

Title of Rule: Revision to the Medical Assistance Client and Clinical Care Durable Medical Equipment Rule Concerning Complex Rehabilitation Technology, Section 8.590
Rule Number: MSB 14-07-28-D
Division / Contact / Phone: Client & Clinical Care/Pharmacy Unit/Eskedar Makonnen/4079

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).

HB 14-1211 requires the Department of Health Care Policy and Financing (Department) to recognize Complex Rehabilitation Technology (CRT) as a unique category of services under Medicaid. The Department must adopt CRT supplier standards and restrict the provision of CRT to only suppliers meeting the standards; and ensure clients receiving CRT are evaluated or assessed as needed by both a qualified healthcare professional and a qualified CRT professional. The proposed rule will make changes to Section 8.590 to reflect these new benefit standards for CRT.

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:

4. State Authority for the Rule:

25.5-1-301 through 25.5-1-303, C.R.S. (2013);

EM

Initial Review **10/10/2014**

Final Adoption **11/14/2014**

Proposed Effective Date **12/30/2014**

Emergency Adoption

DOCUMENT #04

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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.

The proposed rule change benefits clients who qualify for CRT by ensuring the Department continues to protect access to CRT for individual clients with unique medical, physical and functional needs. Current practices allow for any DME supplier to provide CRT. The rule restricts the provision of CRT to only qualified CRT suppliers who meet certain standards. While that may exclude some DME suppliers, it will ensure CRT suppliers maintain a level of quality so that clients receive the appropriate CRT that meets their unique medical, physical and functional needs.

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

The established CRT supplier standards ensures clients getting CRT will receive the appropriate design and configuration by limiting the provision of CRT to qualified suppliers. Clients will also receive specialty evaluation or assessment by a health care professional and a CRT professional. This can cut time and cost that would have otherwise resulted from improperly fitted CRT. Providers who wish to be CRT suppliers would have to take the necessary steps to comply with all the CRT supplier standards to ensure they are delivering access to quality services for all CRT clients.

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.

HB 14- 1211 appropriated the Department \$51,133 comprised of \$16,533 from the general fund and \$34,600 from federal for Fiscal Year 2014-15 to implement the CRT bill. The Department does not anticipate the cost of implementing the bill will exceed the appropriated amount.

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

The proposed rule change ensures the Department is compliant with state law. Failure to implement the proposed rule change would cause the Department to be noncompliant with state law.

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

There is no less costly methods or less intrusive methods, the rule change is to comply with HB 14-1211.

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.

Not applicable.

1 **8.590 DURABLE MEDICAL EQUIPMENT AND DISPOSABLE MEDICAL SUPPLIES**

2 **8.590.1 DEFINITIONS**

3 Abuse, for purposes of this rule only, means the intentional destruction of or damage to
4 equipment that results in the need for repair or replacement.

5 Cochlear Implant or cochlear prosthesis means an electrode or electrodes surgically
6 implanted in the cochlea which are attached to an induction coil buried under the skin
7 near the ear, and the associated unit which is worn on the body.

8 Complex Rehabilitation Technology means individually configured manual Wheelchair
9 systems, power Wheelchair systems, adaptive seating systems, alternative positioning
10 systems, standing frames, gait trainers, and specifically designated options and
11 accessories, which qualify as Durable Medical Equipment that:

12 a) Are individually configured for individuals to meet their specific and unique medical,
13 physical, and functional needs and capacities for basic activities of daily living and
14 instrumental activities of daily living, including employment, identified as medically
15 necessary to promote mobility in the home and community or prevent hospitalization
16 or institutionalization of the client;

17 b) Are primarily used to serve a medical purpose and generally not useful in the
18 absence of illness or injury; and

19 c) Require certain services provided by a qualified Complex Rehabilitation Technology
20 Supplier to ensure appropriate design, configuration, and use of such items, including
21 patient evaluation or assessment of the client by a Qualified Health Care
22 Professional, and that are consistent with the client's medical condition, physical and
23 functional needs and capacities, body size, period of need, and intended use.

24 Complex Rehabilitation Technology Professional means an individual who is certified by
25 the Rehabilitation Engineering and Assistive Technology Society of North America or
26 other nationally recognized accrediting organizations as an assistive technology
27 professional.

28 Complex Rehabilitation Technology Supplier means a provider who meets all the
29 requirements of Section 8.590.5.D.

30 Disposable Medical Supplies (Supplies) means supplies prescribed by a physician that
31 are specifically related to the active treatment or therapy for an illness or physical
32 condition. Supplies are non-durable, disposable, consumable and/or expendable.

