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Health-Care Definitions
Discussion Paper
Updated: July 11, 2006
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Areas to discuss in the second phase of the review:

- Worn vs. not worn

During the drafting of the definitions, a decision was made that in addition to the other requirements of the Prosthetic Device and Durable Medical Equipment definitions, a bright line of worn in or on the body would be required. Accordingly, Prosthetics included the phrase “worn in or on the body” with Durable Medical Equipment including the phrase “is not worn in or on the body”. A question recently arose as to the placement of Dialysis Equipment, Oxygen Delivery Equipment and Enteral Feeding Systems based on this bright line in the definitions with the states being surveyed as to their treatment of these items both before and after the adoption of the definitions in the agreement. The updated survey results are attached.

Based on discussions held during the July 6th teleconference, consensus was given that the term “worn in or on the body” means the item is implanted or attached in such a manner that the item becomes part of or is carried by the body and does not hinder the mobility of the individual. The term “is not worn in or on the body” would mean the item is attached to the body but is either stationary or placed on something of mobility thus giving the item portability, such as pole with wheels or a cart. With the utilization of this interpretation, the three surveyed items, Dialysis Equipment, Oxygen Delivery Equipment and Enteral Feeding Systems would all be deemed Durable Medical Equipment.

Placement of other selected items in this area:

Worn – also meets other requirements of Prosthetics

- Tens units - "TENS" is the acronym for Transcutaneous Electrical Nerve Stimulation. A "TENS unit" is a pocket size, portable, battery-operated device that sends electrical impulses to certain parts of the body to block pain signals. The electrical currents produced are mild, but can prevent

pain messages from being transmitted to the brain and may raise the level of endorphins (natural pain killers produced by the brain).

- Bone Growth stimulator non-invasive– The bone growth stimulator is a portable, non-invasive, device which utilizes combined magnetic field technology to stimulate bone growth in non-union fractures, which are fractures that have not healed after nine months. In a non-union fracture the production of bone has either slowed or ceased after nine months from the time of injury. The external stimulation delivered by this apparatus stimulates bone cells at the fracture site to produce insulin-like growth factors. These growth factors are small proteins which have the capability of directly stimulating bone cells to divide and produce collagen, which is the precursor to bone. These events stimulate the production of bone and ultimately the healing of the non-union fracture. In a normal healing situation, the body produces the growth factor without the need for external stimulation. However, in the case of a non-union fracture, the bone cells at the fracture site have slowed or ceased to produce bone. This condition presents a serious health risk if the fracture is in a weight-bearing bone since failure to intervene and correct this situation often results in the amputation of a limb. This device can only be obtained by prescription from a licensed physician. The physician will fit the stimulator to the patient and explain its use. The patient will then use the device daily for a period of up to nine months until the fracture heals. The bone growth stimulator is dedicated to that patient and at the completion of treatment it is returned to the physician and then the company for disposal. There is no reuse. The bone growth stimulator is a U.S. Food and Drug Administration approved device which has been designated as a proprietary Class III device. Other Class III medical devices include the artificial heart and valves.
- Bone Growth stimulator implanted – A surgically implanted bone growth stimulator for the treatment of long bone non-unions. Surgically implanted bone growth stimulator is a useful adjunct for the treatment of non-unions when surgery is already planned or when patient compliance may be a concern. Because it is totally surgically implanted, patients are assured of therapeutic treatment directly at the nonunion site 24 hours a day for up to 6 months.
- C.P.A.P. - The CPAP machine delivers a constant stream of compressed air via a face mask and hose, splinting the airway (keeping it open under air pressure) so that unobstructed breathing becomes possible, reducing and/or preventing apneas and hypopneas. This example is a U-shaped neck pillow that is worn while being used.

Not worn – also meets other requirements of Durable Medical Equipment

- C.P.A.P. - The CPAP machine delivers a constant stream of compressed air via a face mask and hose, splinting the airway (keeping it open under air pressure) so that unobstructed breathing becomes possible, reducing and/or preventing apneas and hypopneas. This is a unit that is placed on a table or night stand next to the bed with tubing attached to the user.

