WISCONSIN DEPARTMENT OF HEALTH SERVICES

PROPOSED ORDER TO ADOPT PERMANENT RULES

The Wisconsin Department of Health Services ("the Department") proposes an order to **amend** DHS 107.24 (1), (2) (a), and (c) 1., 4., 6.,, (3) (g), and (h) 4., and (5) (b); and to **create** ss. DHS 101.03 (28g) and (28m); DHS 105.54; and DHS 107.24 (1) (b), (2) (a) 2., (2) (c) 9., (3) (i), (3) (j), and (4) (i), relating to the use of complex rehabilitation technology.

RULE SUMMARY

Statute interpreted

The Department is authorized by 2017 Wis. Act 306 to promulgate rules for use of complex rehabilitation technology by recipients of Medical Assistance, including defining complex rehabilitation technology, defining provider certification for providers, and defining the circumstances under which complex rehabilitation technology may be covered or reimbursed by Medicaid fee-for-service and managed care organizations.

Statutory authority

The Department's authority to promulgate the proposed rules is provide in s. 49.45 (9r), Stats.

Explanation of agency authority

The Department's authority to promulgate the proposed rules is explicitly granted by the Legislature in s. 49.45 (9r) (b), Stats., and in 2017 Wis. Act 306, Section 3.

Related statute or rule

The following statutes and rules directly relate to or address complex rehabilitation technology or more generally durable medical equipment, of which complex rehabilitation technology is a subset:

42 USC 1395m
42 USC 1395w-3(a)
42 USC 1395x(n)
42 USC 1396b(i)(27)
42 CFR 440.70
42 CFR 441.15
CMS SMD# 18-001
s. 49.45 (9r), Stats.
s. 49.46 (2) (b) 6. dm., Stats.
s. 49.471 (11) (L), Stats.
s. DHS 101.03 (50)
s. DHS 105.40
s. DHS 107.02 (2m) (a) 9.
s. DHS 107.08 (4) (d) 13. b.
s. DHS 107.11 (4) (b)
s. DHS 107.113 (2) (e)
s. DHS 107.113 (4) (c)
s. DHS 107.122 (4) (d)
s. DHS 107.24
s. DHS 107.30 (4) (a) 8.
s. DHS 107.31 (2) (d) 5.
s. DHS 107.36 (1) (i)
s. DHS 107.36 (3) (L)

Plain language analysis

The intent of the proposed rules is to establish rules defining complex rehabilitation technology, defining provider certification for complex rehabilitation technology suppliers, and identifying the

circumstances under which complex rehabilitation technology may be covered or reimbursed by Medicaid fee-for-service and managed care organizations as directed by the Legislature in 2017 Wis. Act 306.

Summary of, and comparison with, existing or proposed federal regulations

42 CFR 440.70(b)(3) requires that states provide medical equipment, including durable medical equipment of which complex rehabilitation technology is a subset, suitable for use in the home as home health services and that this equipment be reviewed by a physician annually.

42 CFR 441.15 requires that states provide medical equipment, including durable medical equipment of which complex rehabilitation technology is a subset, as home health services.

"Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements," 84 Fed. Reg. 151,38330 (2019) proposes to change 42 CFR 414.234(b) to establish a master list of durable medical equipment, of which complex rehabilitation technology is a subset, requiring a face-to-face encounter with a provider, written authorization or prescription, and prior authorization in order to be a covered Medicare service.

"Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations," 84 Fed. Reg. 201,55766 (2019) proposes to change 42 CFR 411.351 and 441.357 to exclude durable medical equipment suppliers from being value-based enterprise participants.

Comparison with rules in adjacent states

Illinois:

As of August 15, 2019, the state has rules related to the provision of durable medical equipment services, of which complex rehabilitation technology is a subset, under 225 Ill. Stat. 51, 305 Ill. Stat. 5, 50 Ill. Adm. Code Part 2019, 68 Ill. Adm. Code Part 1253, 89 Ill. Adm. Code Part 120, 89 Ill. Adm. Code Part 140, and 89 Ill. Adm. Code Part 590. These services must be prescribed by a physician and certain types of durable medical equipment require a face-to-face encounter in order to qualify for coverage. Equipment providers must be licensed, including requirements to maintain a physical facility, inventory, patient records, and liability insurance. Durable medical equipment providers must also be accredited by an organization approved by the Centers for Medicare & Medicaid Services and recognized by the state. Additionally, prior authorization is required for certain durable medical equipment, such as repair of wheelchairs costing more than $400.