33 Durable Medical Equipment (DME) means medically necessary equipment prescribed by
34 a physician that can withstand repeated use, serves a medical purpose, and is
35 appropriate for use outside of a medical facility.

1 Financial Relationship means any ownership interest, investment interest or
2 compensation arrangement between a Qualified Health Care Professional and a
3 Complex Rehabilitation Technology Supplier, or their officers, directors, employees or
4 Immediate Family Members. An ownership or investment interest may be reflected in
5 equity, debt, or other instruments and includes, but is not limited to, mortgages, deeds of
6 trust, notes or other obligations secured by either entity.

7 Facilitative Device means DME with a retail price equal to or greater than one hundred
8 dollars that is exclusively designed and manufactured for a client with disabilities to
9 improve, maintain or restore self-sufficiency or quality of life through facilitative
10 technology. Facilitative Devices do not include Wheelchairs.

11 Hearing Aid means a wearable instrument or device designed or offered for the purpose
12 of aiding or compensating for impaired human hearing and any parts, attachments, or
13 accessories thereto, including ear molds but excluding batteries and cords.

14 Immediate Family Member means any spouse, natural or adoptive parent, natural or
15 adoptive child, stepparent, stepchild, sibling or stepsibling, in-laws, grandparents and
16 grandchildren.

17 Medical Necessity, for purposes of rule 8.590, means DME, Supplies and Prosthetic or
18 Orthotic Devices that are necessary in the treatment, prevention or alleviation of an
19 illness, injury, condition or disability.

20 Misuse means failure to maintain and/or the intentional utilization of DME, Supplies and
21 Prosthetic or Orthotic Device in a manner not prescribed, recommended or appropriate
22 that results in the need for repairs or replacement. Misuse also means DME, Supply or
23 Prosthetic Device use by someone other than the client for whom it was prescribed.

24 Prosthetic or Orthotic Device means replacement, corrective or supportive devices that
25 artificially replace a missing portion of the body, prevent or correct physical deformity or
26 malfunction, or support a weak or deformed portion of the body.

27 Qualified Health Care Professional means a licensed physical therapist, a licensed
28 occupational therapist, or other licensed health care professional who performs specialty
29 evaluations within his/her scope of practice and who has no Financial Relationship with a
30 Complex Rehabilitation Technology Supplier.

31 Related Owner means an individual with 5% or more ownership interest in a business
32 and one entitled to a legal or equitable interest in any property of the business whether
33 the interest is in the form of capital, stock, or profits of the business.

34 Related Party means a provider who is associated or affiliated with, or has control of, or
35 is controlled by the organization furnishing the DME, Supplies and Prosthetic or Orthotic
36 Device. An owner related individual shall be considered an individual who is a member of
37 an owner's immediate family, including a spouse, natural or adoptive parent, natural or
38 adoptive child, stepparent, stepchild, sibling or stepsibling, in-laws, grandparents and
39 grandchildren.

1 Wheelchair means any wheelchair or scooter that is motor driven or manually operated
2 for the purposes of mobility assistance, purchased by the Department or donated to the
3 client.

4 Wrongful Disposition means the mismanagement of DME, Supplies and Prosthetic or
5 Orthotic Devices by a client by selling or giving away the item reimbursed by the
6 Department.

7 **8.590.2 BENEFITS**

8 8.590.2.A. DME, Supplies and Prosthetic or Orthotic Devices are a benefit when Medically
9 Necessary. To determine Medical Necessity the equipment, supplies, and Prosthetic or
10 Orthotic Device shall:

- 11 1. Be prescribed by a physician and when applicable, be recommended by an
12 appropriately licensed practitioner.
- 13 2. Be a reasonable, appropriate and effective method for meeting the client's
14 medical need.
- 15 3. Have an expected use that is in accordance with current medical standards or
16 practices.
- 17 4. Be cost effective, which means that less costly and medically appropriate
18 alternatives do not exist or do not meet treatment requirements.
- 19 5. Provide for a safe environment.
- 20 6. Not be experimental or investigational, but generally accepted by the medical
21 community as standard practice.
- 22 7. Not have as its primary purpose the enhancement of a client's personal comfort
23 or to provide convenience for the client or caretaker.

