

Wisconsin Department of Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 0020482	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED C 01/28/2025
NAME OF PROVIDER OR SUPPLIER HUNTER MEADOW		STREET ADDRESS, CITY, STATE, ZIP CODE 1432 HUNTER AVE FOND DU LAC, WI 54937		
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M 000	INITIAL COMMENTS On 01/07/2025, with additional information gathered through 01/28/2025, Surveyor investigated 2 complaints. One (1) of 2 complaints were substantiated and 1 new deficiency was identified. Census 4	M 000		
M 580	88.10(3)(p) Prompt and Adequate Treatment Prompt and adequate treatment. To receive prompt and adequate treatment and services appropriate to the resident's needs. This Rule is not met as evidenced by: Based on observation, interview and record review, the adult family home did not ensure residents received treatment and services appropriate to the resident's needs for Resident 1. Findings Include: On 12/30/2024, the department received a complaint alleging the provider did not manage resident diabetic needs. On 01/07/2025, at approximately 2:00PM, Surveyor interviewed Advanced Practice Nurse Prescriber A (APNP-A). APNP-A reported Resident 1 had type 1 diabetes that was difficult to control. APNP-A felt the best option for Resident 1 was the use of an automated system as the use of this system is intended to decrease the likelihood of human error. APNP-A explained the automated system worked with Bluetooth and all information could be uploaded for APNP-A to review remotely.	M 580		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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M 580	Continued From page 1 APNP-A described there are two devices involved. The first is the Dexcom, which provides continuous blood glucose monitoring. There is a small censor placed under the skin and it communicates with the Dexcom device to provide continuous blood glucose readings. The second device is the Omnipod, which has a built-in censor and is loaded with a pre-filled insulin pod. The pod has enough insulin to last approximately 72 hours. The pod attaches to the user's skin. The user must enter the blood sugar reading from the Dexcom into the hand held Omnipod device. The Omnipod censor then makes calculations and delivers the appropriate amount of insulin through a small cannula. APNP-A further explained the Dexcom only reads blood glucose up to 400. The Dexcom will read, "high" for blood glucose reading of 400. APNP-A reported when the blood glucose reading is at 400, a manual finger stick with a traditional glucometer should be used to get the true reading. The glucometer reading from the fingerstick should be entered into the Omnipod, so the correct dose of insulin is administered. APNP-A explained blood glucose levels were to be checked with the Dexcom before meals, 2 hours after meals and prior to bed. Each time, the glucose reading is checked, the number should be entered into the Omnipod so it can calculate and deliver insulin if needed. APNP-A reported the Omnipod also has a feature to program meals with an estimated amount of carbohydrates. When the user enters a meal into the Omnipod it considers the estimated carbohydrates and the blood glucose readings and administers the insulin accordingly. APNP-A stated these were all pre-set by him/her.	M 580		

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M 580	Continued From page 2 APNP-A advised training was provided when Resident 1 began using the automated system (2023). The first training was at the home and the second at the provider office location. An official Omnipod representative completed the training. Additionally, APNP-A advised s/he and the diabetes educator came after hours and provided training and guidance. APNP-A stated s/he assumed the adult family home provider would continue the training as caregivers quit and were replaced. APNP-A explained the adult family home was provided a step-by-step guide with pictures for caregivers to reference if needed. APNP-A further stated, if there was a failure with the Omnipod delivering insulin, there was an ordered backup plan and insulin with parameters at the home. On 01/15/2025, at approximately 2:00PM, Surveyor met with APNP-A at St. Agnes Hospital for a tutorial of how the equipment worked. APNP-A explained and provided a demonstration. APNP-A reported Resident 1 passed away at his/her home on 12/20/2024. APNP-A stated s/he downloaded the readings from the Dexcom system and saw Resident 1's blood glucose was reading 400 all day on 12/18/2024 and 12/19/2024. APNP-A stated there was no evidence of a manual fingerstick and glucometer reading entered in the Omnipod, as the data shows 400 all the way across. APNP-A explained, since 400 was entered, the Omnipod only dispensed enough insulin for that specific reading and not the true reading obtained through the fingerstick. Surveyor inquired how APNP-A knew the fingersticks were not conducted with the glucometer. APNP-A presented Resident 1's glucometer. The glucometer had a memory that stores the data by date and time and can be reviewed later. Surveyor reviewed the data in the	M 580			

