozaril, so he looked in her medication tote and found a bottle of 50 mg tables, where on the bottle it said, "do not use." He used this bottle to fill "around 400 or 450 mg of the medication" to fill a couple of days until P1 could get her refill. Clinical psychiatry note dated 3/10/23, indicated there was an error with P1's medication set-up, missed Cymbalta, Clozaril and Chantix, this was realized yesterday. Thoughts of suicidal ideation, self-injurious behaviors have worsened, came really close to self-injury on Wednesday but did not act on it. P1 felt like her brain was being shocked and zapped P1 had increased nightmares, restlessness, was more jittery, increased command hallucinations, difficulty with sleep, nausea, diarrhea, urinary urgency, some confusion, and vivid dreams. Daughter-in-law noticed in the past week P1 has been more agitated, anxious, and not sleeping. P1's social worker was at the visit with P1, where concerns of the medication errors were brought up. P1 had been Clozapine and Cymbalta and had experienced symptoms of anticholinergic rebound from abrupt discontinuation of Clozapine. P1 had been experiencing discontinuation syndrome from abrupt discontinuation of Cymbalta. P1 had been experienced significant worsening of command auditory hallucinations to harm or kill herself. Clozapine last dispensed 12/29/22 [SIC], clozapine level drop from 982 ng/ml to <25 ng/ml and the Cymbalta was last dispensed 1/26/23. P1 reported to psychiatrist that when the	G0536		

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G0536	Continued from page 25 error was noted during nursing visit on 3/9/23, the nurse obtained Clozaril and set-up 450 mg in her med set, which she took 3/9/23. P1 was advised to not take any Clozapine 3/10/23, due to risks with resuming a high dose. Titration dosage was given. P1's family was aware and would be setting-up the medications and if family notices any cognitive changes, encouraged them to take P1 to the emergency department. An email dated 4/3/23 from P1's psychiatrist indicated she was informed P1 was admitted to a hospital due her psychiatric symptoms that could not be managed safely at home and was directly related to the "medication error". Upon interview on 3/22/23, 9:36 a.m. P1 stated "my agency messed up my meds." She stated she was not certain how long she had been without her medications but stated it "gets confusing" as sometimes she has three different medication boxes set-up in her home by the home as the agency when they come out every other week. She stated she started to unravel, but could not figure out why, her legs were shaking, her mind was racing and was "being careless," she did not care if she lived, she had many ideas of how to harm herself. P1 reported 2-3 hours of sleep a night, she joined a health club and reported she had diarrhea for a week. Her daughter-in-law locked up her medications and all the knives in the house. When her son and daughter-in-law, who live with her, went to work on their overnight shifts, the daughter-in-law had P1 stay with her father so she would always have supervision. P1 was in contact with her psychologist during this time and called the crisis line multiple times. P1 stated she has always been compliant taking her medications because they have kept her stable. She did question that it appeared she had less medications but did not think any of it and did not have a detailed medication list to follow. P1 stated, I do not know if I can trust the agency, my daughter-in-law has really stepped up and fixed the problem. The agency did not come out and perform a visit when they heard that my Clozaril level had a significant drop. P1 stated that some of the agency nurses come in and just set-up her medications, other nurses take her vital signs, some inquire about her weight, some check her legs and feet and other do not. "I don't know what they are supposed to be doing." P1 does not recall an exact date a post-it note was left on her medication box. She stated some nurses leave her a note of what to fill in the medication set-up box, others just tell her pick-up her medications and place them in the boxes. P1 denied any	G0536		