24 8.590.2.B. DME, Supplies and Prosthetic or Orthotic Devices shall not be provided to clients
25 residing in a hospital, nursing facility or other facility receiving daily Medicaid
26 reimbursement except under the following circumstances:

- 27 1. DME, Supplies and Prosthetic or Orthotic Devices may be provided to clients
28 residing in a hospital, nursing facility or other facility receiving daily Medicaid
29 reimbursement if the client is within fourteen days of discharge and when prior
30 authorization and/or training are needed to assist the client with equipment usage
31 and the equipment is needed immediately upon discharge from the facility.
- 32 2. Repairs and modifications to client owned DME, Prosthetic or Orthotic Devices
33 not required as part of the per diem reimbursement shall be provided to clients
34 residing in a hospital, nursing facility or other facility receiving daily Medicaid
35 reimbursement.

- 1 3. Prosthetic or Orthotic Devices may be provided to clients residing in a hospital,
2 nursing facility or other facility receiving daily Medicaid reimbursement if
3 Prosthetic or Orthotic benefits are not included in the facilities' per diem rate.
- 4 8.590.2.C. DME, Supplies and Prosthetic or Orthotic Devices shall not be duplicative or
5 serve the same purpose as items already utilized by the client unless it is medically
6 required for emergency or backup support. Backup equipment shall be limited to one.
- 7 8.590.2.D. All items purchased by the Department shall become the property of the client
8 unless the client and provider are notified otherwise by the Department at the time of
9 purchase.
- 10 8.590.2.E. Rental equipment shall be provided if the Department determines it to be cost
11 effective and Medically Necessary.
- 12 8.590.2.F. Supplies shall be for a specific purpose, not incidental or general purpose usage.
- 13 8.590.2.G. The following DME and Supplies are benefits for clients regardless of age:
- 14 1. Ambulation devices and accessories including but not limited to canes, crutches
15 or walkers.
- 16 2. Bath and bedroom safety equipment.
- 17 3. Bath and bedroom equipment and accessories including, but not limited to,
18 specialized beds and mattress overlays.
- 19 4. Manual or power Wheelchairs and accessories.
- 20 5. Diabetic monitoring equipment and related disposable supplies.
- 21 6. Elastic supports/stockings.
- 22 7. Blood pressure, apnea, blood oxygen, Pacemaker and uterine monitoring
23 equipment and supplies.
- 24 8. Oxygen and oxygen equipment in the client's home, a nursing facility or other
25 institution. The institutional oxygen benefit is fully described in 10 C.C.R. 2505-
26 10, Section 8.580.
- 27 9. Transcutaneous and/or neuromuscular electrical nerve stimulators
28 (TENS/NMES) and related supplies.
- 29 10. Trapeze, traction and fracture frames.
- 30 11. Lymphedema pumps and compressors.
- 31 12. Specialized use rehabilitation equipment.

- 1 13. Oral and enteral formulas and supplies.
- 2 14. Parenteral equipment and supplies.
- 3 15. Environmental controls for a client living unattended if the controls are needed to
- 4 assure medical safety.
- 5 16. Facilitative Devices.
- 6 a. Telephone communication devices for the hearing impaired and other
- 7 facilitative listening devices, except hearing aids, and cochlear implants.
- 8 b. Computer equipment and reading devices with voice input or output,
- 9 optical scanners, talking software, Braille printers and other devices that
- 10 provide access to text.
- 11 c. Computer equipment with voice output, artificial larynges, voice
- 12 amplification devices and other alternative and augmentative
- 13 communication devices.
- 14 d. Voice recognition computer equipment software and hardware and other
- 15 forms of computers for persons with disabilities.
- 16 e. Any other device that enables a person with a disability to communicate,
- 17 see, hear or maneuver including artificial limbs and orthopedic footwear.

18 17. Complex Rehabilitation Technology.

- 19 8.590.2.H. The following DME are benefits to clients under the age of 21:
- 20 1. Hearing aids and accessories.
 - 21 2. Phonic ear.
 - 22 3. Therapy balls for use in physical or occupational therapy treatment.
 - 23 4. Selective therapeutic toys.
 - 24 5. Computers and computer software when utilization is intended to meet medical
 - 25 rather than educational needs.
 - 26 6. Vision correction unrelated to eye surgery.
- 27 8.590.2.I. The following Prosthetic or Orthotic Devices are benefits for clients regardless of
- 28 age:
- 29 1. Artificial limbs.
 - 30 2. Facial Prosthetics.