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M 580	Continued From page 3 glucometer and noted the last fingerstick reading was dated 12/09/2024 at 12:12PM. There were no readings for 12/18/2024 or 12/19/2024. APNP-A expressed concern that the blood glucose remained high with no intervention. Additionally, the downloaded information showed blood glucose levels were not checked as many times as ordered. On 01/09/2025, at approximately 3:00PM, Surveyor reviewed Resident 1's office visit with APNP-A, dated 10/01/2024. The office visit noted Resident 1 has the following diagnosis: Diabetes mellitus with peripheral angiopathy, uncontrolled type 1 diabetes mellitus with hyperglycemia and brittle diabetes mellitus. Further review of the office visit noted the following: "[S/he] does not skip meals at the group home and meal assistance is provided and prepared by [his/her] caregivers ... When [his/her] Dexcom is unreadable due to high glucose they do use backup glucometer and perform fingerstick readings ..." Surveyor reviewed specific information about the Dexcom. Information obtained on 01/22/2025 at 3:02PM from https://www.adces.org/education/danatech/glucose-monitoring/continuous-glucose-monitors-(cgm)/cgm-selection-training/dexcom-g7-and-stelo-differences#:~:text=Glucose%20Reading%20Range%3A%20Stelo%20reads,40%20and%20400%20mg%2FdL. Glucose Reading Range: " ... the G7 (Dexcom) reads between 40 and 400 mg/dL." "Agreement of CGM to Reference When CGM	M 580		

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M 580	Continued From page 4 Reads "Low" or "High" [sic]The System reports glucose readings between 40 and 400 mg/dL. When the System determines the glucose reading is below 40 mg/dL, it displays "LOW" in the Receiver Status Box. When the System determines that the glucose level is above 400 mg/dL, it displays "HIGH" in the Receiver Status Box." Information regarding high readings for continuous glucose monitoring Dexcom obtained on 01/27/2025, at 10:29AM, from https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120005S018b.pdf. Surveyor reviewed specific information about the Omnipod. Information retrieved on 01/21/2025 at 5:35PM from https://consumerguide.diabetes.org/products/omnipod-dash. "The Omnipod Dash is a tubeless insulin delivery system that includes a Pod that is worn for up to three days, and a personal diabetes manager (PDM) with color touch screen that controls the Pod's functions. The PDM is available in English and Spanish and communicates with the Pod via Bluetooth to deliver the programmed basal and boluses based on patient entered data. The Dash system can pair to a Contour Next One BG meter via Bluetooth such that BG values are automatically entered into the PDM or glucose values can be manually entered from other meters or CGMs into the PDM. The Pod delivers basal insulin regardless of distance from the PDM but must be within five feet of the PDM to deliver boluses. The Omnipod Display app allows users to view PDM data on their smartphones and the View app allows users to share their insulin data	M 580		

