Title of Rule: Revision to the Medical Assistance Durable Medical Equipment Rule Concerning DMEPOS Reimbursement, Section 8.590.7
Rule Number: MSB 17-09-22-B
Division / Contact / Phone: Client and Clinical Care Office, Pharmacy Unit / Carrie Smith / 303-866-3406

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

   The proposed rule will increase the Durable Medical Equipment (DME) encounter rate by 1.402% to account for General Assembly funding appropriation, pursuant to SB17-254; and will bring the Department into compliance with the Consolidated Appropriations and the 21st Century Curest Act (Acts). The Acts require the Department to set their resimbursement for certain DME items to Medicare payment rates. These rule revisions implement the portion of the Acts that pertain solely to used DME items. The proposed revisions will also correct a numeration error.

2. An emergency rule-making is imperatively necessary

   ☐ to comply with state or federal law or federal regulation and/or
   ☐ for the preservation of public health, safety and welfare.

   Explain:

3. Federal authority for the Rule, if any:

   A state plan amendment (SPA) was submitted to CMS with a requested effective date of July 1, 2017. To date, reimbursement for the Durable Medical Equipment encounter rate has been made under the current rate. The SPA was approved on February 1, 2018 and all reimbursements made after July 1, 2017 will be adjusted to reflect the new rate contained in the rule.

   Consolidated Appropriations Act

   Section 1903(i)(27) of the Social Security Act

   21st Century Cures Act

4. State Authority for the Rule:

Initial Review	**[date]**	Final Adoption	**[date]**
Proposed Effective Date	**[date]**	Emergency Adoption	**[date]**
			DOCUMENT #

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25.5-1-301 through 25.5-1-303, C.R.S. (2016);
Senate Bill 17-254

Initial Review	**[date]**	Final Adoption	**[date]**
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REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

   DME providers will receive increased reimbursement for equipment and supplies provided, pursuant to SB17-254, but may see a fluctuation in reimbursement for those used DME items subject to Medicare's Upper Payment Limit as required by Section 1903(i)(27).

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   Reimbursement to DME providers is estimated to be increased by $2,360,084 for FY 2017 - 18. However, there may be a reduction of $142,000 in reimbursement for those used DME items subject to Medicare's Upper Payment Limit as required by Section 1903(i)(27).

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   No costs beyond the estimated expenditures due to the rate increase are anticipated.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   The rate increase will give providers the ability to continue supplying DME items to clients at their incremental threshold margin. Inaction can result in decreased client services and access to benefits, as well as noncompliance with SB 17-254. Furthermore, inaction would render the Department noncompliant with Section 1903(i)(27) of the Social Security Act concerning Medicare designated used DME items subject to the Upper Payment Limit.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

   There is not a less costly method for achieving the purpose of the proposed rule which is to comply with SB 15-234.

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6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

   An alternative method for achieving a rate increase for the proposed rule was not considered.

8.590.7 REIMBURSEMENT

8.590.7.A. A provider, as defined at Section 25.5-4-414, C.R.S. (2016), is prohibited from making a referral to an entity providing DME and Supplies under the Medical Assistance Program if the provider or an Immediate Family member of the provider has a Financial Relationship with the entity unless the Financial Relationship meets the requirements of an exception to the prohibitions established by 42 U.S.C. Section 1395nn, as amended or any regulations promulgated thereunder, as amended. 42 U.S.C. §1395nn is hereby incorporated by reference. Such incorporation, however, excludes later amendments to or editions of the referenced material. Pursuant to 24-4-103(12.5), C.R.S. (2016), the Department of Health Care Policy and Financing maintains either electronic or written copies of the incorporated texts for public inspection. Copies may be obtained at a reasonable cost or examined during regular business hours at 1570 Grant Street, Denver, Colorado.

8.590.7.B. If a provider refers a Medicaid member for DME and Supplies services in violation of Section 25.5-4-414, C.R.S. (2016), or this rule, then the Department may

1. Deny any claims for payment from the provider;

2. Require the provider to refund payments for services or items;

3. Refer the matter to the appropriate agency for investigation for fraud; or

4. Terminate the provider's Colorado Medicaid provider participation agreement.

8.590.7.C. Invoices received from Related Owners or Related Parties shall not be accepted. Only invoices received from unrelated manufacturers or wholesale distributors shall be recognized as allowable invoices.

8.590.7.D. The provider shall not bill the Department for authorized accessory items included by the manufacturer as part of a standard package for an item.

8.590.7.E. The provider shall credit the cost of any accessory or part removed from a standard package to the Department.

~~8~~.590.7.F. Members and providers may negotiate in good faith a trade-in amount for DME items no longer suitable for a member because of growth, development or a change in anatomical and or medical condition. Such trade-in allowances shall be used to reduce the cost incurred by the Department for a replacement item.

8.590.7.G~~F~~. The refund amount due the Department on a returned Wheelchair or Facilitative Device shall be agreed upon by the dealer or manufacturer; wherever the item was returned, and the Department.

8.590.7.H~~G~~. Reimbursement for allowable modifications, service, and repairs on DME is as follows:

1. Labor for modifications, service, and repairs on DME shall be reimbursed at the lesser of submitted charges or the rate specified on the Department's fee schedule.

2. Parts that are listed on the Department's fee schedule, with a HCPCS code, that have a maximum allowable reimbursement rate shall be reimbursed at the lesser of submitted charges or the rate specified on the Department fee schedule.

3. Manually priced parts are reimbursed according to the same methodology used for purchased equipment, as described in 8.590.7.~~I~~K.

4. The provider shall not be reimbursed for labor or parts in excess of unit limitations.

5. Reimbursement for a modification that requires the original equipment provider to supply a part from their own inventory or stock is contingent upon the provider submitting supporting documentation that demonstrates the need and actual cost of the parts to be used in the modification.

