



COMMONWEALTH of VIRGINIA

Office of the Governor

Daniel Carey, MD
Secretary of Health and Human Resources


March 10, 2021

Francis McCullough, Associate Regional Administrator
Centers for Medicare & Medicaid Services
801 Market Street, Suite 9400
Philadelphia, PA 19107-3134

Dear Mr. McCullough:

Attached for your review and approval is amendment 21-004, entitled "Clarifications for Durable Medical Equipment and Supplies—Revisions" to the Plan for Medical Assistance for the Commonwealth. I request that your office approve this change as quickly as possible.

Sincerely,


Daniel Carey, MD, MHCM

Attachment

cc: Karen Kimsey, Director, Department of Medical Assistance Services



COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

KAREN KIMSEY
DIRECTOR

SUITE 1300
600 EAST BROAD STREET
RICHMOND, VA 23219
804/786-7933
800/343-0634 (TDD)
www.dmas.virginia.gov

March 4, 2021

DECISION BRIEF FOR:
The Honorable Daniel Carey, M.D.
Secretary of Health and Human Resources

SUBJECT: AMENDMENT 21-004 to the PLAN for MEDICAL ASSISTANCE, entitled "Clarifications for Durable Medical Equipment and Supplies—Revisions"

ACTION NEEDED
BY 03/15/2021
RETURN TO DMAS

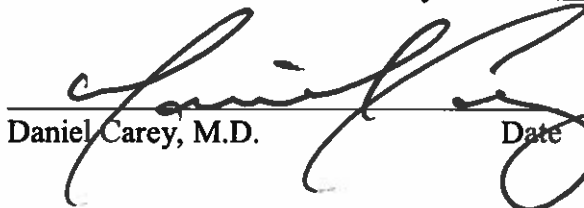
SUMMARY

1. **REQUEST:** The Department of Medical Assistance Services requests the approval of this Plan amendment TN No. 21-004 – Clarifications for Durable Medical Equipment and Supplies—Revisions.
2. **RECOMMENDATION:** Recommend approval of this State Plan amendment. The Agency intends to forward this SPA to the Centers for Medicare and Medicaid Services (CMS) Regional Office no later than March 31, 2021.


 Karen Kimsey, Director 3/4/2021
Date

3. **SECRETARY'S ACTION:** Secretary of Health and Human Resources

Approve X Approve w/ Modifications _____ Deny _____


 Daniel Carey, M.D. 3/9/21
Date

DISCUSSION

4. BACKGROUND: The section of the State Plan for Medical Assistance that is affected by this action is entitled “Amount, Duration, and Scope of Medical and Remedial Care and Services Provided to the Categorically Needy and Medically Needy”.

This state plan amendment proposes to amend *Durable Medical Equipment (DME) and Supplies Suitable for Use in the Home*. DMAS previously submitted SPA 20-011 entitled "Clarifications for Durable Medical Equipment and Supplies" which was approved by CMS on October 20, 2020. Following the approval of SPA 20-011, CMS discovered duplicative wording and the necessity to re-categorize a heading on pages 13.4, 13.5, 14, 15, and 15.1 of the state plan, and requested that DMAS submit a new SPA to revise the text on those pages. There is no change to the content or meaning of the state plan text as a result of the change.

5. AUTHORITY TO ACT: The Code of Virginia (1950) as amended, § 32.1-325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. The Code of Virginia (1950) as amended, § 32.1-324, authorizes the Director of the Department of Medical Assistance Services (DMAS) to administer and amend the Plan for Medical Assistance according to the Board's requirements.
6. FISCAL/BUDGETARY IMPACT: There is no fiscal or budgetary impact.
7. RECOMMENDATION: Recommend approval of this State Plan amendment. This amendment needs to be forwarded to the Centers for Medicare and Medicaid Services Regional Office no later than March 31, 2021.
8. REFERENCES:
 1. Social Security Act, Title XIX.
 2. Code of Federal Regulations, Part 430 to End of Title 42.
 3. Code of Virginia, § 32.1-325.

