Medical Products Listings Workgroup

Participants:

- Alison Jares (SD)
- Myles Vosberg (ND)
- Craig Johnson
- Ellen Thompson (NE)
- Blaine Kreikemeier (NE)
- David Steines (WI)
- Wan Chen (WA)
- Fred Nicely (COST)
- Patrick Reynolds (COST)
- Dana Angell (WV)
- Kathleen Smith (KS)
- Michael Hale (KS)
- Gina Dougherty (AR)
- Pam Cook (SSTGB)

Plan:

- Request states identify items they have concerns with
- Review state responses with workgroup
- Decide if revision/addition to Rule 327.3 – Healthcare Definitions is needed or if revisions/clarifications to Appendix L & M will be sufficient
- Other options – disclosed practice or toggle
- Combine Appendices L & M into a single list
- Bring forth to SLAC and GB for consideration

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Items/Issues Identified By States and BAC

CRIC Interpretation – Nasal Strips

Discussion at GB meeting was to send to SLAC to review the listings and see if other items are of concern and to develop proposed revisions to rule and/or listings for GB approval. BAC has questions on nasal strips, band aids and similar items and does not believe they are prosthetic devices.

Kansas – Kathleen Smith

Some additional, specific items we question as either not defined or question the proposed classification are as follows:

Abduction, cervical, and orthotic pillows as durable medical equipment
Bed pads - Disposable - for incontinent patients not defined
Dialysis Bags - Peritoneal Dialysis Drain not defined
~~Dressings - Compression - Non Medicated-Kansas would consider as tangible personal property~~
~~Dressings - Elastic - Non Medicated - Kansas would consider as tangible personal property~~
~~Dressings - Gauze Wraps - Kansas would consider as tangible personal property~~
~~Dressings – General - Kansas would consider as tangible personal property~~
~~Dressings - Non-Medicated-Kansas would consider as tangible personal property~~
Dressings - Wound Care - Skin Barrier Products-Kansas would consider as OTC drug
Infra-red lamps and bulbs-while Kansas would consider the infra-red lamp as durable medical equipment, we think to extend that classification to the bulbs is not correct.
~~Paraffin wax-Kansas would consider as tangible personal property~~
~~Seat Cushions – Comfort-Kansas would consider as tangible personal property~~

Commented [CJ1]: Kansas agreed these items are not part of these workgroups aftter obtaining an understanding of what "Not Defined" meant.

Commented [CJ2]: Kansas agreed these items are not part of these workgroups aftter obtaining an understanding of what "Not Defined" meant.

Nebraska – From Certificate of Compliance

Gastric Bands
Implanted Expander – Tissue and Breast
Intragastric Balloons
Wheelchair Cushions – Brace//Support

New Jersey – Beth Berniker

The appendix lists “CPAP – Not Worn” as durable medical equipment and “CPAP – Worn” as a prosthetic device. Since these machines require the use of a mask, it is not clear what needs to be worn. Does the actual machine need to be worn? Or is considered worn if a mask is required? Is a mask which is used in conjunction with the CPAP machine also considered durable medical equipment or a prosthetic device? Does it matter if the mask is sold with the machine or if it is purchased separate from the CPAP machine? The same issue exists with BiPAP machines.

What is the difference between an apnea monitor and a CPAP machine? Apnea monitors are listed as durable medical equipment, but does it matter is they are worn or not worn (like the CPAP treatment)?

“Parental – feeding bags – disposable” are listed as durable medical equipment but the definition of durable medical equipment requires that the item can withstand repeated use.

Glue should be added to “staples, sutures and suture alternatives”.

Vaporizers are listed as durable medical equipment. But like humidifiers they are useful to a person in the absence of illness or injury.

North Carolina – Eric Wayne

- It seems that it might be beneficial to adopt an interpretation of the term "device" for purposes of the term "prosthetic device" so that it does not include disposal medical supplies or something of that nature.
- The following seem to be awkward in the category of "prosthetic device:"
  - Casting "materials"
  - Ostomy – "adhesives."
  - Ostomy – barriers. Specifically, "barrier protective film, barrier paste, and stomahesive."
  - Seprafilm
  - Splint "materials"
- The term "durable medical equipment" seems to include items that are not commonly thought of as "equipment" in the appendices. Examples include the following items:
  - Abduction, cervical, and orthodic pillows
  - Bed – kodel pad
  - Parenteral – Feeding Bags – Disposable
  - Tourniquet – Non-Pneumatic
- The adopting of "bath aid – tub and shower stool" as a mobility enhancing equipment seems does not seem to fit.

Wisconsin – Dave Steines

Seems the best approach, from Wisconsin's point of view, is to draft a rule that clarifies some of the definitions in order to maintain the classifications already provided in the appendices. When new products get added to the appendices, the rule could be relied on as the justification, along with the classifications of the items already in the list.

It would be a hard sell to other states to have to change their law if we decided to revise the definitions or start reclassifying items that affect taxability in a state, which is a concern other states have expressed as well. For example in Wisconsin, if an item gets changed from a prosthetic device to durable medical equipment (WI has home use requirement for DME to be exempt but not for PDs), purchases by for profit hospitals, clinics and nursing homes would change to taxable. We are not implying that the items shouldn't be correct, but for a lot of these items there is a fine line and there is a good argument to classify an item as DME, PD, or not defined. One request we would have for the workgroup, make it clear what it means when a product is "not defined." Does this mean the state cannot classify the item as DME, PD or MEE? Or, does this mean that the state is free to treat it as tpp, DME, PD or MEE?