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M 580	Continued From page 5 remotely with up to 12 people. The PDM features a built-in CalorieKing food library with the carb content more than 80,000 foods and beverages (English only) and stores up to 50 preset carb values." On 01/27/2025 at approximately 3:50PM, Surveyor reviewed Resident 1's undated individual support plan (ISP). The ISP noted the following: DIABETIC STATUS ... The patient was diagnosed with diabetes type 1 at age 3, and has been treated with insulin therapy since then. [S/he] has struggled with labile [sic] control and has had frequent hospital visits for hyperglycemia ... Individual's Goals/Desired Outcomes: Maintain healthy diet and find balance with blood glucose readings Client is currently using a Omnipod to control [his/her] blood glucose. The Omnipod gets changed every 3 days by management only. [S/he] is currently receiving Lantus insulin and Humalog insulin through the Omnipod when needed by following directions. Client has a Dexcom that [s/he] wears for 10 days then it is changed by staff. Dexcom tells you what [his/her] blood glucose readings. To [sic] follow by the Omnipod to give blood glucose to client ... Blood sugars are being monitored four times daily, (See MAR) ..." Note: Review of the Medication Administration Record (MAR) below identified blood sugars are checked 6 times daily. On 01/09/2025, at 2:15PM, Surveyor reviewed Resident 1's December 2024 MAR regarding insulin checks. The order was as follows: "Check blood sugars before meals, 2 hours after meals and at bedtime. Use Dexcom to check blood sugar then program result into insulin	M 580			

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M 580	Continued From page 6 pump. (If insulin pump is not working, see PRN insulin orders and follow those orders.)" The times specified on the MAR were 6:00AM, 10:00AM, 12:00PM, 2:00PM, 4:00PM and 8:00PM (6 total). On 01/15/2025, at approximately 2:00PM, Surveyor reviewed the Dexcom and Omnipod readings for 12/15/2024 through 12/19/2024 (Resident 1 passed away on 12/20/2024) and noted several instances where the Dexcom blood glucose reading, and meals were not entered into the Omnipod. Additionally, review of the MAR showed documented blood sugars that were not entered or did not match the data in the Omnipod. Omnipod Reading for 12/15/2024: 8:00AM-9:00AM: 260 8:00PM-9:00PM: 315 9:00PM-10:00PM: 334 10:00PM-11:00PM: 339 Note: There were no blood sugar entries from 9:00AM - 8:00PM (11 hours) to determine the amount if insulin needed. The only meal entered was breakfast and nothing indicating if the meal was skipped. The mid-morning and mid-afternoon checks were not entered. The MAR for 12/15/2024, showed the following entries: 1st check: 260 2nd check: 245 - not entered in Omnipod 3rd check: 70 - not entered in Omnipod 4th check: 147 - not entered in Omnipod 5th check: 118 - not entered in Omnipod 6th check 315 Note: The only matching entry was the 1st check. All other entries were not entered into the Omnipod to determine if insulin was needed and	M 580		

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M 580	Continued From page 7 distributed. Omnipod Reading for 12/16/2024: 7:00AM-8:00AM: 221 10:00AM- 1:00AM: 165 12:00PM-1:00PM: 228 7:00PM-8:00PM: 336 Note: Two out of 6 entries were missing. The mid-afternoon check was not entered. No dinner meal was entered and nothing indicating meal was skipped. The MAR for 12/16/2024, showed the following entries: 1st check: 221 2nd check 223 - Not entered in Omnipod 3rd check 266 - Not entered in Omnipod Omnipod Reading for 12/17/2024: 6:00AM-7:00AM: 326 10:00AM-11:00AM: 475 12:00PM-1:00PM: 400 8:00PM-9:00PM: 283 Note: Two out of 6 missing entries not entered. Mid-afternoon and before dinner meal. Nothing was entered from 12:00PM-8:00PM leaving 8 hours since the last check and possible insulin delivery. The MAR for 12/17/2024, showed the following entries: 1st check 110 2nd check 252 Note: Entries did not match and were not entered into the Omnipod. Omnipod Reading for 12/18/2024: 10:00AM-11:00AM: 400 1:00PM-2:00PM: 400 5:00PM-6:00PM: 400	M 580			