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G0536	Continued from page 26 education on medication set-up from the HHA. Upon interview on 3/22/23, at 11:33, a pharmacist stated P1's last refill of Clozaril was 12/30/22, she had a lab draw on 1/30/23, but no refill request. Her next Clozaril dose was filled 3/15/23 with a titration order. "She went most of February and half of March without Clozaril." "Her Cymbalta was last filled on 1/26/23, so I am assuming she has missed doses of that as well." Upon interview on 3/22/23, at 2:10 p.m., the agency Registered Nurse (RN)-B stated that she completed a visit on 1/26/22, this was her last visit with P1 as the agency was changing branches. She stated she did run out of two medications during the medication set-up. RN-B could not recall the names of the medications, but stated one was an anti-psychotic and one was an antidepressant. She stated she may have charted incorrectly that all medications were set-up as she automatically put in the dates the medications. RN-B stated sometimes she charts her medication set-up in the home and other times after the visit. She stated she is able and has copied and pasted medications and then puts in the dates to save time. RN-B stated on 1/26/23 she was short about 4-5 day of the "anti-psychotic and the antidepressant," she stated she left a post-it note on P1's medication set box to fill in the missing medications when she picked them up from the pharmacy. RN-B could not recall if she ordered refills. RN-B stated she did not reach out to the ordering provider that P1 did not have enough medications to complete the medication set-up. RN-B was aware that Clozaril required lab results prior to refilling but did not discuss with P1. RN-B denied follow-up with P1 to see if medications were refilled and set-up. RN-B did not believe that P1 had been educated on setting-up her own medication. "I haven't seen any formal documentation in the agency on any patients." Upon interview on 3/23/23, at 10:55 a.m. P1's psychologist stated P1 notified her on 3/9/23, that her HHA nurse realized she had not been getting her Clozaril in her past medication set-ups. The psychologist stated P1 first reported she was feeling "off" on 2/27/23. On 3/1/23, P1 was reporting no sleep for days, increased auditory hallucinations, suicidal ideation and thoughts of self-harm, no plan, but definite thought of method, psychomotor agitation, racing thoughts and increased self-directed energy. "I	G0536		

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G0536	Continued from page 27 have worked with her for 16 months and this was the first time I have seen any symptoms of bipolar". On 3/9/23, P1 was reporting her brain felt like a static globe and felt electric shocks, but her body felt tired. P1 was instructed to go to the emergency room. P1 had a psychiatry appointment the following day. The psychologist asked why the HHA did not reach out to her regarding the increase in psychiatric symptoms? Upon interview on 3/23/23, at 3:01 p.m. LPN-A stated on 3/9/23, he completed a visit on P1. He stated this was the first time he had seen her, so he was not familiar with her medications. He stated he filled her medications. He remembered he could not find her anti-psychotic, so he looked in her medication tote and found a bottle of 50 mg tables, where on the bottle it said, "do not use." He used this bottle to fill "around 400 or 450 mg of the medication." He stated he had enough medications to use "9 or 10 tablets to make the dose" of this medication and was able to "make the dose" to fill a couple of days until P1 could get her refill. LPN-A does not recall having a conversation with RN-A about P1 not having the medications prior to his visit. P1 stated he was not aware that Clozaril required a lab level prior to refills and was not certain exactly what assessments he should be doing a patient on Clozaril. LPN-A stated he gave P1 instructions to fill her medication box when she picked up her medications. LPN-A stated he was not certain if P1 was educated to set-up her medications. He stated, "If I had concerns if a patient could be trusted to set-up their own medications, I would visit with them and see where they were at cognitively and if they were safe to set-up their own medications and she seemed safe." LPN-A stated he did not notify the physician following the visit. Upon interview on 3/23/23, at 3:16 p.m. RN-A stated after he received a call from P1's psychiatrist on 3/13/23 [SIC], that P1's Clozaril level was profoundly low and has not been dispensed since 12/29/22 [SIC],it is likely P1 has not been receiving Clozaril since late January about the complaint. P1 denied awareness that there was a concern about P1's Cymbalta as well. RN-A stated he reached out to LPN-A and asked if P1's Clozaril had been set-up on 3/9/23. LPN-A told RN-A that he used 25 mg [SIC] tablets to fill in the dose. RN-A stated he could not explain why the agency nurses documented the medication was given, and P1's lab level was >25 ng/ml and the pharmacy indicated the medication was not filled since 12/30/23. RN-A was not aware of any assessment the nursing staff is doing for P1's	G0536		