Transmittal Summary

SPA 21-004

I. IDENTIFICATION INFORMATION

Title of Amendment: Clarifications for Durable Medical Equipment and Supplies—Revisions

II. SYNOPSIS

Basis and Authority: The Code of Virginia (1950) as amended, § 32.1-325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. The Code of Virginia (1950) as amended, § 32.1-324, authorizes the Director of the Department of Medical Assistance Services (DMAS) to administer and amend the Plan for Medical Assistance according to the Board's requirements.

Purpose: This state plan amendment proposes to amend *Durable Medical Equipment (DME) and Supplies Suitable for Use in the Home*. DMAS previously submitted SPA 20-011 entitled "Clarifications for Durable Medical Equipment and Supplies" which was approved by CMS on October 20, 2020. Following the approval of SPA 20-011, CMS discovered duplicative wording and the necessity to re-categorize a heading on pages 13.4, 13.5, 14, 15, and 15.1 of the state plan, and requested that DMAS submit a new SPA to revise the text on those pages. There is no change to the content or meaning of the state plan text as a result of the change.

Substance and Analysis: The section of the State Plan that is affected by this amendment is entitled Amount, Duration, and Scope of Medical and Remedial Care and Services Provided to the Categorically Needy and Medically Needy.

Impact: None

Prior Public Notice: Not applicable.

Public Comments and Agency Analysis: Not applicable.

Tribal Notice: See Attachment A1.



COMMONWEALTH of VIRGINIA

KAREN KIMSEY
DIRECTOR

Department of Medical Assistance Services

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www.dmas.virginia.gov

Attachment A1

December 16, 2020

SUBJECT: Notice of Opportunity for Tribal Comment: – State Plan Amendments related to:

- Clarifications for Durable Medical Equipment (DME) and Supplies – Revisions
- Removal of the 21 Out of 60 Day Limit

Dear Tribal Leader and Indian Health Programs:

This letter is to notify you that the Department of Medical Assistance Services (DMAS) is planning to amend the Virginia State Plan for Medical Assistance with the Centers for Medicare and Medicaid Services (CMS). Specifically, DMAS is providing you notice about State Plan Amendments (SPAs) that the Agency will file with the CMS entitled *Clarifications for Durable Medical Equipment (DME) and Supplies – Revisions* and *Removal of the 21 Out of 60 Day Limit*.

1. DME and Supplies - Revisions: This SPA will include minor revisions made to a previously approved SPA (SPA 20-011, Clarifications for Durable Medical Equipment and Supplies, approved on October 20, 2020). Following the approval of SPA 20-011, CMS discovered duplicative wording on multiple pages of the state plan, and requested that DMAS submit a new SPA to revise the text on those pages. There is no change to the content or meaning of the state plan text as a result of these changes.

2. Removal of the 21 Out of 60 Day Limit: This SPA will allow the Virginia Medicaid program to conform to the CMS Medicaid Mental Health Parity Rule, which ensures that accessing mental health and substance use disorder services is no more difficult than accessing medical/surgical services. To comply with the Medicaid Mental Health Parity Rule, DMAS must remove a limit for psychiatric hospitalization that was previously removed for non-psychiatric admissions. The limit prevented more than 21 days in a hospital in a 60 day period for the same or similar diagnosis or treatment plan.

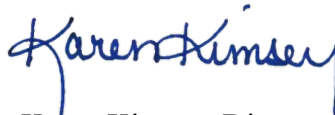
Please contact us if you would like to see the text changes or documents associated with any or all of these SPAs.

The tribal comment period for these SPAs is open through January 16, 2021. You may submit your comments directly to Jimiequa Williams, DMAS Policy Division, by phone (804) 225-3508, or via email: Jimiequa.Williams@dmas.virginia.gov. Finally, if you prefer regular mail, you may send your comments or questions to:

Virginia Department of Medical Assistance Services
Attn: Jimiequa Williams
600 East Broad Street
Richmond, VA 23219

Please forward this information to any interested party.

