Rule Number 13 CSR 70-60.010

Use a “SEPARATE” rule transmittal sheet for EACH individual rulemaking.

Name of person to call with questions about this rule:
Content Sharie Hahn Phone (573) 522-8368 FAX (573) 522-6092
Email address Sharie.L.Hahn@dss.mo.gov

Data Entry Aaron Mealy Phone (573) 526-0414 FAX (573) 522-6092
Email address Aaron.Mealy@dss.mo.gov

Interagency mailing address DLS, Broadway Bldg, 221 W High Street, Room 230

TYPE OF RULEMAKING ACTION TO BE TAKEN
☐ Emergency Rulemaking ☐ Rule ☐ Amendment ☐ Rescission ☐ Termination
  Effective Date for the Emergency
☐ Proposed Rulemaking ☐ Rule ☒ Amendment ☐ Rescission
☐ Rule Action Notice ☐ In Addition ☐ Rule Under Consideration
☐ Request for Non-Substantive Change
☐ Statement of Actual Cost
☐ Order of Rulemaking ☐ Withdrawal ☐ Adopt ☐ Amendment ☐ Rescission
  Effective Date for the Order
☐ Statutory 30 days OR Specific date

Does the Order of Rulemaking contain changes to the rule text? ☐ NO
☐ YES—LIST THE SECTIONS WITH CHANGES, including any deleted rule text:
January 15, 2020

Sharie Hahn
Special Counsel
Missouri Department of Social Services
Broadway State Office Building
Jefferson City, MO 65102

Dear Sharie:

This office has received your Proposed Rulemaking for the following regulation:

- 13 CSR 70-60.010 Durable Medical Equipment Program

Executive Order 17-03 requires this office’s approval before state agencies release proposed regulations for notice and comment, amend existing regulations, rescind regulations, or adopt new regulations. After our review, we approve the submission of this rule to JCAR and the Secretary of State.

Sincerely,

Caroline M. Coulter
Legal Counsel
January 16, 2020

John R. Ashcroft  
Secretary of State  
Administrative Rules Division  
600 West Main Street  
Jefferson City, Missouri 65101

RE: 13 CSR 70-60.010 Durable Medical Equipment Program

Dear Secretary of State Ashcroft:

CERTIFICATION OF ADMINISTRATIVE RULE

I do hereby certify that the attached is an accurate and complete copy of the proposed rulemaking lawfully submitted by the MO HealthNet Division, Department of Social Services.

The MO HealthNet Division, Department of Social Services further certifies that it has conducted an analysis of whether or not there has been a taking of real property pursuant to section § 536.017, RSMo 2000, that the proposed rulemaking does not constitute a taking of real property under relevant state and federal law.

The MO HealthNet Division, Department of Social Services has determined and hereby also certifies that if the proposed rulemaking does affect small business pursuant to sections 536.300 to 536.310, RSMo, a small business impact statement has been filed as required by those sections. If no small business impact statement has been filed the proposed rulemaking either does not affect small business or the small business requirements do not apply pursuant to section 536.300.4, RSMo.

Statutory Authority: sections 208.153, 208.201, and 660.017, RSMo.

If there are any questions regarding the content of this proposed rulemaking, please contact:

Sharie Hahn  
221 West High Street, Room 230  
Jefferson City, MO 65102  
573-526-0414  
Sharie.L.Hahn@dss.mo.gov

Sincerely,

[Signature]

Jennifer Tidball  
Acting Director  
Department of Social Services

Enclosures

AUXILIARY AIDS AND SERVICES ARE AVAILABLE UPON REQUEST TO INDIVIDUALS WITH DISABILITIES  
TDD / TTY: 800-735-2966  
RELAY MISSOURI: 711  

Missouri Department of Social Services is an Equal Opportunity Employer Program.
January 16, 2020

Waylene W. Hiles, Director
Joint Committee on Administrative Rules
Capitol Building, Room B-8
Jefferson City, MO 65101

Dear Ms. Hiles:

RE: 13 CSR 70-60.010 Durable Medical Equipment Program

Attached is an accurate and complete copy of the proposed order regarding the amendment of 13 CSR 70-60.010. This proposed order will be filed concurrently with the Secretary of State.