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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
G0536	Continued from page 28 schizoaffective disorder and Clozaril use. RN-A was not aware that Clozaril required a lab level and did not have knowledge about the REM program. Upon interview on 3/23/23, at 3:53 p.m. RN-F stated she was told by RN-A that there was a concern of possible missed medication. RN-F stated there is a list of high-risk medications that all the agency nurses need to be aware of and Clozaril is on that list. She stated all the nurses have access to the Lippincott medication library right in the software systems, so the nurses should be accessing that. RN-F stated her expectations were if a medication could not be filled per provider until the next visit, the agency nurse should notify the provider, call the pharmacy, follow-up with the patient and do an as needed nursing visit if needed. RN-F stated missing Clozaril is a significant medication error. RN-F was unable to state why the agency staff was documenting all medications were set-up and the pharmacy was saying there had not been a refill since 12/30/23 and her lab level came back at >25 ng/ml. RN-F was not aware there was a Cymbalta medication error. An agency policy titled Medication Error, dated 5/10/21 indicated an Unusual Occurrence Report is to be completed for all medication errors. Information gathered regarding medication errors will be tracked and analyzed as part of the company's performance improvement plan. A medication error was defined as missing a scheduled administration of a medication or any reason, e.g., staffing difficulties, equipment, supplies. A significant medication error was defined any error that requires or results in the following, discontinuing a medication or modifying dose, treatment with a prescribed medication and cognitive deterioration or impairment. If the error is one of omission, follow the corrected medication schedule after discussing with the physician and pharmacist as appropriate. Document the events of the error objectively in the client's clinical record. An agency policy titled Medication management dated 6/8/22, indicated a clinically significant medication issues would be omissions, dosage errors and impairment or decline in a patient's mental or physical condition.	G0536		
G0574	Plan of care must include the following CFR(s): 484.60(a)(2)(i-xvi)	G0574		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 248056	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 03/23/2023

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G0574	Continued from page 29 The individualized plan of care must include the following: (i) All pertinent diagnoses; (ii) The patient's mental, psychosocial, and cognitive status; (iii) The types of services, supplies, and equipment required; (iv) The frequency and duration of visits to be made; (v) Prognosis; (vi) Rehabilitation potential; (vii) Functional limitations; (viii) Activities permitted; (ix) Nutritional requirements; (x) All medications and treatments; (xi) Safety measures to protect against injury; (xii) A description of the patient's risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors. (xiii) Patient and caregiver education and training to facilitate timely discharge; (xiv) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient; (xv) Information related to any advanced directives; and (xvi) Any additional items the HHA or physician or allowed practitioner may choose to include. This ELEMENT is NOT MET as evidenced by: Based on interview and document review, the agency failed to ensure the plan of care (POC) included a description of the risk for emergency department visits and hospital re-admission, advanced directives, and/or education, including all necessary interventions to address the underlying risk factors, and identify parameters for goals and education for 2 of 3 patients	G0574		

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G0574	Continued from page 30 (P1 and P2) reviewed. P1's Home Health Certification and Plan of Care (POC) dated 1/21/23 indicated P1 diagnoses included schizoaffective disorder (a combination of schizophrenia and mood disorders), major depression disorder, bipolar disorder, anxiety disorder, pain, unspecific psychosis, post-traumatic stress disorder, chronic systolic stress disorder, morbid obesity, and type II diabetes. P1's frequency of visits was skilled nursing visits every other week and one as needed (PRN) visit for changes in medical condition. P1's orders of discipline and treatments. The POC failed to identify advanced directives, DME and supplies and a description of the risk for emergency department visits and hospital re-admission, including all necessary interventions to address the underlying risk factors as required so the provider was aware of all risks, interventions, and orders. In addition, the POC indicated skilled nursing for a treatment completed administration of insulin, P1's medication profile dated 1/20/23, does not indicate P1 takes insulin. The POC failed to identify any parameters for P1's blood glucose levels, vital signs, and weight monitoring. P2's (POC) dated 2/9/23 indicated P2's diagnoses included chronic pain syndrome, polyneuropathy (numbness and weakness of multiple nerves), generalized anxiety disorder, post-traumatic stress disorder and occlusion and stenosis of the left carotid artery. P2's frequency of visits was for weekly skilled nursing. The POC failed to identify advanced directives, DME and supplies and a description of the risk for emergency department visits and hospital re-admission, including all necessary interventions to address the underlying risk factors as required so the provider was aware of all risks, interventions, and orders. An agency policy titled Initial Assessment/Certification dated 4/8/21, indicated the assessment will include an evaluation of the following: Patient's medical history, pertinent physical findings, problems and goals, need for strengths, psychosocial status, nutritional status, prevent of advanced directives, equipment presently in the home, medications, patient support systems, involvement of family/caregiver and other support, medical, alcohol and other drug history, preventative ad period health screening, specific, individualized patient needs/problems pertinent to the care provided, age and gender specific findings, home environment, education needs, vulnerability and emergency plan.	G0574		