Iowa:

As of August 1, 2019, the state has rules related to the provision of medically necessary durable medical equipment, of which complex rehabilitation technology is a subset, under 441 IAC ch. 78. These services must be prescribed by a physician, physician assistant, or advanced registered nurse practitioner. Services must also be provided by a durable medical equipment dealer or pharmacy when available in the community in which services are being provided.

Michigan:

As of August 1, 2019, there appear to be no rules in the state that address the activities to be regulated by the proposed rules.

Minnesota:
As of August 6, 2019, the state has rules related to the provision of medically necessary durable medical equipment, of which complex rehabilitation technology is a subset, under Minn. Stat. chs. 62Q, 147, 147A, 148, and 256B and Min. Rules chs. 9505 and 9525. These services must be prescribed by a physician or licensed practitioner, including physician assistants and advanced practice registered nurses. Services must generally be provided by a certified provider that does not have a financial relationship with the ordering physician or licensed practitioner and have been granted prior authorization when the cost exceeds a designated amount. Certified providers must also have a contractual relationship with the county in which services are being provided. In some instances, volume purchases through competitive bidding are required.

Summary of factual data and analytical methodologies
The Department formed an advisory committee including representatives of Agnesian Health Shoppe; Center for Independent Living Western Wisconsin, Inc.; Disability Rights Wisconsin; Home Health Medical, Inc.; National Coalition for Assistive & Rehab Technology; National Seating & Mobility; North Country Independent Living; Numotion; Security Health Plan; and Walking and Wheeling LLC. Advisory committee members were provided a copy of draft language of the proposed rules and asked to provide comments.

The Department also provided a copy of draft language of the proposed rules to and requested comments from Include, Respect, I Self-Direct (IRIS), long-term care, and Medicaid managed care organizations not represented on the advisory committee.

Analysis and supporting documents used to determine effect on small business
The Department published a solicitation in the Administrative Register from December 23, 2019 to January 6, 2020, in which it requested comments on the economic impact of the proposed rule.

Effect on small business
Based on the economic impact public commenting period and the analysis provided in fiscal estimate and economic impact analysis, the proposed rule is anticipated to have little to no economic impact on small businesses.

Agency contact person
Laura Brauer, DHSDMSAdminRules@dhs.wisconsin.gov, 608.266.5368

Statement on quality of agency data
The data used by the Department to prepare these proposed rules and analysis comply with s. 227.14 (2m), Stats.

Place where comments are to be submitted and deadline for submission
Comments may be submitted to the agency contact person that is listed above until the deadline given in the upcoming notice of public hearing. The notice of public hearing and deadline for submitting comments will be published in the Wisconsin Administrative Register and to the department's website, at https://www.dhs.wisconsin.gov/rules/permanent.htm. Comments may also be submitted through the Wisconsin Administrative Rules Website, at: https://docs.legis.wisconsin.gov/code/chr/active.

RULE TEXT

SECTION 1. DHS 101.03 (28g) is created to read:

DHS 101.03 (28g) “Complex rehabilitation technology” means items identified in s. 49.45 (9r) (a) 2., Stats.

SECTION 2. DHS 101.03 (28m) is created to read:

DHS 101.03 (28m) “Complex rehabilitation technology professional” means an individual who is certified as an assistive technology professional by the Rehabilitation Engineering and Assistive Technology Society of North America.

SECTION 3. DHS 105.54 is created to read:

DHS 105.54 **Qualified complex rehabilitation technology suppliers.** (1) CERTIFICATION. For MA certification, complex rehabilitation technology suppliers shall do all of the following:

(a) Be accredited by a department recognized accrediting organization.

(b) Employ at least one complex rehabilitation technology professional.

(c) Have the capability to service and repair all complex rehabilitation technology provided.

(2) CLIENT SERVICES. Complex rehabilitation technology suppliers shall do all of the following:

(a) Require a complex rehabilitation technology professional to be present for evaluation and determination of recipients’ complex rehabilitation technology needs.

(b) Provide recipients’ with written information about how to receive service and repair for complex rehabilitation technology supplied at the time of delivery.

(c) Maintain records of proof of delivery in recipients’ files.