Statutory authority: sections 208.153, 208.201, and 660.017, RSMo.

Sincerely,

[Signature]

Jennifer Tidball
Acting Director
Department of Social Services

Attachment
DECLARATION  
OF PUBLIC COST

I, Jennifer Tidball, Acting Director of the Missouri Department of Social Services, do declare that it is my opinion that the attached fiscal note for the proposed amendment to 13 CSR 70-60.010 is a reasonably accurate estimate.

Jennifer Tidball  
Acting Director  
Department of Social Services
FISCAL NOTE
PUBLIC COST

I. Department Title: Title 13 – Department of Social Services
Division Title: Division 70 – MO HealthNet Division
Chapter Title: Chapter 60 – Durable Medical Equipment Program

<table>
<thead>
<tr>
<th>Rule Number and Name:</th>
<th>13 CSR 70-60.010 Durable Medical Equipment Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Rulemaking:</td>
<td>Amendment</td>
</tr>
</tbody>
</table>

II. SUMMARY OF FISCAL IMPACT

<table>
<thead>
<tr>
<th>Affected Agency or Political Subdivision</th>
<th>Estimated Cost of Compliance in the Aggregate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Social Services, MO HealthNet Division</td>
<td>$261,547.79</td>
</tr>
</tbody>
</table>

III. WORKSHEET

The MO HealthNet Division (MHD) anticipates that there will be an overall 2% increase in expenditures pertaining to mobility Durable Medical Equipment (DME) items due to an increase in places of service where DME services may be provided. To determine this, expenditures from FY 2016, 2017, 2018, and 2019 were averaged, then multiplied by .02 to determine an amount of $261,547.79.

| FY 16 expenditures | $12,014,502.26 |
| FY 17 expenditures | $13,205,656.37 |
| FY 18 expenditures | $13,335,085.78 |
| FY 19 expenditures | $13,754,314.41 |
| Total expenditures for FY16-FY19 | $52,309,558.82 |
| Average expenditures (Total divided by 4 years) | $13,077,389.71 |
| 2% increase (2% of Average) | $261,547.79 |

IV. ASSUMPTIONS

MHD has engaged the DME industry throughout the process of drafting this proposed amendment to keep stakeholders involved and to solicit feedback. One way in which MHD achieves stakeholder engagement is by hosting quarterly DME Advisory Committee meetings, in which this proposed amendment has been a topic of discussion.

This feedback is what drives the MHD assumptions when determining fiscal impact. MHD anticipates that there will be a minimal change (increase of 2%) in utilization of services due to the addition of places of services outside of the home. Items expected to see an increase in utilization are those used for mobility, such as crutches, canes, walkers, wheelchairs, and wheelchair accessories.
MHD does not expect to see a substantial increase in utilization of mobility items due to the addition of places of service outside of the home, as most participants in need of mobility items will already utilize them inside the home.
I. Department Title: Title 13 – Department of Social Services  
Division Title: Division 70 – MO HealthNet Division  
Chapter Title: Chapter 60 – Durable Medical Equipment Program

<table>
<thead>
<tr>
<th>Rule Number and Title:</th>
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II. SUMMARY OF FISCAL IMPACT

<table>
<thead>
<tr>
<th>Estimate of the number of entities by class which would likely be affected by the adoption of the rule:</th>
<th>Classification by types of the business entities which would likely be affected:</th>
<th>Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,214</td>
<td>DME providers</td>
<td>$534,999.75</td>
</tr>
<tr>
<td>34,542</td>
<td>Practitioners (Physicians, Physician Assistants, and Nurse Practitioners)</td>
<td>$164,275.83</td>
</tr>
</tbody>
</table>

III. WORKSHEET

The MO HealthNet Division (MHD) estimated the number of entities likely to be affected by adoption of this proposed rule by calculating utilization data using the Missouri Medicaid Audit and Compliance (MMAC) Provider Enrollment Unit’s report of active MO HealthNet Providers. As of March 29, 2019, the MMAC Enrollment Unit reported that there were 1,214 Durable Medical Equipment (DME) providers; 845 Physician - D.O.s; 25,246 Physician - M.D.s; 1,172 Physician Assistants; and 7,279 Nurse Practitioners.

