PART C – Decision under Appeal

The decision under appeal is the Ministry of Social Development and Social Innovation (ministry) reconsideration decision dated August 19, 2014 which denied the appellant's request for a supplement to cover the cost of glucose sensors. The ministry found that the following requirements of Schedule C of the *Employment and Assistance for Persons With Disabilities Regulation* (EAPWDR) were not met:

- the supply is not required for one of the purposes as set out in Section 2(1)(a)(i); and,
- the supply is considered an accessory and does not fit within the definition of a "non-conventional glucose meter" pursuant to Section 3.12(1).

PART D – Relevant Legislation

Employment and Persons with Disabilities Regulation (EAPWDR), Sections 62 and 69 and Schedule C, Sections 2 and 3.12

PART E – Summary of Facts

The evidence before the ministry at the time of the reconsideration decision included:

1) Quote by the manufacturer for mini-link transmitter($799) and glucose sensors(5/box) at $325;
2) Letter dated June 10, 2014 from the appellant's physician, a specialist in internal medicine and endocrinology ("endocrinologist"), 'To whom it may concern' regarding the Pharmacare funding of continuous glucose sensing devices. The physician wrote in part that:
    - The appellant has been under her care for assistance in self-management of Type I diabetes over the past 18 years.
    - The appellant suffers hypoglycemic unawareness with recurrent episodes of severe hypoglycemia including recurrent night seizures.
    - He has been hospitalized on many occasions, including currently since January 8, 2014 continuously;
    - She and her colleagues in the division of endocrinology, in the clinical teaching unit and in the high acuity unit (HAU), have struggled to design a solution, now involving two pumps augmented by continuous glucose sensing devices.
    - Any discharge plan hinges on a warning system.
    - This is truly an exceptional case.
3) Letter dated July 30, 2014 from the endocrinologist 'To whom it may concern' regarding the ministry funding of continuous glucose sensing devices. The physician repeated much of the information in her June 10, 2014 letter and added:
    - She and her colleagues feel that it would be unsafe to discharge the appellant from hospital without continuous glucose monitoring augmented by alarm amplification.
    - Sensors are absolutely necessary to avoid imminent and substantial danger to the appellant's health by way of hypoglycemia induced seizure, coma and death; and,
4) Request for Reconsideration dated August 5, 2014 and fax dated August 6, 2014.

In his Request for Reconsideration, the appellant wrote:

- The items requested are necessary to avoid imminent and substantial danger to his health.
- He is a Type I diabetic with hypoglycemic unawareness and has found himself unconscious out in public. He was once unconscious in the middle of a busy intersection in the city. These episodes are increasing over the years.
- The sensors will allow him an early-warning with an alarm and will shut down his pump, allowing his body to recoup his sugar levels.
- Without the sensors, he may not survive the next 5 years.

In the fax dated August 6, 2014, the appellant's advocate, a social worker, stated that the appellant only requires funding for the sensors and not the transmitter. The appellant will remain in hospital until the funding is received.

In his Notice of Appeal dated September 3, 2014, the appellant expressed his disagreement with the ministry's reconsideration decision and wrote:

- He has been hospitalized since January 8, 2014 for blood sugar control.
- All alternatives have been ruled out and still he cannot get adequate control.
- This has a life or death situation every day of his life. Without the sensors, he will most certainly die.

Prior to the hearing, the advocates for the appellant provided the following additional documents:

