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**State/Territory Name:** **Virginia**

**State Plan Amendment (SPA) #:** **20-0011**

This file contains the following documents in the order listed:

**DEPARTMENT OF HEALTH & HUMAN SERVICES**
Centers for Medicare & Medicaid Services
601 E. 12th Street, Room 355
Kansas City, Missouri 64106

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Medicaid and CHIP Operations Group

October 19, 2020

Karen Kimsey, Director
Department of Medical Assistance Services
600 East Broad Street, Suite 1300
Richmond, VA 23219

RE: Virginia State Plan Amendment 20-0011

Dear Ms. Kimsey:

The Centers for Medicare & Medicaid Services (CMS) has reviewed Virginia's State Plan Amendment (SPA) 20-0011, Clarifications for Durable Medical Equipment (DME) and Supplies.

The purpose of this SPA is to update coverage and documentation requirements for enteral nutrition and allow the use of implantable pumps for delivering home infusion therapy. The SPA also streamlines and enhances flexibility for delivery ticket components and identifies the process and requirements for replacement DME to Medicaid beneficiaries who have lost DME or had DME destroyed because of a disaster.

This SPA is acceptable. Therefore, we are approving SPA 20-0011 with an effective date of August 30, 2020. Enclosed are the approved SPA pages and signed CMS-179 form.

If you have any questions concerning this information, please contact me at (816) 426-6417, or your staff may contact Margaret Kosherzenko at Margaret.Kosherzenko@cms.hhs.gov or (215) 861-4288.

Sincerely,

Digitally signed by James G. Scott -S
Date: 2020.10.19 13:49:46 -05'00'

James G. Scott, Director
Division of Program Operations

Enclosures

cc:
Emily McClellan

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB No. 0938-0193

# TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

**FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER: 20-011

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: ~~08/1/2020~~ JW 8/30/20

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 2020 $ -0-
b. FFY 2021 $ -0-

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Revised Pages: Attachment 3.1-A&B, pages 13, 13.1, 13.2, 13.3, 14, 14.1, 14.2, ~~15,~~ 15.1

New Pages: Attachment 3.1-A&B, pages ~~14.3~~ 15.1.1, 15.1.2, 15.1.3 JW

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

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

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT 2020
☐ 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: Karen Kimsey

13. TYPED NAME: Karen Kimsey

14. TITLE: Director

15. DATE SUBMITTED: 7/15/2020

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: 07/28/2020

18. DATE APPROVED: 10/14/2020

**PLAN APPROVED - ONE COPY ATTACHED**

19. EFFECTIVE DATE OF APPROVED MATERIAL: 08/30/2020

20. SIGNATURE OF REGIONAL OFFICIAL: James G. Scott
Digitally signed by James G. Scott -S
Date: 2020.10.19 13:50:11 -05'00'

21. TYPED NAME: James G. Scott

22. TITLE: Director, Division of Program Operations

23. REMARKS

FORM CMS-179 (07/92)

***Instructions on Back***

Save

**STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT**

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§ 7.5. Durable medical equipment (DME) and supplies suitable for use. (12 VAC 30-50-165)

A. Definitions. The following words and terms when used in this section shall have the following meaning unless the context clearly indicates otherwise:

"Affirmative contact" means speaking, either face-to-face or by phone, with either the individual or caregiver in order to ascertain that the DME and supplies are still needed and appropriate. Such contacts shall be documented in the individual's medical record.

"Certificate of Medical Necessity" or "CMN" means the DMAS-352 form that operates as a plan of care, and that must be completed and submitted in order for DMAS to provide coverage.

"Designated agent" means an entity with whom DMAS has contracted to perform functions such as provider audits and prior authorizations of services.

"DMAS" means the Department of Medical Assistance Services.

"DME provider" means those entities enrolled with DMAS to render DME services.

"Durable medical equipment" or "DME" means medical supplies, equipment, and appliance suitable for use consistent with 42 CFR 440.70(b)(3) that treat a diagnosed condition or assist the individual with functional limitations.

"Enteral nutrition" refers to any method of feeding that uses the gastrointestinal tract to deliver part or all of an individual's caloric requirements. "Enteral nutrition" may include a routine oral diet, the use of liquid supplements, or delivery of part or all of the daily requirements by use of a tube, which is called a tube feeding.

"Expendable supply" means an item that is used and then disposed of.

