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Sent via email to: Craig.Johnson@sstgb.org
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Mr. Craig Johnson, Executive Director
Streamlined Sales Tax Governing Board, Inc.
100 Majestic Drive, Suite 400
Westby, WI 54667

Subject: Request for Withdrawal of or No Vote on CRIC Interpretation for CGM System

Dear Mr. Johnson,

I respectfully withdraw my March 2015 request for interpretation concerning the classification of the Continuous Glucose Monitoring System ("CGM System"), and urge the SST Governing Board not to adopt the proposed CRIC Interpretative Opinion 2015-1 (aka IO15001). IO15001 concludes that two out of the three main components of the CGM System (Sensors and Transmitters) are neither prosthetics nor durable medical equipment ("DME"), and they are therefore undefined under the SSUTA. This conclusion is neither a clarifying nor a fair outcome for my undisclosed client.

The proposed interpretation does not add clarity because:

- One member state recently wrote an opinion concerning the CGM System. That state classified the Sensors and Transmitters as Prosthetics, the Receiver as DME, and the optional arm/waist-band carrying Case for the receiver as an accessory which is neither.

- A second member state wrote an opinion concerning the CGM System and reached yet another conclusion. This state classified all parts of the CGM System as DME.[1] However, the state concluded their DME exemption was inapplicable because the system devices go everywhere the user goes, both within and without the home setting; thus the CGM System fails to meet the state's exemption criteria that DME be specifically for "home use".[2]

Either of the above noted opinions is preferable to my client than the proposed IO15001. Most notably, adoption of IO15001 would contradict, and therefore also invalidate, the one member state's opinion which classified CGM System Sensors and Transmitters as prosthetic devices.

[1] While it is not expressly stated in the opinion why the entire CGM System is DME, including the parts worn on the body (i.e., the Sensors and Transmitters), we presume those were deemed to be "attachments and replacement parts" for DME (i.e., for the Receiver). The Receiver, after all, cannot function without a Sensor and wireless Transmitter.
[2] It appears the "home use" restriction for DME may be applied more liberally in other member states: "home use" restrictions for DME were found in ½ of the member states. Of those, the term is undefined in 7 states; in 3 states it means when sold to an individual for use where they live, regardless of where they reside; in 1 state home use means it can be used by a person without specialized training.

The proposed interpretation is not fair for two reasons. First, it is based on a vote of just the 5 committee members who were present on April 2 (representing AR, ND, WA, WI & WY). But the main reason it is not fair is because the CGM system is used to prevent physical malfunction (i.e., to prevent potentially life-threatening episodes of hypoglycemia or hyperglycemia in diabetics), despite the fact that it does not actually dispense insulin to correct the condition of hyperglycemia.

- The fact that Sensors and Transmitters are worn on the body is not in question; it is their function which is at issue.
- The committee concluded that none of the CGM System items either alone or together constituted a prosthetic device because of their function, which is "diagnostic" in nature.
- A "diagnostic test" is any kind of medical test performed to aid in the diagnosis or detection of disease. It is also a generic term for any test used to determine the nature or severity of a particular condition.
- Persons utilizing a CGM System have already been diagnosed as diabetic. Moreover, it is the severity of their condition that is the reason for doctors prescribing its use.[3] Even so, the labeling of CGM Sensors and Transmitters as diagnostic items appears to be a distinction without a difference, so far as the SSUTA prosthetics definition is concerned, because preventing physical malfunction is, in and of itself, a valid purpose described therein:
    - The definition of "prosthetic device" includes "replacement, corrective or supportive devices … worn on or in the body to: A. Artificially replace …; B. Prevent or correct physical deformity or malfunction; or C. Support a weak or deformed portion of the body."

Based on the preceding points, it remains my belief that CGM Sensors and Transmitters meet the SSUTA definition of prosthetic devices because they are corrective devices worn on the body to prevent physical malfunction. Alternatively, they are attachments and replacement parts for DME. However, both positions are at odds with IO15001, so we would prefer to request opinions from the member states, individually, rather than be bound by a conclusion with which we (and at least two member states) do not entirely agree. Therefore, I urge you to please vote no on adopting IO15001.

Thank you for your time and kind consideration of this matter.

Very truly yours,

Suzanne Beaudelaire

[3] By way of background, the Receiver of the CGM System is a biofeedback tool that operates 24/7. The Sensor and transmitter are worn on the abdomen, and continuously monitor blood glucose level. That data is transmitted to the Receiver at programmed intervals, such as every 3, 5 or 10 minutes. The Receiver shows the data plotted on a line graph which is superimposed onto a color-coded field showing target glucose levels for optimal health, and danger zones above and below it. The Receiver also produces an audible alarm or vibration to alert the person when glucose is not within the target range, intended to prompt immediate corrective action.