Sincerely,



Karen Kimsey, Director
Va. Department of Medical Assistance Services

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER
2 1 — 0 0 4

2. STATE
Virginia

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
4/01/2021

5. TYPE OF PLAN MATERIAL (*Check One*)

- NEW STATE PLAN AMENDMENT TO BE CONSIDERED AS NEW PLAN AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (*Separate transmittal for each amendment*)

6. FEDERAL STATUTE/REGULATION CITATION

42 CFR Part 410

7. FEDERAL BUDGET IMPACT

a. FFY 2021 \$ \$0
b. FFY 2022 \$ \$0

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment 3.1-A&B, Supplement 1,
pages 13.4, 13.5, 14, 14.2, 15, 15.1

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (*If Applicable*)

Same as Box #8

10. SUBJECT OF AMENDMENT

Clarifications for Durable Medical Equipment and Supplies—Revisions

11. GOVERNOR'S REVIEW (*Check One*)

- GOVERNOR'S OFFICE REPORTED NO COMMENT
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

OTHER, AS SPECIFIED

Secretary of Health and Human Resources

12. SIGNATURE OF STATE AGENCY OFFICIAL



13. TYPED NAME

Karen Kimsey

14. TITLE

Director

15. DATE SUBMITTED

3/4/2021

16. RETURN TO

Dept. of Medical Assistance Services
600 East Broad Street, #1300
Richmond VA 23219

Attn: Regulatory Coordinator

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED

18. DATE APPROVED

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL

20. SIGNATURE OF REGIONAL OFFICIAL

21. TYPED NAME

22. TITLE

23. REMARKS

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

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- ~~6. Items and services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (for example, dentifrices; toilet articles; shampoos which do not require a physician's prescription; dental adhesives; electric toothbrushes; cosmetic items, soaps, and lotions which do not require a practitioner's prescription; sugar and salt substitutes; and support stockings;~~
- ~~7. Orthotics, including braces, diabetic shoe inserts, splints, and supports;~~
- ~~8. Home or vehicle modifications;~~
- ~~9. Items not suitable for or not used primarily in the home setting (i.e., car seats, equipment to be used while at school, etc.);~~
- ~~10. Equipment for which the primary function is vocationally or educationally related (i.e., computers, environmental control devices, speech devices, etc.);~~
- ~~11. Diapers for routine use by children younger than three years of age who have not yet been toilet trained;~~
- ~~12. Equipment or items that are not suitable for use in the home; and~~
- ~~13. Equipment or items that the Medicaid individual or caregiver is unwilling or unable to use in the home.~~
- ~~14. All medically necessary supplies and equipment shall be covered; unusual types shall be preauthorized based on a medical necessity determination. Individuals shall be notified of their right to appeal any denial determination.~~

~~E. For coverage of blood glucose meters for pregnant women, refer to Supplement 3 to Attachment 3.1 A & B.~~

~~1. Coverage of home infusion therapy:~~

~~1. Home infusion therapy shall be defined as the intravenous (I.V.) administration of fluids, drugs, chemical agents, or nutritional substances to recipients in the home setting. DMAS shall cover these services, supplies, and drugs on a service day rate methodology established in Attachment 4.19 B (12 VAC 30-80-30) page 4.8. The therapies to be covered under this policy shall be: hydration therapy, chemotherapy, pain management therapy, drug therapy, and total parenteral nutrition (TPN). All the therapies which meet criteria shall be covered and do not require prior authorization. The established service day rate shall cover all services delivered in a single day. There shall be no additional reimbursement for special or extraordinary services. In the event of incompatible drug administration, a separate HCPCS code shall be used to allow for rental of a second infusion pump and purchase of extra administration tubing. When applicable, this code may be billed in addition to the other service day rate codes. There shall be documentation to support the use of this code on the I.V. Implementation Form. Proper documentation shall include the need for pump administration of the medications ordered, frequency of administration to support that they are ordered simultaneously, and indication of incompatibility.~~