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G0574 G0578	Conformance with physician orders CFR(s): 484.60(b) Standard: Conformance with physician or allowed practitioner orders. This STANDARD is NOT MET as evidenced by: Based on interview and document review, the agency failed to provide medications as ordered by the patient's physician for 1 of 3 patients (P1) reviewed, when nursing staff failed to set-up the patient's anti-psychotic medication and anti-depressant medications as ordered and did not notify the provider. This practice caused P1 to go without her anti-psychotic medication for over a month, leading to abnormal lab values, and increased mental health symptoms. P1’s Home Health Certification and Plan of Care (POC) dated 1/21/23, indicated P1s diagnoses included schizoaffective disorder (a combination of schizophrenia and mood disorders), major depression disorder, bipolar disorder, anxiety disorder, pain, unspecific psychosis, post-traumatic stress disorder, chronic systolic stress disorder, obesity, and type II diabetes. R1’s frequency of visits was skilled nursing visits every other week and one as needed (PRN) visit for changes in medical condition. R1’s orders of discipline and treatments. P1's medications included clozapine (an anti-psychotic medication) 200 mg 2 tablets in the morning for a total of 400 mg. P1's treatments included skilled nursing which included that during every skilled nurse visit, the nurse was to perform medication management, including medication set-up, refill ordering, and compliance monitoring. An outpatient lab result dated 3/6/23, indicated an abnormal lab for Clozapine level of <25 nanograms per milliliter (ng/ml). Normal range is 350 – 600 ng/ml. A clinical psychiatry visit note dated 3/10/23, indicated an error with medication set-up. P1 missed Cymbalta (an anti-depressant), Clozapine (anti-psychotic) and Chantix (smoking cessation). The note indicated P1s thoughts of suicidal ideation and serious injurious behavior have worsened. P1 feels like her brain is being shocked with zaps. P1 was suffering from increased nightmares, restless, more jittery, increased command hallucinations, difficulty with sleep, nausea, diarrhea, urinary urgency, some	G0574 G0578		

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G0578	Continued from page 32 confusion, and vivid dreams. Upon interview on 3/22/23, at 11:33, a pharmacist stated P1's last refill of Clozaril was 12/30/23, she had a lab draw on 1/30/23, but no refill request. Her next Clozaril dose was filled 3/15/23 with a titration order. "She went most of February and half of March without Clozaril." "Her Cymbalta was last filled on 1/26/23, so I am assuming she has missed doses of that as well." Upon interview on 3/22/23, at 2:10 p.m., the agency Registered Nurse (RN)-B stated that she completed a visit on 1/26/22, this was her last visit with P1 as the agency was changing branches. She stated she did run out of two medications during the medication set-up. RN-B could not recall the names of the medications, but stated one was an anti-psychotic and on was an antidepressant. She stated she may have charted incorrectly that all medications were set-up as she automatically put in the dates the medications should have been set-up for. RN-B stated sometimes she charts her medication set-up in the home and other times after the visit. She stated she is able and has copied and pasted medications and then puts in the dates filled. RN-B stated on 1/26/23 she was short about 4-5 day of the "anti-psychotic and the antidepressant," she stated she left a post-it note on P1's medication set box to fill in the missing medications when she picked them up from the pharmacy. RN-B could not recall if she ordered refills. RN-B stated she did not reach out to the ordering provider that she did not have enough medications to complete the medication set-up. RN-B was aware that Clozaril required lab results prior to refilling. RN-B denied follow-up with P1 to see if medications were refilled and set-up. Upon interview on 3/22/23, at 3:53 p.m. RN-F stated it is the expectation of the HHA for the nurse to call the provider if there is a concern of not having enough medications in the home and to follow-up with the patient if medication set-up is not completed in full during visit. An agency policy titled Medication Management, Home Care dated 5/19/22, indicated to notify the practitioner regarding any unresolved concerns regarding the patient's medication regimen.	G0578		

