HCFA Rulings

Department of Health and Human Services

Health Care Financing Administration

Ruling No. 96-3 Date: December 1996

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, Medicare contractors, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, the Departmental Appeals Board, and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the existing policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provision, section 1879 of the Social Security Act, to a provider, practitioner, or other supplier for parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items for which Medicare payment is denied. This Ruling supplements HCFAR 95-1 with respect to section 1879(g) of the Act.

HCFAR 96-3-1

MEDICARE PROGRAM

Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B)

REQUIREMENTS FOR DETERMINING LIMITATION ON LIABILITY OF A MEDICARE BENEFICIARY, PROVIDER, PRACTITIONER, OR OTHER SUPPLIER FOR PARENTERAL AND ENTERAL NUTRITION THERAPY, INCLUDING INTRADIALYTIC PARENTERAL NUTRITION THERAPY, SERVICES AND ITEMS FOR WHICH MEDICARE PAYMENT IS DENIED.

PURPOSE: This Ruling states the existing policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provision, section 1879 of the Social Security Act, to a provider, practitioner, or other supplier for parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items for which Medicare payment is denied.

More specifically, this Ruling states the policy that any claims for intradialytic parenteral nutrition therapy, or any form of parenteral and enteral nutrition therapy, from a Medicare beneficiary who does not qualify for the prosthetic device benefit must be denied under section 1861(s)(8) of the Act. Medicare payment under limitation on liability

cannot be made for any parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, denials which are based on section 1861(s)(8).

This Ruling supplements HCFA Ruling 95-1 with respect to section 1879(g) of the Act. The sunset date of December 31, 1995 for that provision is erroneous; section 1879(g) of the Act does not sunset.

CITATIONS: Sections 1142, 1154, 1814, 1815, 1833, 1834, 1861, 1862, 1866, and 1879 of the Social Security Act (42 U.S.C. 1320b-12, 1320c, 1395f, 1395g, 1395l, 1395m, 1395x, 1395y, 1395cc, and 1395pp), 42 CFR 411.400, 411.402, 411.404, 411.406, and HCFAR 95-1.

RULING APPLICABLE TO DETERMINING LIMITATION ON LIABILITY OF A MEDICARE BENEFICIARY, PROVIDER, PRACTITIONER, OR OTHER SUPPLIER FOR PARENTERAL AND ENTERAL NUTRITION THERAPY, INCLUDING INTRADIALYTIC PARENTERAL NUTRITION THERAPY, SERVICES AND ITEMS FOR WHICH MEDICARE PAYMENT IS DENIED

I. BACKGROUND

Section 1879 of the Social Security Act (the Act) provides financial relief to beneficiaries, providers, practitioners, and other suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain services and items for which Medicare payment would

otherwise be denied. We refer to this section of the Act as "the limitation on liability provision."

The purpose of this Ruling is to provide a detailed clarification of our policy with regard to the limitation on liability provision as it applies to parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items to ensure that Medicare payment under the policy is made in an appropriate and consistent manner. This Ruling supplements HCFA Ruling 95-1 with respect to section 1879(g) of the Act.

II. COVERAGE DENIALS TO WHICH THE LIMITATION ON LIABILITY PROVISION APPLIES - STATUTORY BASES

A coverage determination for an item or service must be made before there can be a decision with respect to whether Medicare payment may be made under the limitation on liability provision. Medical review entities, acting for the Secretary, are authorized to make the coverage determinations. These entities include fiscal intermediaries, carriers, and Utilization and Quality Control Peer Review Organizations (PROs). In this Ruling, we refer to these entities collectively as Medicare contractors. These entities must act in accordance with the Medicare statutes, regulations, national coverage instructions, accepted standards of medical practice, and HCFA Rulings when making coverage determinations.

The claims payment and beneficiary indemnification provisions (sections 1879(a) and (b)) of the limitation on liability provision are applicable only to claims for beneficiary items or services submitted by providers, or by practitioners and other suppliers that have taken assignment, and only to claims for services, not otherwise statutorily excluded, that are denied on the basis of section 1862(a)(1), 1862(a)(9), 1879(e), or 1879(g) of the Act, which, under current law, include the following:

- Services and items found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (section 1862(a)(1)(A) of the Act).
- Pneumococcal vaccine and its administration, influenza vaccine and its administration, and hepatitis B vaccine and its administration, furnished to an individual at high or intermediate risk of contracting hepatitis B, that are not reasonable and necessary for the prevention of illness (section 1862(a)(1)(B) of the Act).
- Services and items which, in the case of hospice care, are not reasonable and necessary for the palliation or management of terminal illness (section 1862(a)(1)(C) of the Act).
- Clinical care services and items furnished with the concurrence of the Secretary and, with respect to research and experimentation conducted by, or under contract with,

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the Prospective Payment Assessment Commission or the Secretary, that are not reasonable and necessary to carry out the purposes of section 1886(e)(6) of the Act (which concerns identification of medically appropriate patterns of health resources use) (section 1862(a)(1)(D) of the Act).