"Frequency of use" means the rate of use by the individual as documented by the number of times per day, week, or month, as appropriate, a supply is used by the individual. Frequency of use must be recorded on the face of the CMN in such a way that reflects whether a supply is used by the individual on a daily, weekly, or monthly basis. Frequency of use may be documented on the CMN as a range of the rate of use. By way of example and not limitation, at the frequency of use of a supply may be expressed as a range, such four to six adult diapers per day. However large ranges shall not be acceptable documentation of frequency of use (for example, the range of one to six adult diapers per day shall not be acceptable.) The frequency of use provides the justification for the total quantity of supplies ordered on the CMN.

"Functional limitation" means the inability to perform a normal activity.

"Physician" means a provider of physician services as defined in 42 CFR 440.50.

"Prior authorization" or "PA" means the process of approving either by DMAS or its prior authorization contractor for the purposes of DMAS reimbursement for the service for the individual before it is rendered or reimbursed.

"Quantity" means the total number of supplies ordered on a monthly basis as reflected on the CMN. The monthly quantity of supplies ordered for the individual shall be dependent upon the individual's frequency of use.

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B. General requirements and conditions.

1. a. All medically necessary medical supplies and equipment shall be covered. Unusual amounts, types, and duration of usage must be authorized by DMAS in accordance with published policies and procedures. When determined to be cost-effective by DMAS, payment may be made for rental of the equipment in lieu of purchase.
   b. No provider shall have a claim of ownership on DME reimbursed by Virginia Medicaid once it has been delivered to the Medicaid individual. Providers shall only be permitted to recover DME, for example, when DMAS determines that it does not fulfill the required medically necessary purpose as set out in the Certificate of Medical Necessity, when there is an error in the ordering practitioner's CMN, or when the equipment is rented.

2. DME providers shall adhere to all applicable federal laws and regulations, including the face-to-face requirements in 42 CFR 410.38. DME providers shall also adhere to all applicable state laws and regulations and DMAS' policies for DME and supplies. DME providers shall comply with all other applicable Virginia laws and regulations requiring licensing, registration, or permitting. Failure to comply with such laws and regulations that are required by such licensing agency or agencies shall result in denial of coverage for DME or supplies which are regulated by a licensing agency. Upon post payment review, DMAS or its designated contractor may deny coverage for any DME products or supplies that have not been provided and billed in accordance with these regulations and DMAS policies.

3. DME and supplies must be furnished pursuant to a properly completed Certificate of Medical Necessity (CMN) (DMAS-352). In order to obtain Medicaid coverage, specific fields of the DMAS-352 form shall be completed as specified in Attachment 3.1-C, p. 17.1 (12 VAC 30-60-75).

4. DME and supplies shall be ordered by the physician and shall be related to medical treatment of the Medicaid individual. The complete DME order shall be recorded on the CMN for Medicaid individuals to receive such services. In the absence of a different effective period determined by DMAS or its designated agent, the CMN shall be valid for a maximum period of six months for Medicaid individuals younger than 21 years of age. In the absence of a different effective period determined by DMAS or its designated agent, the maximum valid time period for CMNs for Medicaid individuals 21 years of age and older shall be 12 months. The validity of the CMN shall terminate when the individual's medical need for the prescribed DME or supplies no longer exists as determined by the physician.

5. DME shall be furnished exactly as ordered by the physician who signed the CMN. The CMN and any supporting verifiable documentation shall be fully completed, signed and dated by the physician, and in the DME provider's possession within 60 days from the time the ordered DME and supplies are initially furnished by the DME provider. Each component of the DME shall be specifically ordered on the CMN by the physician. The order shall not be backdated to cover prior dispensing of all DME products and supplies. If the order is not signed within 60 days of the service initiation, then the date the order is signed becomes the effective date.

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6. The CMN shall not be changed, altered, or amended after the attending physician has signed it. If individual's condition indicates that changes in the ordered DME or supplies are necessary, the DME provider shall obtain a new CMN. All CMNs shall be signed and dated by the physician within 60 days from the time the ordered supplies are furnished by the DME provider.

7. DMAS or its designated agent shall have the authority to determine a different length of time from those specified in subdivisions 4, 5, and 6 of this subsection that a CMN may be valid based on medical documentation submitted on the CMN. The CMN may be completed by the DME provider or other appropriate health care professionals, but it shall be signed and dated by the physician, as specified in subdivision 5 of this subsection. Supporting documentation may be attached to the CMN but the attending physician's entire order shall be on the CMN.