- 1 3. Ankle-foot/knee-ankle-foot orthotics.
- 2 4. Recumbent ankle positioning splints.
- 3 5. Thoracic-lumbar-sacral orthoses.
- 4 6. Lumbar-sacral orthoses.
- 5 7. Rigid and semi-rigid braces.
- 6 8. Therapeutic shoes.
- 7 9. Orthopedic footwear, including shoes, related modifications, inserts and heel/sole
8 replacements.
- 9 10. Specialized eating utensils and other medically necessary activities of daily living
10 aids.
- 11 11. Augmentative communication devices and communication boards.
- 12 8.590.2.J. Repairs and replacement parts are covered under the following conditions:
- 13 1. The item was purchased by Medicaid; or
- 14 2. The item is owned by the client, client's family or guardian; and
- 15 3. The item is used exclusively by the client; and
- 16 4. The item's need for repair was not caused by client misuse, abuse or neglect;
17 and
- 18 5. The item is no longer under the manufacturer warranty.
- 19 8.590.2.K. Repairs, replacement, and maintenance shall be based on the manufacturer's
20 recommendations and shall be performed by a qualified rehabilitation professional.
21 Repairs, replacement and maintenance shall be allowed on the client's primary
22 equipment and/or one piece of backup equipment. Multiple backup equipment will not be
23 repaired, replaced or maintained.
- 24 8.590.2.L. If repairs are frequent and repair costs approach the purchase price of new
25 equipment, the provider shall make a request for the purchase of new equipment. The
26 prior authorization request shall include supporting documentation explaining the need for
27 the replacement equipment and the cost estimates for repairs on both the old equipment
28 and the new equipment purchase.
- 29 8.590.2.M. Supplies are a covered benefit when related to the following:
- 30 1. Surgical, wound or burn care.

- 1 2. Syringes or needles.
- 2 3. Bowel or bladder care.
- 3 4. Antiseptics or solutions.
- 4 5. Gastric feeding sets and supplies.
- 5 6. Tracheostomy and endotracheal care supplies.
- 6 7. Diabetic monitoring.
- 7 8.590.2.N. Quantities of supplies shall not exceed one month's supply unless they are only
8 available in larger quantities as packaged by the manufacturer.
- 9 8.590.2.O. Medicaid clients for whom Wheelchairs, Wheelchair component parts and other
10 specialized equipment were authorized and ordered prior to enrollment in a Managed
11 Care Organization, but delivered after the Managed Care Organization enrollment shall
12 be the responsibility of the Department. All other DME and disposable supplies for clients
13 enrolled in a Managed Care Organization shall be the responsibility of the Managed Care
14 Organization.
- 15 8.590.2.P. Items used for the following are not a benefit to a client of any age:
16 1. Routine personal hygiene.
17 2. Education.
18 3. Exercise.
19 4. Participation in sports.
20 5. Client or caretaker convenience.
21 6. Cosmetic purposes.
22 7. Personal comfort.
- 23 8.590.2.Q. For clients age 21 and over, the following items are not a benefit:
24 1. Hearing aids and accessories.
25 2. Phonic ears.
26 3. Therapeutic toys.
27 4. Vision correction unrelated to eye surgery.
- 28 8.590.2.R. Rental Policy.

- 1 1. The Department may set a financial cap on certain rental items. The monetary
2 price for those items shall be determined by the Department and noted in the
3 Medicaid bulletin. The provider is responsible for all maintenance and repairs as
4 described at 8.590.4.P-Q, until the cap is reached.
- 5 2. Upon reaching the capped amount, the equipment shall be considered
6 purchased and shall become the property of the client. The provider shall give
7 the client and/or caregiver all applicable information regarding the equipment as
8 described at 8.590.4.C.4. The equipment shall not be under warranty after the
9 rental period ends.
- 10 3. The rental period may be interrupted, for a maximum of sixty consecutive days.
- 11 4. If the rental period is interrupted for a period greater than sixty consecutive days,
12 the rental period must begin again. The interruption must be justified,
13 documented by a physician, and maintained in the provider file.
- 14 5. If the client changes providers, the current rental cap remains in force.

15 8.590.2.S DME and Supply Benefit Coverage Standards Incorporated by Reference

16 All eligible providers of Durable Medical Equipment and Disposable Medical Supplies enrolled in
17 the Colorado Medicaid program shall be in compliance with the following Colorado Medicaid
18 Benefit Coverage Standards, which are hereby incorporated by reference:

- 19 1. Alternative and Augmentative Communication Devices (AACD) (approved June
20 28, 2013). The incorporation of the AACD Benefit Coverage Standard excludes
21 later amendments to, or editions of, the referenced material.

