

Compliance Review and Interpretations Committee Minutes

March 19, 2015

10:00 AM Central

- **Call to order and roll call**

Chair Myles Vosberg called the Compliance Review and Interpretations Committee meeting to order by teleconference at 10:01 am central. The Committee roll was called and the participants were Myles Vosberg, Chair (ND), Tim Jennrich, Co-Chair (WA), Dan Noble (WY), David Steines (WI), Richard Cram (KS), and Wayne Harper (UT). Absent was Tom Atchley (AR). Other participants were Craig Johnson, SSTGB, Pam Cook, SSTBG and Suzanne Beaudeliare.

- **Review Interpretation Request ([RI15001](#)) to Determine if Further Action is Warranted In Accordance with SSTGB Rule 902.B.1.**

Chair Vosberg reported that the purpose of this teleconference meeting is for the CRIC to decide whether they would accept the interpretation request received. On March 4, Suzanne Beaudeliare of Sheridan, Wyoming submitted an expedited Interpretation and Definition Request. The Agreement section involved is Appendix C, Part II Definitions: Prosthetic device, Durable Medical Equipment (DME).

Ms. Beaudeliare provided the background of her request. A continuous glucose monitoring (CGM) system is worn by diabetics to provide them sensory cues about glucose levels throughout the day and night: visual data, plus a vibrating or audible alert for when levels get too high or too low. These CGM cues prompt the diabetic to confirm their glucose level using a traditional blood glucose meter and test strip (items not at issue here), then to take appropriate action to prevent an episode of hyperglycemia or hypoglycemia, such as the use of a prescribed dose of medication, diet and/or exercise. The issue is whether all or parts of a CGM system meet the SSUTA definition of Prosthetic device or DME, including: (1) a single-use Sensor probe, inserted under skin and replaced weekly; an enzyme on the sensor converts glucose in tissue fluids into an electronic signal picked up by (2) a reusable Transmitter worn on the abdomen, attached to the probe; at preprogrammed intervals, it measures and sends signals to a (3) wireless Receiver where it is converted to a glucose reading on the receiver screen display, carried in the person's pocket* or in (4) an optional clip/strap-on carrying case.

Proposed Interpretation

All four parts of the CGM system meet the SSUTA definition of "Prosthetic device" which means: "a replacement, corrective, or supportive device including repair and replacement parts for same worn on or in the body to: A. Artificially replace a missing portion of the body; B. Prevent or correct physical deformity or malfunction; or C. Support a weak or deformed portion of the body." CGM is a system of devices worn on or in the body to support a person with a missing or malfunctioning pancreas by providing sensory cues to help them prevent physical malfunction of other organs and systems caused by episodes of hyperglycemia or hypoglycemia which can occur when the body's normal warning signals go undetected, such as is sometimes caused by central and autonomic nervous system dysfunction. Components (1) through (3) are all necessary for the system to function, as is item (4) when the person is on the go and has no pocket, to keep the receiver in close proximity to the Transmitter and the person to continually remain in use. *Alternatively, the Receiver meets A through D in the definition of DME, because it may be placed *near* the body (in a purse, on a desk, etc.), as long as it stays within 20 feet of the Transmitter. Note: future CGM systems will offer a software app in lieu of a Receiver, to enable the display of glucose levels on the person's existing smart-phone.

Chair Vosberg asked the Committee for questions or comments. Tim Jennrich said he felt that the CRIC should take on the request on an expedited basis. He asked for clarification as to whether the Committee would or would not discuss the future system. Ms. Beaudeliare said it would be great if they did because that would help her company and others know how that is going to be treated. In the future there will be a charge for it. She said that all 3-items mentioned are sold separately because they each have a different useful life. The software application will be sold within the next 12-months and is not worn on the body but is part of the system that is not functional without it. She believed the software is currently in use, but is not yet sold as a separate item. Tim Jennrich said it may be premature to take up that issue. Ms. Beaudeliare said she could submit a second request later if necessary. Chair Vosberg said he thought that may be an issue because the Committee does not know the exact facts and Richard Cram agreed. Dan Noble said the Committee should stick to the facts that have been provided. Tim Jennrich motioned that the Committee take on the request on an expedited basis, excluding the future applications. The roll of the Committee was called, six (6) CRIC members voted affirmatively and the motion passed.

Chair Vosberg said on April 2, the Committee will meet by teleconference for discussion and to make a decision. Craig Johnson said the public comment end period will be March 31. If approved, it can be noticed for the May Governing Board Meeting.

- **Old Business**

None

- **New Business**

None

- **Adjournment**

With no further business, the meeting adjourned at 10:21 am central.