The DME provider cost for obtaining documentation of the face-to-face visit is $534,999.75. This was calculated by averaging the number of new referrals for FY 2017, FY 2018, and FY 2019 and multiplying the number of referrals by an estimated cost of $75 per referral.
<table>
<thead>
<tr>
<th></th>
<th>Served</th>
<th>Served in Prior Year</th>
<th>New Referrals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>14,764</td>
<td>5,146</td>
<td>9,618</td>
</tr>
<tr>
<td>2018</td>
<td>10,537</td>
<td>4,441</td>
<td>6,096</td>
</tr>
<tr>
<td>2019</td>
<td>9,882</td>
<td>4,196</td>
<td>5,686</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td>21,400</td>
</tr>
<tr>
<td>AVERAGE</td>
<td></td>
<td></td>
<td>7133.33</td>
</tr>
<tr>
<td>Cost Per Referral</td>
<td></td>
<td></td>
<td>$75</td>
</tr>
<tr>
<td>TOTAL COST</td>
<td></td>
<td></td>
<td>$534,999.75</td>
</tr>
</tbody>
</table>

Physician, nurse practitioners, and physician assistant costs for documenting the face-to-face visit is $164,275.83. This was calculated (as indicated in the Federal Register Volume 81, No. 21, which contains the face-to-face requirement) by multiplying the average number of new referrals by the estimated wage for each practitioner, then multiplied by an estimated 10 minutes per new referral. The mean hourly wage per practitioner was based on the U.S. Bureau of Labor Statistics’ May 2018 National Occupational Employment and Wage Estimates (the cost of fringe benefits was calculated at 100 percent of the mean hourly wage and added to the mean hourly wage to determine the adjusted hourly wage).

<table>
<thead>
<tr>
<th>Practitioner</th>
<th>Adjusted Hourly Wage</th>
<th>1/3 of new referrals</th>
<th>10 minutes</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>$203.64</td>
<td>2,377.78</td>
<td>0.167</td>
<td>$80,863.26</td>
</tr>
<tr>
<td>Nurse Practitioner</td>
<td>$105.80</td>
<td>2,377.78</td>
<td>0.167</td>
<td>$42,012.04</td>
</tr>
<tr>
<td>Physician Assistant</td>
<td>$104.26</td>
<td>2,377.78</td>
<td>0.167</td>
<td>$40,400.53</td>
</tr>
<tr>
<td>TOTAL COST</td>
<td></td>
<td></td>
<td></td>
<td>$164,275.83</td>
</tr>
</tbody>
</table>

IV. ASSUMPTIONS

DME providers enrolled with MO HealthNet will be required to comply with the proposed rule. This change will require those agencies to obtain documentation of the participant’s face-to-face visit from the prescribing physician/practitioner. Prescribing physicians will be required to document in the medical record and provide documentation of the participant face-to-face visit.

Cost to DME providers to obtain face-to-face documentation from the practitioner is estimated to be $75 per new referral.

It is assumed that participants are already seeing their healthcare providers for regular visits, so the proposed changes would not create an increase of utilization to the Physician program above the average number of new referrals.
The number of different practitioners performing the face-to-face documentation is unknown; therefore, the number of new referrals was used as the number of practitioners impacted.

The calculations used were based on the calculations used per the Federal Register Volume 81, Number 21, dated February 2, 2016, that contained the home health final rule requirements.
Small Business Regulatory Fairness Board
Small Business Impact Statement

Date: January 16, 2020

Rule Number: 13 CSR 70-60.010 Durable Medical Equipment Program

Name of Agency Preparing Statement: Department of Social Services, MO HealthNet Division (MHD)

Name of Person Preparing Statement: Desiree Vitale, MHD Legal Counsel

Phone Number: (573) 751-6937 Email: Marissa.Crump@dss.mo.gov

Name of Person Approving Statement: Todd Richardson, MHD Director

Please describe the methods your agency considered or used to reduce the impact on small businesses (examples: consolidation, simplification, differing compliance, differing reporting requirements, less stringent deadlines, performance rather than design standards, exemption, or any other mitigating technique).