22 These Benefit Coverage Standards are available from Colorado Medicaid's Benefits Collaborative
23 Web site at Colorado.gov/hcpf. Click "Boards & Committees," and click "Benefits Collaborative,"
24 and click "Approved Benefit Coverage Standards." Pursuant to § 24-4-103 (12.5), C.R.S., the
25 Department maintains copies of this incorporated text in its entirety, available for public inspection
26 during regular business hours at: Colorado Department of Health Care Policy and Financing,
27 1570 Grant Street, Denver, CO 80203. Certified copies of incorporated materials are provided at
28 cost upon request.

29 **8.590.3 PRIOR AUTHORIZATION**

- 30 8.590.3.A. Selected DME, Supplies, and Prosthetic or Orthotic Devices require prior
31 authorization before they will be provided. All items requiring prior authorization are listed
32 in the Medicaid bulletin.
- 33 8.590.3.B. Prior authorization shall not be required for Medicare Crossover claims.
- 34 8.590.3.C. Prior authorization shall be required for clients who have other primary insurance
35 besides Medicare.
- 36 8.590.3.D. Prior authorization requests shall include the following information:

- 1 1. A full description of the item(s).
- 2 2. The requested number of items.
- 3 3. A full description of all attachments, accessories and/or modifications needed to
4 the basic item(s).
- 5 4. The effective date and estimated length of time the item(s) will be needed.
- 6 5. The diagnosis, prognosis, previous and current treatments and any other clinical
7 information necessary to establish Medical Necessity for the client.
- 8 6. Any specific physical limitations the client may have that are relevant to the prior
9 authorization consideration.
- 10 7. The client's prescribing physician's, primary care physician's and provider's
11 name and identification numbers.
- 12 8. The serial numbers for all Wheelchair repairs.
- 13 9. The ordering physician's signature. The physician can either sign the
14 authorization or attach a written prescription or letter of medical necessity to the
15 authorization.

16 8.590.3.E. Diagnostic and clinical information shall be completed prior to the physician's
17 signature. The provider shall not complete or add information to the prior authorization
18 after the physician has signed the request.

19 8.590.3.F. Requests for prior authorization shall be submitted in a timely fashion. Requests
20 submitted with a begin date in excess of three months prior to the date of submission
21 shall include additional, updated documentation indicating the continued Medical
22 Necessity of the request. Retroactive approval beyond three months without such
23 documentation shall be considered only in cases of client retroactive program eligibility.

24 8.590.3.G. Approval of a prior authorization does not guarantee payment or constitute a
25 waiver of any claims processing requirements including eligibility and timely filing.

26 **8.590.4 PROVIDER RESPONSIBILITIES**

27 Providers shall issue express warranties for Wheelchairs and Facilitative Devices and shall
28 assure that any refund resulting from the return of a Wheelchair or other Facilitative Device is
29 returned to the Department in compliance with Sections 6-1-401 to 6-1-412, C.R.S. (2005) and
30 Sections 6-1-501 to 6-1-511, C.R.S. (2005). Sections 6-1-401 to 6-1-412 and 6-1-501 to 6-1-511,
31 C.R.S. (2005) are incorporated herein by reference. No amendments or later editions are
32 incorporated. The Acute Care Benefits Section Manager, Colorado Department of Health Care
33 Policy and Financing may be contacted at 1570 Grant Street, Denver, Colorado 80203, for a copy
34 of the statute, or the materials may be examined at any publications depository library.

1 8.590.4.A. The Provider shall implement a system that supports client autonomy and
2 describes how equipment will be serviced and maintained, routine follow-up and
3 response procedures to prevent any interruption of services to the clients. This system
4 shall include provisions describing how service and repairs may occur at the client's
5 location when appropriate.

6 8.590.4.B. The Provider shall implement and maintain a process for honoring all warranties
7 expressed and implied under applicable State laws.

8 8.590.4.C. Providers of custom Wheelchairs, seating products and any other DME shall be
9 able to appropriately assess and provide adequate repairs, adjustment and service by
10 qualified rehabilitation professionals for all products they distribute.

11 8.590.4.D. Providers shall maintain the following for all items provided to a client:

- 12 1. Physician prescriptions.
- 13 2. Approved prior authorization requests.
- 14 3. Additional documentation received from physicians or other licensed
15 practitioners.
- 16 4. Documentation that the client and/or caregiver have been provided with the
17 following:
 - 18 a. Manufacturer's instructions.
 - 19 b. Warranty information.
 - 20 c. Registration documents.
 - 21 d. Service manual.
 - 22 e. Operating guides.
- 23 5. Documentation on all reimbursed equipment, which shall include:
 - 24 a. Manufacturer's name and address.
 - 25 b. Date acquired.
 - 26 c. Acquisition cost.
 - 27 d. Model number.
 - 28 e. Serial number.
 - 29 f. Accessories, attachments or special features included in the item.