1) Special Authority Request to the Ministry of Health dated March 1, 2014 made by the endocrinologist on behalf of the appellant on the basis of treatment failure on reference drug and diagnosis and other patient-specific indicators;
2) Special Authority Request to the Ministry of Health dated April 11, 2014 made by the endocrinologist on behalf of the appellant on the basis of diagnosis and other patient-specific indicators, including: Type I diabetes, hospitalized repeatedly with severe hypoglycemic seizures, recurrent loss of consciousness, unable to discharge due to recurrent unperceived unconscious lows on any insulin regimen so far, despite insulin pump, but recurrent night seizures unless he has access to the continuous glucose sensor with auto-off pump feature and impending low glucose alarm;
3) Letter dated August 8, 2014 from the endocrinologist to the Director of Special Authority regarding Pharmacare coverage of continuous glucose sensing device for the appellant. The physician wrote in part that:
    - The appellant 's insulin pump has been registering all of his glucose meter testing over the past few weeks.
    - Without the sensor, the appellant was logging in the range of 30 glucose tests per day with the help of nursing staff through the night.
    - Hospital Records of glucometer readings for the period April 5, 2014 through June 1, 2014 were enclosed;
4) Letter dated September 16, 2014 to the Minister of Health in which the appellant wrote in part:
    - Since January 8, 2014 he has been confined to hospital and his doctors have been trying to control his blood sugars with very little success.
    - Since his diagnosis for Type I Diabetes Mellitus in the late 1970's, there have been a number of hospitalizations and life-threatening emergencies, including being found face down in the middle of a busy intersection in the city.
    - He has now been classified as 'hypoglycemic unaware' and as being a severe 'brittle diabetic'.
    - His doctor has tried many different treatment plans with little success, which have included, but not limited to, bed side alarms, heparin with his insulin, and diet changes.
    - One treatment plan that has shown success is the sensor/transmitter device which transmits his blood sugars to his insulin pump which will alarm when his blood sugar drops below a preset limit.
    - The cost of the sensors is estimated at $325 per month while the cost of him being in the hospital is $1,304 per day.
    - He is not eligible for discharge from the hospital until he has the system in place.
    - He has currently exhausted any of his and his family's personal finances and Pharmacare has denied the requests of his endocrinologist.
5) Report dated September 2014 by the manufacturer regarding Continuous Glucose Monitoring systems for patients with Type I diabetes. The Report included the following points:
    - Diabetes mellitus is a chronic metabolic disorder caused by a lack of insulin resulting in a loss of blood glucose control.
    - Complications associated with diabetes are classified as acute or chronic. Acute complications include hypoglycemia and diabetic ketoacidosis, both of which can be life-threatening.
    - Hypoglycemia is caused when the glucose level falls below the normal blood glucose concentration and can result in seizure/coma, cognitive dysfunction and can even be

fatal. The average estimated direct cost of a single severe hypoglycemic event in Canada is $2,074 per episode.

- The current standard of care in patients with Type I diabetes on insulin is to self-monitor blood glucose levels with finger-stick measurements at least 3 times per day, though for many patients they may conduct it up to 12 times per day.
- Finger-stick blood glucose measurements and conventional blood glucose meters provide patients with only a single point in time measurement of the current blood glucose level and not its trending (increasing or decreasing) nor its rate of change (fast or slow).
- The cornerstone of the diabetes technology system is the insulin pump, which continuously delivers rapid-acting insulin 24 hours a day. This eliminates the need for manual insulin injections and allows for insulin delivery to more closely mimic the function of a healthy pancreas.
- An insulin pump and continuous glucose monitoring system consists of: 1) a sensor-augmented insulin pump, 2) glucose sensor, and 3) mini-link transmitter.
- The glucose sensor is a small electrode that is inserted into the subcutaneous adipose tissue using an automatic insertion device by the patient. Each sensor is worn for up to 6 days.
- Continuous glucose monitoring requires the use of a mini-link transmitter and glucose sensors.
- The sensor continuously measures glucose levels in the interstitial fluid and wirelessly relays these readings to the pump by means of a radiofrequency transmitter.
- The pump displays the glucose readings every 5 minutes; the immediate glucose level as well as the direction of glucose transition is displayed.
- The continuous glucose monitoring component of the insulin pump and the continuous glucose monitoring system monitors patients' glucose levels and provides regular updates of these readings up to 288 times per day, allowing patients and their physicians to evaluate the changes in interstitial glucose levels.
- The insulin pump and continuous glucose monitoring system have several settings which can be used to help optimize glycemic control including upper and lower threshold limits set to define the target glucose range. When the sensor detects glucose values that exceed the preset limits, the pump will alert the patient. With the predictive alerts turned on, the pump will notify the patient of a potential pending hypo or hyper glycemic episode before it happens, therefore helping to keep the glucose level in the target range.
- The 'low glucose suspend' functionality helps to prevent severe hypoglycemic episodes day or night by automatically suspending insulin delivery for up to 2 hours when the hypoglycemic threshold is crossed , and to avoid hypoglycemic rebound by enabling resumption of insulin delivery when glucose levels recover, or at the 2-hour interval.