8. The DME provider shall retain a copy of the CMN and all supporting verifiable documentation on file for purposes of the DMAS post payment audit review. DME providers shall not create or revise CMNs or supporting documentation for this service after the initiation of the post payment review audit process. Physicians shall not complete, nor sign and date CMNs once the post payment audit review has begun.

9. The DME provider shall be responsible for knowledge of items requiring prior authorization and the limitation on the provision of certain items as described in the Virginia Medicaid Durable Medical Equipment and Supplies Manual, Appendix B. (This limitation may be exceeded based upon medical necessity.) Appendix B shall be the official listing of all items covered through the Virginia Medicaid DME program and lists the service limits, items that require prior authorization, billing units, and reimbursement rates.

10. The DME provider shall be required to make affirmative contact with the individual or his caregiver and document the interaction prior to the next month's delivery and prior to the recertification CMN to assure that the appropriate quantity, frequency, and product are provided to the individual.

11. Supporting documentation, added to a completed CMN, shall be allowed to further justify the medical need for DME but shall not replace the requirement for a properly completed CMN.

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12. DMAS shall deny payment to the DME provider if any of the following occur:

    a. Absence of a current, fully completed CMN appropriately signed and dated by the practitioner;
    b. Documentation does not verify that the item was provided to the individual;
    c. Lack of medical documentation, signed by the practitioner to justify the DME products or supplies; or
    d. Item is non-covered or does not meet DMAS criteria for coverage.

13. If coverage is denied by Medicaid, the DME provider shall not bill the Medicaid individual for the service that was provided.

C. The billing unit for incontinence supplies (such as diapers, pull-ups, and panty liners) shall be by each product. For example, if the incontinence supply being provided is diapers, DMAS will cover them by each individual diaper, rather than a case of diapers. Prior authorization shall be required for incontinence supplies requested in quantities greater than the allowable service limit per month. This service shall be provided as a sole source contract.

D. 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. Supplies, equipment, or appliances that are generally not covered include, but are not limited to, the following:

1. Space conditioning equipment, such as room humidifiers, air cleaners, and air conditioners

2. Furniture or appliances not defined as medical equipment (such as blenders, bedside tables, mattresses other than for a hospital bed, pillows, blankets or other bedding, special reading lamps, chairs with special lift seats, hand-held shower devices, exercise bicycles, and bathroom scales)

3. Items that are only for the recipient's comfort and convenience or for the convenience of those caring for the recipient (e.g., a hospital bed or mattress because the recipient does not have a decent bed; wheelchair trays used as a desk surface;) mobility items used in addition to primary assistive mobility aide the convenience of the individual or his caregiver (i.e., an electric wheelchair plus a manual chair); and cleansing wipes.

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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.

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.

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2. 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 DME 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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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.

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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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2. Service units and service limitations.
   a. DME and supplies shall be furnished pursuant to the Certificate of Medical Necessity (DMAS 352).
   b. The DME provider shall include documentation related to the nutritional evaluation findings on the CMN and may include supplemental information on any supportive documentation submitted with the CMN.
   c. DMAS shall reimburse medically necessary formulae and medical foods when used under a licensed practitioner's direction to augment dietary limitations or provide primary nutrition to individuals via enteral or oral feeding methods.
   d. The CMN shall contain a licensed practitioner's order for the enteral nutrition products that are medically necessary to treat the diagnosed condition and the individual's functional limitation. The justification for enteral nutrition products shall be demonstrated in the written documentation either on the CMN or on the attached supporting documentation. The CMN shall be valid for a maximum period of six months.
   e. Regardless of the amount of time that may be left on a six-month approval period, the validity of the CMN shall terminate when the individual's medical need for the prescribed enteral nutrition products ends, as determined by the licensed practitioner.
   f. A face-to-face nutritional assessment completed by trained clinicians (e.g., physician, physician assistant, nurse practitioner, registered nurse, or a registered dietitian) shall be completed as required documentation of the need for enteral nutrition products.
   g. Prior authorization of enteral nutrition products shall not be required. The DME provider shall assure that there is a valid CMN (i) completed every six months in accordance with subsection B of this section and (ii) on file for all Medicaid individuals for whom enteral nutrition products are provided.