- 1 6. Providers shall verify that equipment requiring repairs belongs to the presenting
2 client.
- 3 8.590.4.E. Providers shall retain all documentation for a period of six years.
- 4 8.590.4.F. Providers shall provide a copy of all documentation to a client or his/her
5 representative, if requested.
- 6 8.590.4.G. Providers shall be responsible for delivery of and instructing the client on the
7 proper use of the ordered/authorized equipment or supplies appropriate for the stated
8 purpose consistent with the requirements, goals and desired outcomes at the time of the
9 prescription and delivery.
- 10 8.590.4.H. The provider shall be responsible for client evaluation, wheelchair measurements
11 and fittings, client education, adjustments, modifications and delivery set-up installation of
12 equipment in the home. If modifications require the provider to fabricate customized
13 equipment or orthotics to meet client needs, the provider shall justify the necessity and
14 the cost of additional materials of the modifications. Modifications shall not alter the
15 integrity, safety or warranty of the equipment.
- 16 8.590.4.I. The provider shall pick-up inappropriate or incorrect items within five business
17 days of being notified. The provider shall not bill the Department for items known to be
18 inappropriate or incorrect and awaiting pick-up. The provider shall submit a credit
19 adjustment to the Department within twenty business days following the pick-up date if a
20 claim was submitted prior to notification an item was inappropriate or incorrect.
- 21 8.590.4.J. Providers shall confirm continued need for disposable supplies with the client or
22 caretaker prior to supply shipment.
- 23 8.590.4.K. All purchased equipment shall be new at the time of delivery to the client unless
24 an agreement was reached in advance with the client and Department.
- 25 8.590.4.L. Providers shall provide DME, Supplies, Prosthetic or Orthotic Devices, repairs
26 and all other services in the same manner they provide these services to non-Medicaid
27 clients.
- 28 8.590.4.M. Providers shall ensure the equipment provided will be warranted in accordance
29 with the manufacturer's warranty. The provider shall not bill Medicaid or the client for
30 equipment, parts, repairs, or other services covered by the warranty.
- 31 8.590.4.N. The following requirements shall apply to warranted items:
- 32 1. The provider shall be able to provide adequate repairs, adjustments and services
33 by appropriately trained technicians for all products they distribute.
- 34 2. The provider shall complete services or repairs in a timely manner and advise the
35 client on the estimated completion time.

- 1 3. The provider shall arrange for appropriate alternative, like equipment in the
2 absence of client owned backup equipment. The provider shall provide the
3 alternative equipment at no cost. If the backup equipment is not available as loan
4 equipment, the provider shall arrange for a temporary equipment rental through
5 the Department.
- 6 4. The provider shall exclude from warranty provisions, replacement or repairs to
7 equipment that are no longer able to meet client needs due to changes in
8 anatomical and/or medical condition that occurred after purchase.
- 9 5. The provider may refuse warranty services on items for which there have been
10 documented patterns of specific client abuse, misuse or neglect. The provider
11 shall notify the Department in all documented cases of abuse, misuse or neglect
12 within ten business days of learning of the incident of abuse.
- 13 8.590.4.O. Previously used or donated DME may be provided to the client if agreed upon by
14 the client and the Department Departmental approval will be coordinated by the Acute
15 Care Benefits Section.
- 16 8.590.4.P. The Provider shall assure the item provided meets the following conditions:
- 17 1. The item is fully serviced and reconditioned.
- 18 2. The item is functionally sound and in good operating condition.
- 19 3. The item will be repaired and have parts replaced in a manner equivalent to an
20 item that is new. The item will have parts available for future repairs in a manner
21 equivalent to the manufacturer's warranty on a like item which is new.
- 22 4. The provider will make all adjustments and modifications needed by the client
23 during the first year of use, except for changes and adjustments required due to
24 growth or other anatomical changes or for repairs not covered by the
25 manufacturer's warranty on a like new item.
- 26 8.590.4.Q. The provider shall receive and perform service and repairs in the same manner
27 they provide services for non-Medicaid clients for rental equipment.
- 28 8.590.4.R. The provider shall assure the following for rental equipment:
- 29 1. Appropriate service to the item.
- 30 2. Complete services or repairs in a timely manner with an estimate of the
31 approximate time required.
- 32 3. Appropriate alternative equipment during repairs.
- 33 4. Provision and replacement of all expendable items, including but not limited to
34 hoses, fuses, and batteries.