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M 580	Continued From page 8 6:00PM-7:00PM: 400 7:00PM-8:00PM: 400 8:00PM-9:00PM: 400 9:00PM-10:00PM: 400 10:00PM-11:00PM: 400 Note: Early morning check or dinner meal was not entered in the Omnipod. Blood sugar read 400 throughout the day. The MAR for 12/18/2024, showed the following entries: 1st check 400 2nd check 400 Omnipod/Dexcom reading for 12/19/2024: 6:00AM-7:00AM: 400 2:00PM-3:00PM: 400 8:00PM-9:00PM: 400 Note: Three of 3 checks were not entered into the Omnipod - mid-morning, noon, mid-afternoon and evening. No meals were entered. The MAR for 12/19/2024, showed the following entries: 1st check 400 2nd check 400 3rd check 255 4th check 323 5th check 369 Note: The 3rd, 4th, and 5th check did not match the readings entered in the Omnipod (400). The 6th check was not documented. On 01/15/2025, at approximately 11:15AM, Surveyor interviewed Caregiver B. Caregiver B confirmed s/he worked the second shift, 2:00PM-10:00PM on 12/18/2024 and 12/19/2024. Caregiver B reported both days, Resident 1 was "sick." Caregiver B reported Resident 1 did not	M 580			

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M 580	Continued From page 9 skip meals but did not want to eat on those two days. Caregiver B explained s/he tried to feed Resident 1, but s/he only wanted to drink water. Caregiver B reported Resident 1 kept saying s/he wanted to go home to be with his/her family member. Caregiver B reported s/he entered the reading of 400 from the Dexcom into the Omnipod, but the blood glucose reading never came down. Caregiver B stated s/he did not know anything about needing to do a fingerstick if the Dexcom read 400-high. Caregiver B recalled reporting the concern to the manager. On 01/22/2025, at 3:26PM, Surveyor interviewed Manager C. Manager C explained the Omnipod representatives provided training on how to use it. The Omnipod representative provided training to the previous nurse, who has now retired, Manager A, another manager and a few staff who are no longer employed. Manager B reported s/he, the other manager and the prior nurse provided training to caregivers. Manager C advised the Omnipod representative provided them with training material. Manager C confirmed knowledge of the Dexcom's limitation of only reading glucose levels up to 400 as s/he recalled reading it somewhere in the training materials. Manager C confirmed the Dexcom would read "high" if it was over 400. Manager C reported a fingerstick and glucometer needed to be conducted if the Dexcom read high or 400. Manager C reported staff usually notified him/her if Resident 1's blood sugar was in the 300's and increasing. Caregivers were directed to follow the protocols listed on the MAR. Manager C advised caregivers should notify the on-call number if blood sugar is elevated for direction. During the interview, Manager C reviewed his/her notes and stated s/he was not notified of any elevated blood glucose readings on 12/18/2024 or 12/19/2024.	M 580		

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M 580	Continued From page 10 On 01/28/2025, at approximately 11:00AM, Surveyor interviewed Area Director D (AD-D). AD-D advised the nurse would have all the training information and related delegations, but s/he retired on 12/27/2024. AD-D stated s/he will attempt to obtain the information as soon as possible. AD-D advised the provider has hired a new nurse. The new nurse will be reviewing all diabetic protocols and providing in-depth training for caregivers. The new nurse also has plans to work with the diabetes educator from Aurora to achieve this task. Additionally, AD-D reported they will be implementing a new system to improve medication management, which will simplify the process for caregivers. Note: On 01/28/2025 at 12:03PM, AD-D provided documentation of delegations related to Resident 1's insulin pump. There was no information related to training. Resident 1's blood glucose level on the Dexcom was reading 400. Dexcom does not read over 400. Fingersticks were not performed to determine the true blood glucose level and the high reading from the Dexcom was entered into the Omnipod. This resulted in Resident 1 only being medicated with enough insulin for a blood glucose of 400. Interviews with APNP-A and Manager C confirm knowledge of the Omnipod's inability to read over 400, thus requiring a fingerstick. The Omnipod and Dexcom data showed entries were not being conducted in the intervals that were ordered and meals were not always entered. Additionally, the MAR showed readings that did not match the readings entered in the Omnipod, and readings that were not entered into the Omnipod.	M 580		