   (1) The DME provider is further responsible for assuring that enteral nutrition products are provided in accordance with DMAS reimbursement criteria in 12VAC30-80-30 A 6.

   (2) Upon post payment review, DMAS or its designated contractor may deny reimbursement for any enteral nutrition products that have not been provided and billed in accordance with this section and DMAS policies.

   h. DMAS shall have the authority to determine that the CMN is valid for less than six months based on medical documentation submitted.

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3. Provider responsibilities.

a. The DME provider shall provide the enteral nutrition products as prescribed by the licensed practitioner on the CMN. Physician orders shall not be changed unless the DME provider obtains a new CMN prior to ordering or providing the enteral nutrition products to the individual.

b. The licensed practitioner's order on the CMN shall specify either a brand name of the enteral nutrition product being ordered or the category of enteral nutrition products that must be provided. If a licensed practitioner orders a specific brand of enteral nutrition product, the DME provider shall supply the brand prescribed. The licensed practitioner order shall include the daily caloric intake and the route of administration for the enteral nutrition product. Supporting documentation may be attached to the CMN, but the entire licensed practitioner's order shall be on the CMN.

c. The CMN shall be signed and dated by the licensed practitioner within 60 days of the CMN begin service date. The order shall not be backdated to cover prior dispensing of enteral nutrition products. If the CMN is not signed and dated by the licensed practitioner within 60 days of the CMN begin service date, the CMN shall become valid on the date of the licensed practitioner's signature.

d. The CMN shall include all of the following elements:

(1) Height of individual (or length for pediatric patients);

(2) Weight of individual. For initial assessments, indicate the individual's weight loss over time;

(3) Tolerance of enteral nutrition product (e.g., is the individual experiencing diarrhea, vomiting, constipation). This element is only required if the individual is already receiving enteral nutrition products;

(4) Route of administration; and

(5) The daily caloric order and the number of calories per package or can

e. Medicaid reimbursement shall be recovered when the enteral nutrition products have not been ordered on the CMN. Supporting documentation is allowed to justify the medical need for enteral nutrition products. Supporting documentation shall not replace the requirement for a properly completed CMN. The dates of the supporting documentation shall coincide with the dates of service on the CMN, and the supporting documentation shall be ~~fully~~ signed and dated by the licensed practitioner.

K. Reimbursement denials.

1. DMAS shall deny payment to the DME provider if any of the following occur:

a. Absence of a current, fully completed CMN appropriately signed and dated by the licensed practitioner;

b. Documentation does not verify that the item was provided to the individual;

c. Lack of medical documentation, signed by the licensed practitioner to justify the DME; or

d. Item is non-covered or does not meet DMAS criteria for reimbursement.

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2. If reimbursement is denied by Medicaid, the DME provider shall not bill the Medicaid individual for the service that was provided.

L. Replacement DME following a disaster.

1. Medicaid individuals who (i) live in areas that have been declared by the Governor to be subject to a state of emergency in accordance with § 44-146.16 of the Code of Virginia, (ii) live in Virginia and were present in an area of the state that has been declared by the Governor to be subject to a state of emergency in accordance with § 44-146.16 of the Code of Virginia, or (iii) live in Virginia and can prove they were present in a state or federally declared disaster or emergency area in another state when the disaster occurred, and who need to replace DME previously approved by Medicaid that were damaged as a result of the disaster or emergency, may contact a DME provider (either enrolled in fee-for-service Medicaid or a Medicaid health plan) of their choice to obtain a replacement.

a. If the individual's DME provider has gone out of business or is unable to provide replacement DME, the individual may choose another provider who is enrolled as a DME provider with Medicaid or the Medicaid health plan. The original authorization will be canceled or amended and a new authorization will be provided to the new DME provider.

b. The DME provider shall submit a signed statement from the Medicaid individual requesting a change in DME provider in accordance with the declaration by the Governor as a state of emergency due to a disaster and giving the Medicaid individual's current place of residence.

c. The individual can contact the state Medicaid office or the Medicaid health plan to get help finding a new DME provider.

2. For Medicaid enrolled providers, the provider shall make a request to the service authorization contractor; however, a new CMN and medical documentation is not required unless the DME is beyond the service limit (e.g., the individual has a wheelchair that is older than five years). The provider shall keep documentation in the individual's record that includes the individual's current place of residence and states that the original DME was lost due to the disaster.