At the hearing, the ministry provided the following additional documents:

1) Ministry emails between departments on September 18, 2014; and,
2) Print out from the manufacturer's website with the cost of the sensors.

At the hearing, the appellant and his advocates stated:

- The lack of glucose sensors as part of the monitoring system poses a detrimental risk to his health. Without the sensors, there is a high possibility of death.

- As has been set out in the documents, he has been found unconscious, face down, in the middle of the street because of low blood sugar.
- His situation is unusual since he goes from super high levels to him being non-responsive in a period of 40 minutes. This is outside the parameters of a normal diabetic. For him, the glucose sensors are more than "something nice to have," they are essential. He would consider an "accessory" to be something like a nice case for the pump.
- Normal blood sugar is in the range of 3.5 to 8 and anything in the 20's is high and below 3 is detrimental to a person's health. Treatment would start at a reading of 4.
- His blood sugar levels can drop extremely quickly and the continuous glucose monitoring system will alert him that his levels are dropping or going up at a fast rate.
- His endocrinologist has tried everything else and the continuous glucose monitoring system is the only thing that will work.
- The appellant cannot be discharged from the hospital unless he has the continuous glucose monitoring system. No physician will sign his discharge papers without this in place because the appellant will have an event and be back into acute care.
- During his time in the hospital, the appellant has been in and out of the intensive care unit (ICU) and the HAU in order to stabilize him after problems with his blood glucose levels.
- The hospital has started providing the appellant with the continuous glucose monitoring system, including the glucose sensors, because he is in acute care and it is required to keep him alive. The hospital cannot continue to provide the glucose sensors after the appellant's discharge.
- If he leaves the hospital without the continuous glucose monitoring system, there will be a fatal event.
- If the appellant is equipped with the glucose monitoring system, the hospital will discharge him "the next day." There is nothing else keeping him in hospital.
- The appellant wants to go home. He has been in hospital for 8 months and, while there, he is also at risk of contracting other infections.
- The appellant's need for the continuous glucose monitoring system is not necessarily for the rest of his life. There is a chance that after a few years his condition will stabilize sufficiently not to need the continuous monitoring.
- While the cost of 1 box of sensors, which includes 5 sensors, is $325 and will last for 1 month, there are savings that can be realized by purchasing a 6 month's supply at one time.
- The glucose sensor can only stay in a person's body for up to 6 days. If it is left in longer than 6 days, it will either cause an infection or the body will start to reject it.
- The sensors provide a glucose reading every 5 minutes which is picked up by the transmitter and sent to the pump. The sensor takes the cellular liquid from the body and determines the blood sugar level and, through the transmitter, sends the reading to the pump.
- When the sensor is changed after 6 days, it takes the new sensor approximately 2 hours to become effective and start providing readings.
- In the appellant's situation, the problem with the hand prick blood glucose measurement and a conventional blood glucose meter is that the appellant's blood sugar level can go from a reading of 25 to 3 in a period of 15 to 20 minutes. When it has reached that low level, the appellant would not be thinking clearly and would "not be in a mindset to do any self glucose monitoring." His levels drop and increase too quickly for him to react in time.
- The higher levels are not as life-threatening as the low levels of blood glucose.
- The continuous glucose monitoring system identifies trends in blood sugar levels and provides alerts when there is a high rate of change. The record of trends provided also allows the

endocrinologist to adjust the appellant's medications.

- The glucose sensor is "internally imbedded" in the body and is a required part of the continuous glucose monitoring system. The system is a necessity for him to be able to live out of an institution.
- The system also needs to be calibrated twice a day through use of a finger prick measurement. An alarm goes off to alert the appellant and to indicate that the calibration is required.
- In the appellant's situation, he has to wear two pumps. One provides his body with insulin and the other provides glucose.

Admissibility of New Information

The ministry had not received a copy of the appellant's additional documents and the hearing recessed to allow the ministry to review the documents for admissibility. Neither the ministry nor the appellant objected to the admissibility of the additional information provided by the other party. The representatives for the appellant provided additional information regarding the appellant's diabetes and his need for glucose sensors. The ministry provided additional information regarding the cost of the glucose sensors. The panel admitted this additional information as being in support of information and records that were before the ministry at the time of reconsideration, in accordance with Section 22(4)(b) of the *Employment and Assistance Act*. The ministry also provided emails between departments and the panel considered this as part of the ministry's argument and not evidence.