SSTGB Rules on HealthCare Items

Medical Products Listings Workgroup

Rule 327.3 – Healthcare Definitions

Member states enacting product-based exemptions for defined healthcare products or utilizing the defined healthcare terms in entity or use based exemptions shall include all products within each defined term unless specific exceptions are provided for in the definition. Contained in Appendices L and M to these Rules, which are not all inclusive lists of all products within each defined term, is the placement of products within the correct defined healthcare term included in Part II of the Library of Definitions. Each member state shall utilize the defined terms and the placement of products within each of the defined terms if a member state adopted any of the healthcare definitions contained in Part II of the Library of Definitions. Where a product is not included in the lists, member states shall use the lists as guidance in placement of products within the defined terms.

Definitions from SSUTA Appendix C

HEALTH-CARE

"Drug" means a compound, substance or preparation, and any component of a compound, substance or preparation, other than "food and food ingredients," "dietary supplements" or "alcoholic beverages:"

A. Recognized in the official United State Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, and supplement to any of them; or
B. Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; or
C. Intended to affect the structure or any function of the body.

A member state may independently:

A. Limit the definition of "drug" to human use (as opposed to both human and animal use) in the administration of its exemption;
B. Draft its exemption for "drug" to specifically add insulin and/or medical oxygen so that no prescription is required, even if a state requires a prescription under its exemption for drugs;
C. Determine the taxability of the sales of drugs and prescription drugs to hospitals and other medical facilities;
D. Determine the taxability of free samples of drugs; and
E. Determine the taxability of bundling taxable and nontaxable drug, if uniform treatment of bundled transactions is not otherwise defined in the Agreement.

Interpretation issued: On June 23, 2007 the Governing Board issued Interpretation 2007-01 relating to the definition of "drug." That interpretation can be found in the Library of Interpretations in Appendix D.

"Durable medical equipment" means equipment including repair and replacement parts for same, but does not include "mobility enhancing equipment," which:

A. Can withstand repeated use; and
B. Is primarily and customarily used to serve a medical purpose; and

C. Generally is not useful to a person in the absence of illness or injury; and
D. Is not worn in or on the body.

A member state may limit its exemption to "durable medical equipment:"

A. By requiring a prescription;
B. Based on Medicare or Medicaid payments or reimbursement; or
C. For home use.

A member state may limit the exemption using any combination of the above but in no case shall an exemption certificate be required.

Repair and replacement parts as used in this definition include all components or attachments used in conjunction with the "durable medical equipment." A member state may exclude from repair and replacement parts items which are for single patient use only.

A member state may exclude from the product definition of "durable medical equipment" any of the following for purposes enacting a product-based exemption:

1. Oxygen delivery equipment not worn in or on the body, including repair and replacement parts;
2. Kidney dialysis equipment not worn in or on the body, including repair and replacement parts; or
3. Enteral feeding systems not worn in or on the body, including repair and replacement parts.

A member state choosing to enact a product-based exemption for oxygen delivery equipment, kidney dialysis equipment, or enteral feeding systems, if those items are not worn in or on the body, must also enact a product-based exemption for oxygen delivery equipment, kidney dialysis equipment, or enteral feeding systems, if those are worn in or on the body.

A member state may limit the product-based exemption for oxygen delivery equipment, kidney dialysis equipment, or enteral feeding systems using any combination of the following:

a. By requiring a prescription;
b. Based on Medicare or Medicaid payments or reimbursement; or
c. For home use.

"Feminine Hygiene Products" means tampons, panty liners, menstrual cups, sanitary napkins, and other similar tangible personal property designed for feminine hygiene in connection with the human menstrual cycle, but does not include "grooming and hygiene products" as defined in this Agreement.

"Grooming and hygiene products" are soaps and cleaning solutions, shampoo, toothpaste, mouthwash, antiperspirants, and sun tan lotions and screens, regardless of whether the items meet the definition of "over-the-counter-drugs."

"Mobility enhancing equipment" means equipment including repair and replacement parts to same, but does not include "durable medical equipment," which:

A. Is primarily and customarily used to provide or increase the ability to move from one place to another and which is appropriate for use either in a home or a motor vehicle; and
B. Is not generally used by persons with normal mobility; and
C. Does not include any motor vehicle or equipment on a motor vehicle normally provided by a motor vehicle manufacturer.

A member state may limit the application of this definition by requiring a "prescription," or limit an exemption based on Medicare or Medicaid payments or reimbursements.

"Over-the-counter-drug" means a drug that contains a label that identifies the product as a drug as required by 21 C.F.R. § 201.66. A member state may exclude "grooming and hygiene products" from this definition. The "over-the-counter-drug" label includes:

A. A "Drug Facts" panel; or
B. A statement of the "active ingredient(s)" with a list of those ingredients contained in the compound, substance or preparation.

"Prescription" means an order, formula or recipe issued in any form of oral, written, electronic, or other means of transmission by a duly licensed practitioner authorized by the laws of the member state.

"Prosthetic device" 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.

A member state may exclude any or all of the following from the definition of "prosthetic device:"

A. Corrective eyeglasses;
B. Contact lenses;
C. Hearing aids; and
D. Dental prosthesis.

A member state may limit the application of this definition by requiring a "prescription," or limit an exemption based on Medicare or Medicaid payments or reimbursements.