The proposed amendment incorporates the requirements of 42 CFR 440.70, establishing face-to-face encounter and documentation requirements for the durable medical equipment program.

The MHD has worked with stakeholder members of the Durable Medical Equipment (DME) Advisory Committee to obtain the industry’s input on the face-to-face requirements. The advisory committee represents DME providers statewide, as advisory committee members include providers from different areas of the state, covering a broad area of DME as well as the specialty areas of orthotics and prosthetics, oxygen and respiratory therapy, wheelchairs, and other mobility equipment.

During DME advisory committee meetings, the MHD provides updates regarding the upcoming changes and requests feedback on these changes from committee members. These outreach efforts lessened the impact on small businesses by giving them the opportunity to be fully informed and better prepared for the changes, while assisting the MHD in giving notice of proposed changes, and affording agencies and small businesses the opportunity to comment on proposed changes.

Please explain how your agency has involved small businesses in the development of the proposed rule.

MHD staff collaborated with the DME Advisory Committee members regarding these changes in-person at advisory committee meetings, during which these changes were an item of discussion. The committee members understand that Missouri must reach compliance with the federal regulation 42 CFR 440.70.
Committee meeting dates: 11/9/18 and 4/23/19

Please list the probable monetary costs and benefits to your agency and any other agencies affected. Please include the estimated total amount your agency expects to collect from additionally imposed fees and how the moneys will be used.

The assumption is that there will be an overall 2% increase in expenditures pertaining to mobility DME items. It is assumed that there will be a slight increase in utilization of services resulting from the increase in places of service where DME services may be provided.

The cost to the Department of Social Services (DSS), MO HealthNet Division (MHD), is estimated to be $261,547.79. To determine this, expenditures from FY 2016, FY 2017, FY 2018, and FY 2019 were averaged and multiplied by .02 to determine an amount of $261,547.79.

The benefit to the DSS/MHD is that the DME program will be brought into compliance with federal rule 42 CFR 440.70, and MHD will continue to receive the federal matching funds through the DME program.

No other state agencies will be affected.

No fees will be collected in conjunction with implementation of this rule.

Please describe small businesses that will be required to comply with the proposed rule and how they may be adversely affected.

DME provider agencies enrolled with MO HealthNet will be required to comply with the proposed rule. This change will require those agencies to obtain documentation of the participant’s face-to-face visit from the prescribing practitioner. Prescribing practitioners will be required to document in the medical record and provide documentation of the participant face-to-face visit.

Please list direct and indirect costs (in dollars amounts) associated with compliance.

DME provider agencies: $534,999.75 to obtain face-to-face documentation;

Practitioners: $164,275.83 to document face-to-face visits; and

MO HealthNet: $261,547.79 for reimbursement of additional services

Please list types of business that will be directly affected by, bear the cost of, or directly benefit from the proposed rule.
DME provider agencies and practitioners performing face-to-face visits enrolled with MO HealthNet (Missouri Medicaid) will be directly affected by this change.

Does the proposed rule include provisions that are more stringent than those mandated by comparable or related federal, state, or county standards?

Yes___  No_X___

If yes, please explain the reason for imposing a more stringent standard.

For further guidance in the completion of this statement, please see §536.300, RSMo.
PROPOSED AMENDMENT

13 CSR 70-60.010 Durable Medical Equipment Program. The Division is amending sections (1), (2), (4), (6), (7), adding a new section (9), and renumbering existing sections (9) through (11).

PURPOSE: This amendment incorporates the requirements of federal regulation, 42 CFR 440.70. These changes include a definition of where durable medical equipment (DME) services may be provided, and adds face-to-face encounter and documentation requirements. In addition, this amendment updates terminology, the MO HealthNet Division website address, and the incorporated by reference date.