The ministry relied on its reconsideration decision, as summarized at the hearing. The ministry also clarified at the hearing:

- With the conventional glucose meters, a person's blood is placed on a test strip.
- The ministry covers the cost of the test strips as they are set out on a list of eligible items.
- The glucose sensors are not on the ministry's list of eligible items.
- The ministry is not aware if the glucose sensors are on the ministry's list of non-eligible items.

PART F – Reasons for Panel Decision

The issue on the appeal is whether the ministry's reconsideration decision, which denied the appellant's request for a supplement to cover the cost of glucose sensors because not all of the requirements of Sections 2 or 3.12 of Schedule C of the EAPWDR were met, is reasonably supported by the evidence or a reasonable application of the applicable enactment in the circumstances of the appellant.

Pursuant to Section 62 of the EAPWDR, the applicant must be a recipient of disability assistance, or be a dependent of a person in receipt of disability assistance in a variety of scenarios. If that condition is met, Schedule C of the EAPWDR specifies additional criteria that must be met in order to qualify for a health supplement for various items. In this case, the ministry has not disputed that the requirement of Section 62 has been met in that the appellant has been approved as a recipient of disability assistance.

Section 2(1) of Schedule C of the EAPWDR provides in part:

General health supplements

2 (1) The following are the health supplements that may be paid for by the minister if provided to a family unit that is eligible under section 62 [general health supplements] of this regulation:

(a) medical or surgical supplies that are, at the minister's discretion, either disposable or reusable, if the minister is satisfied that all of the following requirements are met:

(i) the supplies are required for one of the following purposes:

(A) wound care;

(B) ongoing bowel care required due to loss of muscle function;

(C) catheterization;

(D) incontinence;

(E) skin parasite care;

(F) limb circulation care;

(ii) the supplies are

(A) prescribed by a medical practitioner or nurse practitioner,

(B) the least expensive supplies appropriate for the purpose, and

(C) necessary to avoid an imminent and substantial danger to health;

(iii) there are no resources available to the family unit to pay the cost of or obtain the supplies;

(a.1) the following medical or surgical supplies that are, at the minister's discretion, either disposable or reusable, if the minister is satisfied that all the requirements described in paragraph (a) (ii) and (iii) are met in relation to the supplies:

(i) lancets;

(ii) needles and syringes;

(iii) ventilator supplies required for the essential operation or sterilization of a ventilator;

(iv) tracheostomy supplies;

(a.2) consumable medical supplies, if the minister is satisfied that all of the following requirements are met:

(i) the supplies are required to thicken food;

(ii) all the requirements described in paragraph (a) (ii) and (iii) are met in relation to the supplies; . . .

Section 3.12 of Schedule C of the EAPWDR provides:

Medical equipment and devices — non-conventional glucose meters

3.12 (1) In this section, "non-conventional glucose meter" includes

(a) a continuous glucose monitoring meter, and

(b) a talking glucose meter.

(2) A non-conventional glucose meter is a health supplement for the purposes of section 3 of this Schedule if the minister is satisfied that

(a) the glucose meter is medically essential to test blood glucose levels, and

(b) the person for whom the non-conventional glucose meter has been prescribed is unable to use a conventional glucose meter.

(3) The period of time referred to in section 3 (3) (b) of this Schedule with respect to replacement of a non-conventional glucose meter is 5 years from the date on which the minister provided the glucose meter being replaced.

Section 2(1) of Schedule C of the EAPWDR

The ministry's position is that the appellant is eligible to receive health supplements under Section 62 of the EAPWDR, but the appellant's request for a supplement to cover the cost of glucose sensors does not meet the requirement set out in Section 2(1)(a) of Schedule C of the EAPWDR. The ministry argued that the evidence does not establish that glucose sensors are a disposable or reusable medical or surgical supply required for one of the purposes set out in the section, namely: wound care, ongoing bowel care required due to loss of muscle function, catheterization, incontinence, skin parasite care, or limb circulation care.