- Pacemaker (non-implanted) - External pacemakers can be used for initial stabilization of a patient, but implantation of a permanent internal pacemaker is usually required for most conditions. External cardiac pacing is typically performed by placing two pacing pads on the chest wall. Usually one pad is placed on the upper portion of the sternum, while the other is placed along the left axilla, near the bottom of the rib cage. **The electric current is controlled by a console not worn by the patient.** When an electrical impulse goes from one pad to the other, it will travel through the tissues between them and stimulate the muscles between them, including the cardiac muscle and the muscles of the chest wall. Electrically stimulating any muscle, including the heart muscle, will make it contract. The stimulation of the muscles of the chest wall will frequently make those muscles twitch at the same rate as the pacemaker is set.

- Continuous Passive Motion Devices- Continuous Passive Motion (CPM) devices are a controlled treatment modality used to provide early, gentle motion of the upper or lower limb following a surgical procedure. When early motion is provided, the joint receives nutrition by diffusing synovial fluid without jeopardizing the integrity of the repaired tissue. Venous flow increases. Also, deterioration of cartilage can be prevented. CPM helps reduce pain, stiffness and swelling while range of motion is regained and maintained. CPM machines are commonly prescribed for patients who have undergone knee, shoulder or hip replacement surgeries as well as other joint surgeries.

- General Intra-aortic Balloon Pump - The IABP is a polyethylene balloon mounted on a catheter, which augmenting coronary perfusion. The IABP is driven by the balloon pump console.

- Heart/Lung Machine - A cardiopulmonary (heart-lung) bypass machine is a specialized piece of medical equipment commonly used during coronary (heart) artery bypass surgery and other types of surgery where the heart must be stopped. This machine takes the place of the patient's heart and lungs during the time when the heart is stopped by drawing oxygen depleted blood from the body and returning oxygen enriched blood.

Undetermined – Could not find example on internet

- General Anti-Thrombolytic Pumps - ?

- Parts vs. supplies/disposable vs. non-disposable

The three major definitions, Durable Medical Equipment, Mobility Enhancing Equipment and Prosthetic Device, all include the following wording, “including repair and replacement parts for same”. Parts within this meaning would be any non disposable item required to operate the machine but would not include supplies consumed in the performance of the medical service.

During the July 6th teleconference, the majority of the participants indicated that an item attached to DME that is single patient use even if it is used multiple times should be considered a supply. This would include the two examples indicated in the earlier draft that of single patient multiple use tubing used with a dialysis system and single patient use masks used for oxygen delivery.

Supplies, such as tape, one use sensors for monitors, transducer gel or X-Ray Developing Solution, would not be considered a part within the meaning of this definition.

A new item was raised, that being hearing aid batteries. While it is a part of the hearing aid, most of the discussion centered on the ease of replacement and ease of secure the battery. Final resolution was not made.

- Surgical Instruments

During the original drafting the Durable Medical Equipment definition, this particular class of item was not discussed with no determination made as to its placement at that time. During the July 6th teleconference, after discussing the issue, a majority on the call deemed that based on the reading of the definition Surgical Instruments would be included in Durable Medical Equipment.

Final resolution should be made by the full group.

- Bundle/non-bundle

From Industry edit to Bundling Issue Paper:

Example of how section C (4) of the Bundling Definition would apply to medical products which bundles non-taxable and taxable tangible personal property. For medical products, section C (4) only applies to bundling of TPP and TPP for products that are “drugs”, “durable medical equipment”, “mobility enhancing equipment”, “over-the-counter drugs”, “prosthetics” and “medical supplies”.

IV Start Kit Product Value	State Product Taxability	Purchase
Medicated dressing	non-taxable	\$2.25
Gauze sponge	taxable	1.35
Glove	taxable	1.75
Medicated pad	non-taxable	1.90
Sterile sponge	non-taxable	1.65
Alcohol prep swabs	non-taxable	1.60
Sterile tape	non-taxable	1.80
Latex tourniquet	taxable	1.40
Total Purchase Price		\$13.70
Non-taxable		\$ 9.20
Taxable		\$ 4.50
Non-taxable %		67.15%
Taxable %		32.85%

Since the taxable percentage is less than 50%, under section C (4), the product is not a bundled transaction.

Other potential examples, C (4) analysis required before determination of bundle based on 50% test can be made:

- First aid kit, mix of items required before bundling determination can be made.
- Stapler (disposable) preloaded with staple.
- Medication in syringe – pre-filled.