(3) REQUIREMENTS FOR MANAGED CARE ORGANIZATIONS. For MA certification, contracts between the department and managed care plans shall require managed care plans to comply with s. 49.45 (9r) (a) 2., Stats., this section, and s. DHS 107.24.

SECTION 4. DHS 107.24 (1) is amended to read:

DHS 107.24 (1) DEFINITION. In this ~~chapter,~~section:

(a) “~~medical~~Medical supplies” means disposable, consumable, expendable or nondurable medically necessary supplies which have a very limited life expectancy. Examples are plastic bed pans, catheters, electric pads, hypodermic needles, syringes, continence pads and oxygen administration circuits~~; and~~.

SECTION 5. DHS 107.24 (1) (b) is created to read:

DHS 107.24 (1) (b) “Qualified health care professional” means any of the following:

1. A physician or physician assistant licensed under subch. II of ch. 448, Stats.

2. A physical therapist licensed under subch. III of ch. 448, Stats.

3. An occupational therapist licensed under subch. VII of ch. 448, Stats.

4. A chiropractor licensed under ch. 446, Stats.

SECTION 6. DHS 107.24 (2) (a) is amended to read:

DHS 107.24 (2) COVERED SERVICES. (a) Prescription and provision.

1. Durable medical equipment (DME) and medical supplies, excluding complex rehabilitation technology identified in subd. (2) (a) 2., are covered services only when prescribed by a physician and when provided by a certified physician, clinic, hospital outpatient department, nursing home, pharmacy, home health agency, therapist, orthotist, prosthetist, hearing instrument specialist or medical equipment vendor.

SECTION 7. DHS 107.24 (2) (a) 2. is created to read:

DHS 107.24 (2) (a) 2. Complex rehabilitation manual wheelchairs, power wheelchairs, and other seating components identified in the Wisconsin DME and medical supplies indices are covered services only when prescribed by a physician and when provided by a qualified complex rehabilitation technology supplier.

SECTION 8. DHS 107.24 (2) (c) 1. is amended to read:

DHS 107.24 (2) (c) 1. Occupational therapy assistive or adaptive equipment. This is medical equipment used in a recipient's home to assist a ~~disabled~~ person with a disability to adapt to the environment or achieve independence in performing daily personal functions. Examples are adaptive hygiene equipment, adaptive positioning equipment and adaptive eating utensils.

SECTION 9. DHS 107.24 (2) (c) 4. is amended to read:

DHS 107.24 (2) (c) 4. Other home health care durable medical equipment. This is medical equipment used in a recipient's home to increase the independence of a ~~disabled~~ person with a disability or modify certain disabling conditions. Examples are patient lifts, hospital beds and traction equipment.

SECTION 10. DHS 107.24 (2) (c) 6. is amended to read:

DHS 107.24 (2) (c) 6. Physical therapy splinting or adaptive equipment. This is medical equipment used in a recipient's home to assist a ~~disabled~~ person with a disability to achieve independence in performing daily activities. Examples are splints and positioning equipment.

SECTION 11. DHS 107.24 (2) (c) 9. is created to read:

DHS 107.24 (2) (c) 9. Complex rehabilitation technology. These are items identified in the Wisconsin DME and medical supplies indices which are updated to comply with s. 49.45 (9r) (a) 2., Stats.

SECTION 12. DHS 107.24 (3) is amended to read:

DHS 107.24 (3) SERVICES REQUIRING PRIOR AUTHORIZATION. ~~The~~All of the following services require prior authorization:

(a) Purchase of all items indicated as requiring prior authorization in the Wisconsin DME and medical supplies indices, published periodically and distributed to appropriate providers by the department~~;~~.

(b) Repair or modification of an item which exceeds the department−established maximum reimbursement without prior authorization. Reimbursement parameters are published periodically in the DME and medical supplies provider handbook~~;~~.

(c) Purchase, rental, repair or modification of any item not contained in the current DME and medical supplies indices~~;~~.

(d) Purchase of items in excess of department−established frequencies or dollar limits outlined in the current Wisconsin DME and medical supplies indices~~;~~.

(e) The second and succeeding months of rental use, with the exception that all hearing aid or other assistive listening device rentals require prior authorization~~;~~.

(f) Purchase of any item which is not covered by ~~medicare~~Medicare, part b, when prescribed for a recipient who is also eligible for ~~medicare;~~Medicare.