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G0578	Continued from page 33 An agency policy titled Medication Management, dated 6/8/22, indicated the client/caregiver will be instructed on special precautions for high-risk medications identified on the medication profile.	G0578		
G0616	Patient medication schedule/instructions CFR(s): 484.60(e)(2) Patient medication schedule/instructions, including: medication name, dosage and frequency and which medications will be administered by HHA personnel and personnel acting on behalf of the HHA. This ELEMENT is NOT MET as evidenced by: Based on observation, interview, and record review the facility failed to provide 1 of 3 patients (P1) and/or representatives a with a medication regimen, including medication name, dose and frequency and which medications will be set-up by the home health agency (HHA) in the patient's home. P1's Home Health Certification and Plan of Care (POC) dated 1/21/23, indicated P1 diagnoses included schizoaffective disorder (a combination of schizophrenia and mood disorders), major depression disorder, bipolar disorder, anxiety disorder, pain, unspecific psychosis, post-traumatic stress disorder, chronic systolic stress disorder, obesity, and type II diabetes. P1's frequency of visits was skilled nursing visits every other week and one as needed (PRN) visit for changes in medical condition. P1's orders of discipline and treatments. SN to review medication profile and reconcile medications as needed, SN may instruct and reinforce medication teaching related to use of medications to treat disease process, SN may fill medication orders/profile bi-weekly. SN for administration of ability via IM injection every month. Self-management, medication set-up/management, implement pathways, medication management, assess for medication compliance and alert physician of significant issues/missed doses. Teach patient/caregiver how to set-up medications. Teach medication reminders including alarms. Upon observation on 3/23/23, at 9:35 a.m. P1 had a large plastic unlocked tote with medications. In tote was a provider medication list dated 1/17/23. P1 also had a list of a Clozaril titration dated 3/10/23, from the provider. An agency medication profile list was not found.	G0616		

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G0616	Continued from page 34 Upon interview on 3/23/23, at 11:17 a.m. P1 stated she did not have a medication list from the HHA in her home. She stated she would like a list, as there are times when she questions her medications and would like to perform her own reconciliation when she is having a question. Upon interview on 3/23/23, at 11:32 a.m. RN-C stated she has not left a printed medication sheet in P1's home. RN-C was not certain if it was the agencies practice to have an updated medication list in the home or if the providers list was enough. Upon interview on 3/23/23, at 3:53 p.m. RN-E stated it was her expectation that patients have an updated medication profile in the home, especially since P1's plan of care indicated to teach patient/caregiver how to set-up medications and P1 had multiple disciplines in the home. A facility policy titled Medication Management, home care dated 5/19/22, under the heading Patient Teaching, indicated the importance of keeping an accurate, up-to-date list of medications in the home and advise the patient to keep the medication list handy at all times in case of an emergency.	G0616		
G0620	Other pertinent instructions CFR(s): 484.60(e)(4) Any other pertinent instruction related to the patient's care and treatments that the HHA will provide, specific to the patient's care needs. This ELEMENT is NOT MET as evidenced by: Based on observation, interviews, and document review the home health agency (HHA) failed to provide 1 of 3 patients (P1) pertinent instruction related to the patient's specific care needs. The plan of care and a crisis plan were not present P1's home upon visit. P1's Home Health Certification and Plan of Care (POC) dated 1/21/23, indicated P1 diagnoses included schizoaffective disorder (a combination of schizophrenia and mood disorders), major depression disorder, bipolar disorder, anxiety disorder, pain, unspecific psychosis, post-traumatic stress disorder, chronic systolic stress disorder, obesity, and type II diabetes. P1's frequency of visits was skilled nursing visits every other week and one as needed (PRN) visit for changes in medical condition. P1's orders of discipline and treatments. 1. Skilled nursing (SN) to	G0620		