8.590.7.~~I~~H. Reimbursement for used equipment shall include:

1. A written, signed and dated agreement from the member accepting the equipment.

2. Billing the Department, the lesser of 60% of the maximum allowable reimbursement indicated in the most recent Medicaid Bulletin or 60% of the provider's usual submitted charges.

a. For used equipment subject to the upper payment limit provisions of section 1903(i)(27) of the Social Security Act, the maximum allowable reimbursement will be the lower of 100% of the applicable Medicare used reimbursement rate effective as of January 1 and posted by July 1 of each year, or the provider's submitted charges.

8.590.7.~~J~~I. Reimbursement for purchased or rented equipment shall include, but is not limited to:

1. All elements of the manufacturer's warranties or express warranties.

2. All adjustments and modification needed by the member to make the item useful and functional.

3. If item is delivered, set-up and installation of equipment in an appropriate room in the home, if applicable.

4. Training and instruction to the member or caregiver in the safe, sanitary, effective and appropriate use of the item and necessary servicing and maintenance to be done by the member or caregiver.

5. Training and instruction on the manufacturer's instructions, servicing manuals and operating guides.

8.590.7.KJ. Reimbursement rate for a purchased item shall be as follows:

1. Fee schedule items, with a HCPCS code, that have a maximum allowable reimbursement rate, shall be reimbursed at the lesser of submitted charges or the Department fee schedule rate.

2. Manually priced items that do not have an assigned fee schedule rate shall be reimbursed at the lesser of submitted charges or current manufacturer suggested retail price (MSRP) less 18.339.46 percent.

3. Manually priced items that do not have an assigned fee schedule rate and have no MSRP shall be reimbursed at the lesser of submitted charges or by invoice of actual acquisition cost, minus any discount to the provider as set forth in policy, plus 19.507.85 percent.

8.590.7.LK. Reimbursement for rental items shall be billed and paid in monthly increments unless otherwise indicated in the Billing Manual.

8.590.7.ML. Reimbursement for members eligible for both Medicare and Medicaid shall be made in the following manner:

1. The provider shall bill Medicare first unless otherwise authorized by the Department.

2. If Medicare makes payment, Medicaid reimbursement will be based on appropriate deductibles and co-payments.

3. If Medicare denies payment, the provider shall be responsible for billing the Department. Reimbursement is dependent upon the following conditions:

a. A copy of the Explanation of Medicare Benefits shall be maintained in the provider's files when billing electronically or attached to the claim if it is billed manually; or

b. Medicaid reimbursement shall not be made if the Medicare denial is based upon provider submission error.

8.590.7.NM. Face-to-Face Encounters

1. For DME specified in the Billing Manual, a face-to-face encounter must be performed related to the primary reason a member requires the DME.

2. The face-to-face encounter must occur no more than six months before the DME is first provided to a member.

3. The face-to-face encounter must be conducted by one of the following practitioners:

a. The physician responsible for prescribing the DME;

b. A nurse practitioner or clinical nurse specialist, working in collaboration with the prescribing physician; or

c. A physician assistant under the supervision of the prescribing physician.

4. A practitioner may conduct a face-to-face encounter via telehealth or telemedicine if those services are covered by the Medical Assistance Program.

5. If a non-physician practitioner performs a face-to-face encounter they must communicate the clinical findings of the face-to-face encounter to the physician responsible for prescribing the related DME. Those clinical findings must be incorporated into a written or electronic document included in the member's medical record.

6. A physician who prescribes DME requiring face-to-face encounters must document the following:

a. The face-to-face encounter was related to the primary reason the member required the prescribed DME;

b. The practitioner who performed the face-to-face encounter;

c. The date of the face-to-face encounter; and

d. The face-to-face encounter occurred within the required timeframe.

7. Compliance with this section is required as a condition of payment for DME requiring face-to-face encounters.

8.590.7.ON. Reimbursement for Complex Rehabilitation Technology provided to members is subject to the following conditions:

1. The billing provider is a Complex Rehabilitation Technology Supplier;

2. The member has been evaluated or assessed, for selected Complex Rehabilitation Technology identified in the Billing Manual, by:

a. A Qualified Health Care Professional; and

b. A Complex Rehabilitation Technology Professional employed by the billing provider.

3. The Complex Rehabilitation Technology is provided in compliance with all applicable federal and state laws, rules, and regulations, including those rules governing the Medical Assistance Program.

8.590.7.P~~O~~. Reimbursement for Speech Generating Devices (SGD), accessories, and software provided to members is subject to the following conditions:

1. The member has a medical condition resulting in a severe expressive communication impairment; and

2. The SGD, accessories and software is used primarily as a communication device; and

3. The SGD, accessories or software are recommended by a Speech Language Pathologist after a communication assessment as described at 10 CCR 2505-10, Section 8.590.3.E.1; and

a. The recommended device, software or application should be capable of modifications to meet the needs for supportive functional communication when possible. The recommended software or application must be compatible with the prescribed SGD.

b. Accessories and supplies that do not have a primary medical use will not be covered, which includes any items that are unnecessary for operation of the SGD, or are unrelated to the SGD.

i. Covered accessories include but are not limited to:

1. Replacement lithium ion batteries;

2. Non-electric SGD communication board;

3. Mounting systems designated for securing the SGD within reach of the client;

4. Safety and protection accessories designated to maintain the life expectancy of the device,

5. Accessories not otherwise classified may be approved to enhance the use of the SGD system as the member's condition changes; and

6. Orthotic and prosthetic supplies and accessories, and/or service components of another HCPCS L code.

4. Other forms of treatment have been considered or ruled out; and

5. The member's communication impairment will benefit from the SGD, accessories, or software.