The appellant did not directly advance a position that the glucose sensors are required for a purpose under Section 2(1)(a)(i) of Schedule C of the EAPWDR, although he did argue that the glucose sensors meet the requirement in Section 2(1)(a)(ii)(C) as they are necessary to avoid an imminent and substantial danger to his health. The appellant argued that he is a brittle Type I diabetic with hypoglycemic unawareness and has found himself unconscious out in public and these episodes are increasing over the years; he was once unconscious in the middle of a busy intersection in the city. The appellant argued that the sensors will allow him an early-warning with an alarm and will shut down his pump, allowing his body to recoup his sugar levels. The appellant argued that, without the sensors, he may not survive the next 5 years. At the hearing, the appellant and his representatives argued that the appellant cannot be discharged from hospital without the continuous glucose monitoring system augmented by alarm amplification. The appellant argued that no physician will sign his discharge papers without the system in place because it is unsafe and the appellant will have an event and end up back in acute care. The appellant argued that the glucose sensors are absolutely necessary to avoid imminent and substantial danger to the appellant's health by way of hypoglycemia induced seizure, coma and death.

Panel decision

The panel finds that the evidence demonstrates that the glucose sensors function to continuously measure glucose levels in the interstitial fluid and wirelessly relay these readings to the (insulin or glucose) pump by means of a radiofrequency transmitter. The purpose is to continuously measure blood glucose levels. Therefore, the panel finds that the ministry reasonably concluded that the glucose sensors are not required for one of the purposes of wound care, ongoing bowel care,

catheterization, incontinence, skin parasite care or limb circulation care, as set out in Section 2(1)(a)(i) of Schedule C of the EAPWDR.

The ministry did not address the appellant's argument at reconsideration regarding the requirement in Section 2(1)(a)(ii)(C) of Schedule C that the glucose sensors are necessary to avoid an imminent and substantial danger to his health. In her letter dated June 10, 2014 the endocrinologist wrote that the appellant has been under her care over the past 18 years and he suffers hypoglycemic unawareness with recurrent episodes of severe hypoglycemia including recurrent night seizures. She wrote that the appellant has been hospitalized on many occasions, including currently since January 8, 2014 continuously and any discharge plan hinges on a warning system. The endocrinologist reported that the appellant's is "truly an exceptional case." In her letter dated July 30, 2014, the endocrinologist wrote that she and her colleagues feel that it would be unsafe to discharge the appellant from hospital without continuous glucose monitoring augmented by alarm amplification and that the sensors are absolutely necessary to avoid imminent and substantial danger to the appellant's health by way of hypoglycemia induced seizure, coma and death. While the evidence demonstrates that the glucose sensors are necessary to avoid an imminent and substantial danger to the appellant's health, the panel finds that the ministry reasonably concluded that all of the requirements in Section 2(1)(a) of Schedule C must be met in order for the item to be provided by the ministry as a medical or surgical supply.

Section 3.12 of Schedule C of the EAPWDR

The ministry's position is that the appellant is eligible to receive health supplements under Section 62 of the EAPWDR, but the appellant's request for a supplement to cover the cost of glucose sensors does not meet the requirements set out in Section 3.12 of Schedule C of the EAPWDR. The ministry argued that while alternative glucose monitors are provided as a health supplement, there is no provision for accessories such as sensors.

The appellant's position is that his situation is unusual and, for him, the glucose sensors are more than "something nice to have," like an accessory; they are essential for him. The appellant argued that his blood sugar levels go from super high levels to him being non-responsive in a period of 40 minutes and that this is outside the parameters of a normal diabetic. The appellant argued that, in his situation, the problem with the hand prick blood glucose measurement and a conventional blood glucose meter is that his blood sugar level can go from a reading of 25 to a reading of 3 in a period of 15 to 20 minutes and, when it has reached that low level, he would not be thinking clearly and would "not be in a mindset to do any self glucose monitoring." The appellant argued that his levels drop and increase too quickly for him to react in time. In hospital, the appellant was logging in the range of 30 glucose tests per day without the glucose sensor.