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G0620	Continued from page 35 review medication profile and reconcile medications as needed, SN may instruct and reinforce medication teaching related to use of medications to treat disease process, SN may fill medication orders/profile bi-weekly. 4. Skilled nurse for observation/assessment of patient's impaired nutrition related to obesity, instruction patient/caregiver on interventions designed to improve nutritional intake and patient well-being. 5. SN for administration of ability via IM injection every month. 6. SN to perform multifactor fall risk assessment and implement interventions to decrease risk of falls. SN to instruct on home safety, impact of polypharmacy, environmental safety and fall prevention. 7. SN to evaluate and develop plan of care to be countersigned by physician, SN to assess/evaluate co-morbid conditions including schizoaffective disorder and other conditions that present themselves while this episode to identify changes and intervene to minimize complications. 8. SN to observe and assess cardiovascular system to identify changes and intervene to minimize complications. SN to provide skilled teaching related to altered cardiovascular status including pathophysiology, nutrition, medication regimen, and permitted activities. May perform oxygen saturation levels as needed for signs and/or symptoms of possible respiratory complications. 9. SN to provide instructions related to management of congestive heart failure including, but not limited to definition, risk factors, measures to prevent exacerbation, signs/symptoms, and potential complications. 10. SN to monitor plan for current treatment of depression such as effects of medication and/or need for referral for other treatment. 10. All orders disciplines will assess for vulnerability/maltreatment concerns/changes, review the vulnerable/abuse prevention plan, facilitate patient advocacy, notify physician/nurse practitioner and/or refer to MAARC/county common entry point as appropriate for changes/concerns in vulnerability/maltreatment. 11. All ordered disciplines will implement the individual vulnerability/maltreatment/abuse prevention plan, self-management, personal safety, implement pathway, need for skilled care related to fall risk and or behavior and or need for other disciplines. 12. Self-management, medication set-up/management, implement pathways, medication management, assess for medication compliance and alert physician of significant issues/missed doses. Teach patient/caregiver how to set-up medications. Teach medication reminders including alarms. Upon interview on 3/23/23, at 111:40 a.m. P1 stated she was not aware of everything her skilled nursing are to	G0620		

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G0620	Continued from page 36 be completing on her nursing visits. She denied having an updated plan of care in her house following her re-certification assessments and/or any changes in her medical care. P1 stated the HHA nurses have advised her when she is having suicidal ideations or hallucinations to call her father, call psychiatrist and/or psychologist and to call or text the suicide hotline. P1 denied having a documented crisis plan from the HHA at any time. Upon observation on 3/23/22 at 9:30 a.m. P1 had an admission folder from the HHA. In the folder was signed forms including bill or rights, consent form, and service agreement. There was not a copy of P1's plan of care or a crisis plan in the folder. Upon interview on 3/23/22, at 11:32 a.m. RN- C stated she did know of a documented crisis plan for P1 and was unaware if P1 had a plan of care in the home. Upon interview on 3/23/22, at 11:35 a.m. RN-G stated P1 had an emergency plan that she would provide to the surveyor, however, was not certain if P1 had a plan in the home or when a crisis had been updated and provided to the client. Upon interview on 3/23 at 3:53 p.m. RN-F stated it is her expectation that all the patient's especially those diagnosed with mental illness have a crisis in the home and is an HHA expectation that every patient has their plan of care in the home. RN-F stated the agency is in a software transition and they are working getting a patient portal. An agency policy titled Initial Assessment/Certification dated 4/8/21, indicated findings are documented in the clinical record and may be placed in the patient's home.	G0620		
G0706	Interdisciplinary assessment of the patient CFR(s): 484.75(b)(1) Ongoing interdisciplinary assessment of the patient; This ELEMENT is NOT MET as evidenced by: Based on interview and document review the home health agency (HHA) failed to involve an interdisciplinary	G0706		