1 8.590.5 PROVIDER REQUIREMENTS

2 8.590.5.A. Providers are required to have one or more physical location(s), within the State
3 of Colorado, or within fifty (50) miles of any Colorado border.

4 8.590.5.B. The above providers must also have:

- 5 1. A street address; and
- 6 2. A local business telephone number;
- 7 3. An inventory; and
- 8 4. Sufficient staff to service or repair products.

9 8.590.5.C. Providers who do not meet the requirements of 8.590.5.A may apply to become a
10 Medical provider if the DME or disposable medical supplies are medically necessary and
11 cannot otherwise be purchased from a provider who meets the requirements of
12 8.590.5.A.

13 1. Applications from providers who do not meet the requirements of 8.590.5.A must
14 be submitted to the DME Program Coordinator for approval.

15 2. Applications submitted pursuant to this section will be reviewed for approval on a
16 case-by-case basis for those specialty items only.

17 8.590.5.D. To qualify as a Complex Rehabilitation Technology Supplier, a provider must
18 meet the following requirements:

19 1. Be accredited by a recognized accrediting organization as a supplier of Complex
20 Rehabilitation Technology;

21 2. Meet the supplier and quality standards established for Durable Medical
22 Equipment suppliers under the Medicare or Medical Assistance Program;

23 3. Employ at least one Complex Rehabilitation Technology Professional at each
24 physical location to:

25 a. Analyze the needs and capacities of a client for a Complex Rehabilitation
26 Technology item in consultation with the evaluating clinical professionals;

27 b. Assess and determine the appropriate Complex Rehabilitation
28 Technology for a client, with such involvement to include seeing the
29 client either in person or by any other real-time means within a
30 reasonable time frame during the determination process; and

31 c. Provide the client with technology-related training in the proper use and
32 maintenance of the selected Complex Rehabilitation Technology items.

1 4. Maintain a reasonable supply of parts, adequate physical facilities, qualified and
2 adequate service or repair technicians to provide clients with prompt service and
3 repair of all Complex Rehabilitation Technology it sells or supplies; and

4 5. Provide the client with written information at the time of sale on how to access
5 service and repair.

7 **8.590.6 CLIENT RESPONSIBILITIES**

8 8.590.6.A. Clients or client caregivers shall be responsible for the prudent care and use of
9 DME, Supplies, and Prosthetic or Orthotic Devices. Repairs, servicing or replacement of
10 items are not a benefit if there is documented evidence of client Abuse, Misuse, Neglect
11 or Wrongful Disposition.

12 8.590.6.B. Clients shall be responsible for the cost of any additional items or enhancements
13 to equipment not deemed Medically Necessary. The client shall sign an agreement with
14 the provider that states:

15 1. The cost of the items.

16 2. That the client was not coerced into purchasing the items.

17 3. That the client is fully responsible for the cost, servicing and repairs to the items
18 after the warranty period is completed.

19 8.590.6.C. The client shall contact the point of purchase for service and repairs to covered
20 items under warranty. Clients may contact a participating provider of their choice for
21 service and repairs to covered items not under warranty or for an item under warranty if
22 the original point of purchase is no longer a participating provider.

23 8.590.6.D. The client shall become the owner of any equipment purchased by the
24 Department and remains subject to Medicaid DME rules unless otherwise notified by the
25 Department at the time of purchase.

26 8.590.6.E. The client shall be responsible for obtaining a police report for items being
27 replaced due to theft, fire damage or accident. The police report shall be attached to the
28 prior authorization requesting replacement of the item.

29 8.590.6.F. The client shall be responsible for reporting to the manufacturer, dealer or
30 alternative warranty service provider instances where a Wheelchair or Facilitative Device
31 does not conform to the applicable express warranty.

32 8.590.6.G. The client or caregiver shall be responsible for routine maintenance on all
33 equipment purchased or rented by the Department. Routine maintenance is the servicing
34 described in the manufacturer's operating manual as being performed by the user to
35 properly maintain the equipment. Non-performance of routine maintenance shall be
36 considered Neglect. Routine maintenance includes, but is not limited to:

- 1 1. Cleaning and lubricating moving parts.
- 2 2. Adding water to batteries.
- 3 3. Checking tire pressure.
- 4 4. Other prescribed Manufacturer procedures.