Panel decision

Section 3.12(2) of Schedule C of the EAPWDR sets out that a non-conventional glucose meter is a health supplement for the purposes of Section 3 of the Schedule if the ministry is satisfied that the glucose meter is medically essential to test blood glucose levels and the person for whom the non-conventional glucose meter has been prescribed is unable to use a conventional glucose meter. The ministry denied the appellant's request for glucose sensors on the basis that the sensors do not fit within the definition of a "non-conventional glucose meter" but are, rather, accessories to the glucose meter. A definition of a "non-conventional glucose meter" is set out in Section 3.12(1) as including a 'continuous glucose monitoring meter' and a 'talking glucose meter'. The panel notes that this is not a closed list of items that fall within the definition of "non-conventional glucose meter" since the word

"includes" was used rather than a word like "means," possibly to allow for technological advances in the area of diabetes.

In considering whether the glucose sensor falls within the definition of a 'continuous glucose monitoring meter,' the panel considered the dictionary definition of "meter" as "an instrument for measuring, and sometimes recording, the amount or time of something" and applied it to the description of the glucose sensor provided by the manufacturer. In the Report dated September 2014, the glucose sensor is described by the manufacturer as a small electrode that is inserted into the subcutaneous adipose tissue using an automatic insertion device and, regarding its function, that the sensor continuously measures glucose levels in the interstitial fluid and wirelessly relays these readings to the pump by means of a radiofrequency transmitter. The 'continuous glucose monitoring system' is stated to consist of: 1) a glucose sensor, and 2) a mini-link transmitter; i.e. the sensor measures the level of glucose and the transmitter relays this information. Describing the interaction of the insulin pump and the continuous glucose monitoring system, the manufacturer reported that there are several settings which can be used to help optimize glycemic control including upper and lower threshold limits set to define the target glucose range. When the sensor detects glucose values that exceed the preset limits, the pump will alert the patient. With the predictive alerts turned on, the pump will notify the patient of a potential pending hypo or hyper glycemic episode before it happens, therefore helping to keep the glucose level in the target range.

The ministry did not dispute either the description or the function of the glucose sensor as described by the manufacturer; an unsuccessful attempt had been made, internally, for the ministry to obtain more information about the function of a glucose sensor, as set out in the copy of emails provided at the hearing. In the letters from the appellant's endocrinologist in June and July 2014, she wrote that any discharge plan for the appellant hinges on a warning system and that his is "truly an exceptional case." She reported that it would be unsafe to discharge the appellant from hospital without continuous glucose monitoring augmented by alarm amplification and that the sensors are absolutely necessary to avoid imminent and substantial danger to the appellant's health by way of hypoglycemia induced seizure, coma and death.

Considering the dictionary definition of the word "meter", the panel finds that the glucose sensor is an instrument for measuring the amount of glucose levels in the interstitial fluid and that the sensor, along with the transmitter, are parts of a continuous glucose monitoring system, or meter. At the hearing, the appellant stated that the glucose sensor is "internally imbedded" in the body and is a required part of the continuous glucose monitoring system, which is a necessity for him to be able to live out of an institution. The appellant explained that the glucose sensor can only stay in a person's body for up to 6 days since, if it is left in longer than 6 days, it will either cause an infection or the body will start to reject it. The ministry did not offer a reason that the glucose sensor is considered to be an 'accessory', either in the reconsideration decision or at the hearing. The panel finds that the fact that the glucose sensor must be replaced every 6 days does not, in itself, make the glucose sensor an 'accessory.' Rather than being simply an 'accessory' to the continuous glucose monitoring system, the panel finds that the glucose sensor and the transmitter are both integral parts of the system, which then works with the insulin pump to keep glucose levels in the target range. The panel finds that the evidence demonstrates that the glucose sensors fall within the definition of a "continuous glucose monitoring meter" and are, therefore, also a "non-conventional glucose meter" within Section 3.12 of Schedule C of the EAPWDR. The panel finds that the ministry was not reasonable in concluding that the appellant's request for a supplement to cover the cost of glucose sensors does not meet the requirements set out in Section 3.12 of Schedule C of the EAPWDR.

Conclusion

In conclusion, the panel finds that the ministry's decision to deny the request for glucose sensors as not meeting all of the legislated criteria of Section 3.12 of Schedule C of the EAPWDR, was not a reasonable application of the applicable enactment in the appellant's circumstances and the panel rescinds the ministry's reconsideration decision. Therefore, the ministry's reconsideration decision is overturned in favour of the appellant.