(1) Administration. The MO HealthNet Durable Medical Equipment (DME) program shall be administered by the Department of Social Services, MO HealthNet Division. The services and items covered and not covered, the program limitations, and the maximum allowable fees for all covered services shall be determined by the Department of Social Services, MO HealthNet Division and shall be included in the DME provider manual [and bulletins], which [are] is incorporated by reference and made a part of this rule as published by the Department of Social Services, MO HealthNet Division, 615 Howerton Court, Jefferson City, MO 65102/65109, at its website at [www.dss.mo.gov/mhd]/http://manuals.momed.com/collections/collection_dme/print.pdf, [November 1, 2013]/September 6, 2019. This rule does not incorporate any subsequent amendments or additions.

(2) Persons Eligible. Any person who is eligible for MO HealthNet benefits as determined by the Family Support Division is eligible for DME when the DME is medically necessary. [as determined]DME must be prescribed by the [treating]/participant’s physician [or advanced practice nurse in a collaborative practice arrangement] and reviewed by the physician annually. Covered services are limited as specified in the DME provider manual and bulletins.

(4) Definition for Durable Medical Equipment and appliances. DME is equipment and appliances that can withstand repeated use, can be reusable or removable, is primarily and customarily used to serve a medical purpose, generally is not useful to a person in the absence of [an]/a disability, illness, or injury, and is appropriate for use in [the home]/any setting in which normal life activities take place as defined in 42 CFR 440.70(c)(1). All requirements of the definition must be met in order for the equipment to be covered by MO HealthNet. 42 CFR 440.70 is published by the Federal Register, at https://www.ecfr.gov/. A copy of 42 CFR 440.70 as of January 3, 2020, is incorporated by reference and made part of this rule as published by the Department of Social Services, MO HealthNet Division, 615 Howerton Court, Jefferson City, MO 65109, at its website at https://dssruletracker.mo.gov/dss-proposed-rules/welcome.action. This rule does not incorporate subsequent amendments or additions.
(6) Covered Services. It is the provider’s responsibility to determine the coverage benefits for a MO HealthNet eligible participant based on his or her type of assistance as outlined in the DME manual and bulletins. Reimbursement will be made to qualified participating DME providers only for DME items, [determined/prescribed] by the participant’s [treating] physician [or advanced practice nurse in a collaborative practice arrangement] to be medically necessary. Specific procedure codes that are covered under the DME program are listed in Section 19 of the DME provider manual [and bulletins], which [are] incorporated by reference and made a part of this rule [as published by the Department of Social Services, MO HealthNet Division, 615 Howerton Court, Jefferson City, MO 65102, at its website at www.dss.mo.gov/mhd, November 1, 2013. This rule does not incorporate any subsequent amendment or additions]. These items must be suitable for use in [the participant’s home/any setting in which normal life activities take place, as defined in 42 CFR 440.70(e)(1)] when ordered in writing by the participant’s physician [or advanced practice nurse in a collaborative practice arrangement]. Although an item is classified as DME, it may not be covered in every instance. Coverage is based on the fact that the item is reasonable and necessary for treatment of the illness or injury, or to improve the functioning of a malformed or permanently inoperative body part, and the equipment meets the definition of DME. Even though a DME item may serve some useful, medical purpose, consideration must be given by the physician [or advanced practice nurse in a collaborative practice arrangement] and the DME supplier to what extent, if any, it is reasonable for MO HealthNet to pay for the item as opposed to another realistically feasible alternative pattern of care. Consideration should be given by the physician [or advanced practice nurse in a collaborative practice arrangement] and the DME supplier as to whether the item serves essentially the same purpose as equipment already available to the participant. If two (2) different items each meet the need of the participant, the less expensive item must be employed, all other conditions being equal.

(7) Documentation. The DME provider and physician [or advanced practice nurse in a collaborative practice arrangement] shall document how they determined [what was] the least expensive, feasible alternative for treatment of the disability, illness or injury, or to improve the functioning of a malformed or permanently inoperative body part and maintain documentation in compliance with 13 CSR 70-3.030.

(9) Face-to-face encounter and documentation requirements.