5 8.590.6.H. The client utilizing rental equipment shall be responsible for notifying the provider
6 of any change of address. The client shall be responsible for any rental fee accrued
7 during the time the equipment's location is unknown to the provider.

8 8.590.6.I. The client shall not remove rental equipment from Colorado.

9 **8.590.7 REIMBURSEMENT**

10 8.590.7.A. Invoices received from Related Owners or Related Parties shall not be accepted.
11 Only invoices received from unrelated manufacturers or wholesale distributors shall be
12 recognized as allowable invoices.

13 8.590.7.B. The provider shall not bill the Department for authorized accessory items
14 included by the manufacturer as part of a standard package for an item.

15 8.590.7.C. The provider shall credit the cost of any accessory or part removed from a
16 standard package to the Department.

17 8.590.7.D. Clients and providers may negotiate in good faith a trade-in amount for DME
18 items no longer suitable for a client because of growth, development or a change in
19 anatomical and or medical condition. Such trade-in allowances shall be used to reduce
20 the cost incurred by the Department for a replacement item.

21 8.590.7.E. The refund amount due the Department on a returned Wheelchair or Facilitative
22 Device shall be agreed upon by the dealer or manufacture; wherever the item was
23 returned, and the Department.

24 8.590.7.F. Reimbursement for allowable modifications, service, and repairs on durable
25 medical equipment is as follows:

- 26 1. Labor for modifications, service, and repairs on durable medical equipment shall
27 be reimbursed at the lesser of submitted charges or the rate specified on the
28 Department fee schedule.
- 29 2. Parts that are listed on the Department's fee schedule, with a HCPCS code, that
30 have a maximum allowable reimbursement rate shall be reimbursed at the lesser
31 of submitted charges or the rate specified on the Department fee schedule.
- 32 3. Manually priced parts are reimbursed according to the same methodology used
33 for purchased equipment, as described in 8.590.7.I.

- 1 4. The provider shall not be reimbursed for labor or parts in excess of unit
2 limitations.
- 3 5. Reimbursement for a modification that requires the original equipment provider to
4 supply a part from their own inventory or stock is contingent upon the provider
5 submitting supporting documentation that demonstrates the need and actual cost
6 of the parts to be used in the modification.
- 7 8.590.7.G. Reimbursement for used equipment shall include:
- 8 1. A written, signed and dated agreement from the client accepting the equipment.
- 9 2. Billing the Department, the lesser of 60% of the maximum allowable
10 reimbursement indicated in the most recent Medicaid Bulletin or 60% of the
11 provider's usual submitted charges.
- 12 8.590.7.H. Reimbursement for purchased or rented equipment shall include, but is not
13 limited to:
- 14 1. All elements of the manufacturer's warranties or express warranties.
- 15 2. All adjustments and modification needed by the client to make the item useful
16 and functional.
- 17 3. Delivery, set-up and installation of equipment in the home, and if appropriate to a
18 specific room in the home.
- 19 4. Training and instruction to the client or caregiver in the safe, sanitary, effective
20 and appropriate use of the item and necessary servicing and maintenance to be
21 done by the client or caregiver.
- 22 5. Training and instruction on the manufacturer's instructions, servicing manuals
23 and operating guides.
- 24 8.590.7.I. Reimbursement rate for a purchased item shall be as follows:
- 25 1. Fee Schedule items, with a HCPC or CPT code, that have a maximum allowable
26 reimbursement rate shall be reimbursed at the lesser of submitted charges or the
27 Department fee schedule rate.
- 28 2. Manually priced items that do not have an assigned Fee Schedule rate shall be
29 reimbursed at the lesser of submitted charges or current manufacturer suggested
30 retail price (MSRP) less 19.86 percent.
- 31 3. Manually priced items that do not have an MSRP or Fee Schedule rate shall be
32 reimbursed at the lesser of submitted charges or by invoice of actual acquisition
33 cost, minus any discount to the provider as set forth in policy, plus 17.26 percent.

1 8.590.7.J. Reimbursement for rental items shall be billed and paid in monthly increments
2 unless otherwise indicated in the Medicaid Bulletin.

3 8.590.7.K. Reimbursement for clients eligible for both Medicare and Medicaid shall be made
4 in the following manner:

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

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

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

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

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

16 8.590.7.L. Reimbursement for Complex Rehabilitation Technology provided to clients shall
17 be made when the following conditions are met:

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

19 2. The client has been evaluated or assessed, for selected Complex Rehabilitation
20 Technology identified in the Medicaid Bulletin, by:

21 a. A Qualified Health Care Professional; and

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

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

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