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~~2. The service day rate payment methodology shall be mandatory for reimbursement of all I.V. therapy services except for the recipient who is enrolled in the Technology Assisted waiver program.~~

~~3. The following limitations shall apply to this service:~~

~~a. This service must be medically necessary to treat an individual's medical condition. The service must be ordered and provided in accordance with accepted medical practice. The service must not be desired solely for the convenience of the recipient or the recipient's caregiver.~~

~~b. In order for Medicaid to reimburse for this service, the individual shall:~~

~~(a) Reside in either a private home or a domiciliary care facility;~~

~~(b) Be under the care of a physician who prescribes the home infusion therapy and monitors the progress of the therapy.~~

~~(c) Have body sites available for peripheral intravenous catheter or needle placement or have a central venous access; AND~~

~~(d) Be capable of either self administering such therapy or have a caregiver who can be adequately trained, is capable of administering the therapy, and is willing to safely and efficiently administer and monitor the home infusion therapy. The caregiver must be willing to and be capable of following appropriate teaching and adequate monitoring. In those cases where the individual is incapable of administering or monitoring the prescribed therapy and there is no adequate or trained caregiver, it may be appropriate for a home health agency to administer the therapy.~~

~~G. The medical equipment and supply vendor shall provide the equipment and supplies as prescribed by the physician on the CMN. Orders shall not be changed unless the vendor obtains a new CMN, which includes the physician's signature, prior to ordering the equipment or supplies or providing the equipment or supplies to the individual.~~

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4. Items and services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (for example, dentifrices; toilet articles; shampoos which do not require a physician's prescription; dental adhesives; electric toothbrushes; cosmetic items, soaps, and lotions which do not require a practitioner's prescription; sugar and salt substitutes; and support stockings;
5. Home or vehicle modifications;
6. Equipment for which the primary function is vocationally or educationally related (i.e., computers, environmental control devices, speech devices, etc.);
7. Diapers for routine use by children younger than three years of age who have not yet been toilet trained.

E. For coverage of blood glucose meters for pregnant women, refer to Supplement 3 to Attachment 3.1 A & B.

F.

1. Coverage of home infusion therapy. Home infusion therapy shall be defined as the administration of fluids, drugs, chemical agents, or nutritional substances to individuals through intravenous (I.V.) therapy or an implantable pump in the home setting. The therapies to be covered under this policy shall be: hydration therapy, chemotherapy, pain management therapy, drug therapy, and total parenteral nutrition (TPN). All the therapies which meet criteria shall be covered and do not require prior authorization.

TN No. 21-004

Approval Date _____

Effective Date 04-01-21

Supersedes

TN No. 20-011

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

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H. Medicaid shall not provide coverage to the DME and supply vendor for services that are provided (i) prior to the date prescribed by the physician; (ii) prior to the date of the delivery; (iii) or when services are not provided in accordance with DMAS published regulations and guidance documents. If coverage is denied for one of these reasons, the medical equipment and supply vendor shall not bill the Medicaid individual for the service that was provided.

I. The following criteria shall be satisfied through the submission of adequate and verifiable documentation on the CMN satisfactory to DMAS. Medically necessary DME and supplies shall be:

1. Ordered by the licensed practitioner on the CMN;
2. A reasonable and necessary part of the individual's treatment plan;
3. Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual;
4. Not furnished solely for the convenience, safety, or restraint of the individual, the family or caregiver, attending physician, or other licensed practitioner or supplier;
5. Consistent with generally accepted professional medical standards (i.e., not experimental or investigational); and
6. Furnished at a safe, effective, and cost-effective level suitable for ~~use in~~ the individual's home environment use.