(g) Any item required by a recipient in a nursing home which meets the requirements of subd. (4) (c)~~; and~~.

(h) Purchase or rental of a hearing aid or other assistive listening device ~~as follows~~in any of the following circumstances:

1. A request for prior authorization of a hearing aid or other ALD shall be reviewed only if the request consists of an otological report from the recipient's physician and an audiological report from an audiologist or hearing instrument specialist, is on forms designated by the department and contains all information requested by the department. A hearing instrument specialist may perform an audiological evaluation and a hearing aid evaluation to be included in the audiological report if these evaluations are prescribed by a physician who determines t~~hat~~all of the following:

a. The recipient is over the age of 21~~;~~.

b. The recipient is not cognitively or behaviorally impaired~~; and~~.

c. The recipient has no special need which would necessitate either the diagnostic tools of an audiologist or a comprehensive evaluation requiring the expertise of an audiologist~~;~~.

2. After a new or replacement hearing aid or other ALD has been worn for a 30−day trial period, the recipient shall obtain a performance check from a certified audiologist, a certified hearing instrument specialist or at a certified speech and hearing center. The department shall provide reimbursement for the cost of the hearing aid or other ALD after the performance check has shown the hearing aid or ALD to be satisfactory, or 45 days has elapsed with no response from the recipient~~;~~.

3. Special modifications other than those listed in the MA speech and hearing provider handbook shall require prior authorization~~; and~~.

4. Provision of services in excess of the life expectancies of equipment enumerated in the MA speech and hearing provider handbook require prior authorization, except for hearing aid or other ALD batteries and repair services.

SECTION 13. DHS 107.24 (3) (i) and (j) are created to read:

DHS 107.24 (3) (i) A request for prior authorization of complex rehabilitation manual wheelchairs, complex rehabilitation power wheelchairs, and other complex rehabilitation seating components shall be reviewed only if the request consists of all of the following:

1. Documentation of a complex rehabilitative technology clinical evaluation performed by a qualified health care professional that includes all of the following:

a. A detailed description of the qualified health care professional's assessment as outlined in the provider handbook including identification of the specific complex rehabilitation technology items requested.

b. A detailed description of the medical necessity as defined in ss. DHS 101.03 (96m) and 107.02 (3) (e), for each complex rehabilitation technology request.

c. The qualified health care professional's signature and date of completion.

2. Documentation stating that a direct, on-premises complex rehabilitation technology evaluation was performed by a qualified complex rehabilitation technology professional that includes all of the following:

a. A detailed description of the recipient's current durable medical equipment and requested complex rehabilitation technology items, the projected lifespan of both, the accessibility of the setting in which the requested items are to be used, the recipient's applicable methods of transportation, and an analysis of at least one comparable alternative to each requested item including an explanation of why the alternative does not meet the recipient's needs.

b. A statement asserting that the qualified complex rehabilitation technology professional will provide appropriate training to the recipient and will maintain adequate documentation of the training provided.

c. A statement indicating presence at the recipient's complex rehabilitation technology clinical evaluation or other coordination with the qualified health care provider conducting the complex rehabilitation clinical evaluation to assist in selection of the most appropriate complex rehabilitation technology item.

d. The qualified complex rehabilitation technology professional's signature and date of completion.

3. A signed statement from each qualified health care professional, who performs the complex rehabilitation technology clinical evaluation, providing documentation of a complex rehabilitation technology clinical evaluation in subd. 1. indicating he or she does not have a financial relationship with the complex rehabilitation technology supplier providing the requested items.

DHS 107.24 (3) (j) A request for prior authorization of all complex rehabilitation technology not included in par. (i) shall be reviewed only if the request complies with MA policy and procedures as described in MA provider handbooks and bulletins and includes a detailed description of the medical necessity, as defined in s. DHS 101.03 (96m), of the complex rehabilitation technology requested.

SECTION 14. DHS 107.24 (4) (i) is created to read:

DHS 107.24 (4) (i) Reimbursement for complex rehabilitation technology is limited to qualified complex rehabilitation technology suppliers.

SECTION 15. DHS 107.24 (5) (b) is amended to read:

DHS 107.24 (5) (b) Services denied by both ~~medicare~~Medicare and MA for lack of medical necessity.

SECTION 16. EFFECTIVE DATE. This rule shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, as provided in § 227.22 (2) (intro.), Stats.