(A) For certain items of DME, a face-to-face encounter is required, as indicated in 42 CFR 440.70(g)(1). A list of DME items subject to face-to-face encounter requirements may be found at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetoFaceEncounterRequirementforCertainDurableMedicalEquipment.html, revised March 26, 2015. A copy of the list of DME items subject to face-to-face encounter requirements as of January 3, 2020, is incorporated by reference and made part of this rule as published by the Department of Social Services, MO HealthNet Division, 615 Howerton Court, Jefferson City, MO 65109, at its website at https://dssruletracker.mo.gov/dss-proposed-rules/welcome.action. This rule does not incorporate subsequent amendments or additions.

(B) No Medicaid payment for items of DME for which a face-to-face encounter is required shall be made unless there is documentation of a face-to-face encounter that meets the following criteria:

1. Related to the primary reason the beneficiary requires medical equipment;
2. Occurs no more than six (6) months prior to the written order;
3. Occurs prior to the date of service delivery; and
4. Conducted by a physician (M.D. or D.O.) or one of the following non-physician practitioners (NPP):
   (a) a nurse practitioner working in collaboration with a physician;
   (b) a clinical nurse specialist working in collaboration with a physician; or
   (c) a physician assistant, under the supervision of a physician.
   (C) The physician responsible for ordering the DME service must document the face-to-face encounter which is related to the primary reason the participant requires the DME. If an allowed NPP performs the face-to-face encounter, the clinical findings of that face-to-face encounter must be communicated to the enrolled ordering physician and be incorporated into the ordering physician’s medical record for the participant.
   (D) The DME provider must ensure that it has received the face-to-face documentation for each item of DME and for each participant for whom it is required. The DME provider must maintain the documentation in the participant’s record or files at their own location. The documentation must include the following:
      1. The clinical findings of the face-to-face encounter substantiating the need for the DME;
      2. The primary reason that the DME is required;
      3. The name, signature and credentials of the practitioner who conducted the face-to-face encounter; and
      4. The date of the face-to-face encounter; or
      5. The documentation requirements in paragraph (D)1-4 above may be met when incorporated into the pre-certification process, as approved by MHD.
   (E) If a Medicare face-to-face encounter document has already been provided for the same participant episode of care, it will also suffice as the MO HealthNet face-to-face documentation requirement.
   ((9/10) Non-Covered Items. MO HealthNet does not cover items which primarily serve the following purposes: personal comfort, convenience, education, hygiene, safety, cosmetic, new equipment of unproven value, and equipment of questionable current usefulness or therapeutic value. Specific items which are generally not covered can be found in Section 13.32 of the DME manual. Examples of non-covered items are: air conditioners, computers (unless determined to be used for an augmentative communication device), electric bathtub lifts, elevators, furniture, toys, home modifications, refrigerators, seat lift chairs, stair lifts or glides, treadmill, water softening systems, wheelchair lifts, wheelchair ramps, whirlpool tubs, or pumps.
   ((10/11) Medicare/Medicaid Crossovers. For participants having both Medicare and MO HealthNet eligibility, the MO HealthNet program pays the lesser of the amounts indicated by Medicare to be deductible and/or coinsurance due on the Medicare allowed amount or the difference between the amount paid by Medicare and the MO HealthNet allowed amount.
(11/12) Records Retention. Sanctions may be imposed by the MO HealthNet Division against a provider for failing to make available, and disclosing to the MO HealthNet Division or its authorized agents, all records relating to services provided to MO HealthNet participants or records relating to MO HealthNet payments, whether or not the records are commingled with non-Title XIX (Medicaid) records in compliance with 13 CSR 70-3.030. These records must be retained for five (5) years from the date of service. Fiscal and medical records coincide with and fully document services billed to the MO HealthNet agency. Providers must furnish or make the records available for inspection or audit by the Department of Social Services or its representative upon request. Failure to furnish, reveal, or retain adequate documentation for services billed to the MO HealthNet program, as specified above, is a violation of this regulation.


PUBLIC COST: The proposed amendment will cost state agencies or political subdivisions $261,547.79 annually.

PRIVATE COST: The proposed amendment will cost private entities $699,275.58 annually.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Department of Social Services, Legal Services Division-Rulemaking, P.O. Box 1527, Jefferson City, MO 65102-1527, or by email to Rules.Comment@dss.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.