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G0706	Continued from page 37 approach from all health providers for involvement in the patient's initial assessment, follow-up assessments, and plan of care for 1 of 3 patients (P1) reviewed. P1 was taking Clozaril, a high-risk anti-psychotic medication, and did not include P1's psychologist and psychiatrist interventions, assessment expectations, and a crisis plan to meet P1's care needs. P1's Home Health Certification and Plan of Care (POC) dated 1/21/23, indicated P1 diagnoses included schizoaffective disorder (a combination of schizophrenia and mood disorders), major depression disorder, bipolar disorder, anxiety disorder, pain, unspecific psychosis, post-traumatic stress disorder, chronic systolic stress disorder, obesity, and type II diabetes. R1's frequency of visits was skilled nursing visits every other week and one as needed (PRN) visit for changes in medical condition. R1's orders of discipline and treatments. Upon interview on 3/23/23, at 10:55 a.m. P1's psychologist stated she had not any communication with the agency since she had been working with P1 for 16 months. P1 stated she was aware that the agency set-up meds, but uncertain as to what else they provide. She sated she has never been updated about increased symptoms of concerns when P1 has had a crisis. Upon interview on 3/23/23, at 5:12 p.m. P1's psychiatrist stated she has expectations of what an agency should be assessing. The psychiatrist stated she would be sending an e-mail to the surveyor of her expectations. On 3/10/23, the clinic reached out to the HHA requesting a medication list for care involvement, however none was received. "I would like to know what the agency does during the visits and how can they handle all of co-morbidities once every other week?" An email from the psychiatrist dated 3/24/23, at 12:21 indicated expectations as follows: Under the heading Psychiatric Symptoms: Behavior, Mood/Affect, Speech, Thought Processes, Social Judgement, Appearance, Suicide Risk, Hallucinations, Paranoia, Delusions, tardive dyskinesia. Also, hours of sleep, quality of sleep, exercise, and smoking. Under the heading Medical Symptoms: Infections, Gastrointestinal, (Bowel Assessment), Salivation, Cardiovascular/pulmonary (vital signs, cough, shortness of breath), under the heading Screens: Nutrition, Domestic Abuse Assessment, Fall Risk Assessment. A visit summary indicating any	G0706		

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G0706	Continued from page 38 concerns, medication compliance, laboratory compliance, future visits/appointments. Measurable treatment goals listed, and progress of goals made along with education. The visit should include if the provider was contacted, and any refills needed. Upon interview on 3/23/23, at 3:16 p.m. RN-A, clinical supervisor stated he had not had any contact with P1's psychiatrist or psychologist. P1 was uncertain whether other staff had reached out to them since they do not sign P1's orders. Upon interview on 3/23/23, at 3:53 p.m. RN-F denied any agency contact with P1's interdisciplinary team. An agency policy regarding notifying of providers or interdisciplinary team was requested, none was received.	G0706		

DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

Electronically Delivered via Email

April 12, 2023

Administrator
ADARA HOME HEALTH INC
25 1ST AVENUE NE STE 100
BUFFALO, MN 55313

Re: Event ID:

Dear Administrator:

A survey of the Home Care Provider named above was completed on March 23, 2023, for the purpose of assessing compliance with State licensing regulations. At the time of survey, the survey team from the Minnesota Department of Health, Health Regulation Division, noted no violations of the requirements under Minnesota Statutes Sections 144A.43 to 144A.482.

Attached 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,

Kamala Fiske-Downing

Kamala Fiske-Downing
Minnesota Department of Health

Health Regulation Division
Telephone: (651) 201-4112 Fax: (651) 215-9697
Email: Kamala.Fiske-Downing@state.mn.us

Minnesota State Department of Health

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ADARA HOME HEALTH INC	25 1ST AVENUE NE STE 100 , BUFFALO, Minnesota, 55313

(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
00000	Initial Comments On 3/22/23 - 3/23/23, an abbreviated complaint survey was conducted. No licensing orders were issued during this survey.	00000		

Office of Primary Care and Health Systems Management

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