TN No. 21-004

Approval Date _____

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~~L. Coverage of enteral nutrition products. Individuals receive covered enteral nutrition based on medical need. Coverage of enteral nutrition (EN) that does not include a legend drug shall be limited to when the nutritional supplement is the sole source form of nutrition, is administered orally or through a nasogastric or gastrostomy tube, and is necessary to treat a medical condition. Coverage of EN shall not include the provision of routine infant formula. A nutritional assessment shall be required for all recipients for whom nutritional supplements are ordered.~~

~~1. General requirements and conditions.~~

~~a. Enteral nutrition products shall only be provided by enrolled DME providers.~~

~~b. DME providers shall adhere to all applicable DMAS policies, law, and regulations. DME providers shall also comply with all other applicable Virginia Laws and regulations requiring licensing, registration, or permitting. Failure to comply with such laws and regulations shall result in denial of coverage for enteral nutrition that is regulated by such licensing agency or agencies.~~

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~~J. ——— Enteral nutrition products. Coverage of enteral nutrition (EN) drug shall be limited to when the nutritional supplement is administered orally or through a nasogastric or gastrostomy tube, and is necessary to treat a medical condition. DMAS shall provide coverage for nutritional supplements for enteral feeding only if the nutritional supplements are not available over the counter. Additionally, DMAS shall cover medical foods that are (i) specific to inherited diseases and metabolic disorders; (ii) not generally available in grocery stores, health food stores, or the retail section of a pharmacy; and (iii) not used as food by the general population. Coverage of EN shall not include the provision of routine infant formula or feedings as meal replacement only. Coverage of medical foods shall not extend to regular foods prepared to meet particular dietary restrictions, limitations, or needs, such as meals designed to address the situation of individuals with diabetes or heart disease. A nutritional assessment shall be required for all individuals for whom nutritional supplements are ordered.~~

~~1. General requirements and conditions:~~

- ~~a. Enteral nutrition products shall only be provided by enrolled DME providers.~~
- ~~b. DME providers shall adhere to all applicable DMAS policies, law, and regulations. DME providers shall also comply with all other applicable Virginia Laws and regulations requiring licensing, registration, or permitting. Failure to comply with such laws and regulations shall result in denial of coverage for enteral nutrition that is regulated by such licensing agency.~~

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4. Items and services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (for example, dentifrices; toilet articles; shampoos which do not require a physician's prescription; dental adhesives; electric toothbrushes; cosmetic items, soaps, and lotions which do not require a practitioner's prescription; sugar and salt substitutes; and support stockings;
 5. Home or vehicle modifications;
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 7. Diapers for routine use by children younger than three years of age who have not yet been toilet trained.
- E. For coverage of blood glucose meters for pregnant women, refer to Supplement 3 to Attachment 3.1 A & B.
- F.
1. Coverage of home infusion therapy. Home infusion therapy shall be defined as the administration of fluids, drugs, chemical agents, or nutritional substances to individuals through intravenous (I.V.) therapy or an implantable pump in the home setting. The therapies to be covered under this policy shall be: hydration therapy, chemotherapy, pain management therapy, drug therapy, and total parenteral nutrition (TPN). All the therapies which meet criteria shall be covered and do not require prior authorization.

TN No. 21-004

Approval Date _____

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Supersedes

TN No. 20-011

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H. Medicaid shall not provide coverage to the DME and supply vendor for services that are provided (i) prior to the date prescribed by the physician; (ii) prior to the date of the delivery; (iii) or when services are not provided in accordance with DMAS published regulations and guidance documents. If coverage is denied for one of these reasons, the medical equipment and supply vendor shall not bill the Medicaid individual for the service that was provided.

I. The following criteria shall be satisfied through the submission of adequate and verifiable documentation on the CMN satisfactory to DMAS. Medically necessary DME and supplies shall be:

1. Ordered by the licensed practitioner on the CMN;
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3. Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual;
4. Not furnished solely for the convenience, safety, or restraint of the individual, the family or caregiver, attending physician, or other licensed practitioner or supplier;
5. Consistent with generally accepted professional medical standards (i.e., not experimental or investigational); and
6. Furnished at a safe, effective, and cost-effective level suitable for the individual's use.

TN No. 21-004

Approval Date _____

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TN No. 20-011

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