- Services and items that, in the case of research conducted pursuant to section 1142 of the Act, are not reasonable and necessary to carry out the purposes of that section (which concerns research on outcomes of health care services and procedures) (section 1862(a)(1)(E) of the Act).

- Screening mammography that is performed more frequently than is covered under section 1834(c)(2) of the Act or that is not conducted by a facility described in section 1834(c)(1)(B) of the Act and screening pap smears performed more frequently than is provided for under section 1861(nn) of the Act (section 1862(a)(1)(F) of the Act).
- Custodial care (section 1862(a)(9) of the Act).
- Inpatient hospital services or extended care services if payment is denied solely because of an unintentional, inadvertent, or erroneous action that resulted in the beneficiary's transfer from a certified bed (one that does not meet the requirements of section 1861(e) or (j) of the Act) in a skilled nursing facility (SNF) or hospital (section 1879(e) of the Act).
- Home health services determined to be noncovered because the beneficiary was not "homebound" or did not

require "intermittent" skilled nursing care (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act) on or after July 1, 1987 (section 1879(g) of the Act). (The sunset date of December 31, 1995 for this provision, shown in HCFA Ruling 95-1, is erroneous; section 1879(g) of the Act does not sunset.)

Section 1879(h) of the Act provides for refunds by the supplier to the beneficiary in the case of certain claims for medical equipment and supplies, as they are defined in section 1834(j)(5) of the Act and including the prosthetic devices defined in section 1861(s)(8) of the Act, which are furnished on an assignment-related basis, and for which payment is denied. This Ruling deals primarily with section 1879(a) through (g), whereby Medicare payment may be made, or the beneficiary may be indemnified, under certain circumstances.

The refund provision (section 1879(h)) of the limitation on liability provision is applicable only to claims for beneficiary items or services which are furnished on an assignment-related basis by suppliers of medical equipment and supplies, and only to claims for medical equipment and supplies as defined in section 1834(j)(5) of the Act that are not otherwise statutorily excluded, that are denied on the basis of section 1834(j)(1), 1834(a)(15), or 1834(a)(17)(B) of the Act, which, under current law, include the following:

- Services and items for which no payment may be made by reason of the failure of the supplier to meet the supplier number requirements (section 1834(j)(1) of the Act).
- Services and items for which payment is denied in advance, with respect to services listed as potentially overutilized for which no prior authorization was obtained (section 1834(a)(15) of the Act).

- Services and items for which no payment may be made by reason of the prohibition on unsolicited telephone contacts (section 1834(a)(17)(B) of the Act).

III. DENIALS FOR WHICH THE LIMITATION ON LIABILITY PROVISION DOES NOT APPLY

Medicare payment under the limitation on liability provision cannot be made when Medicare coverage is denied on any basis other than one of the provisions of the law specified in section II. of this Ruling. There are certain claims, however, that may appear to involve a question of medical necessity, as described in section 1862(a)(1) of the Act, but the actual Medicare payment denial is based on a statutory provision other than section 1862(a)(1). Under these circumstances, Medicare payment under the limitation on liability provision cannot be made because the denial is not based on one of the statutory provisions specified in section II. of this Ruling.

A particular situation in which protection under the limitation on liability provision cannot be afforded is if parenteral and enteral nutrition therapy items and services, including intradialytic parenteral nutrition therapy items and services, are denied under section 1861(s)(8) of the Act. Medicare coverage of parenteral and enteral nutrition therapy is contained in section 1861(s)(8), the prosthetic device benefit, which provides that: "The term 'medical and other health services' means any of the following items or services: . . .(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens . . . ." Intradialytic parenteral nutrition therapy is a form of parenteral nutrition. Medicare coverage policies which apply to parenteral and enteral nutrition therapy items and services apply identically to intradialytic parenteral nutrition therapy items and services, because intradialytic parenteral nutrition therapy is a subset of parenteral and enteral nutrition therapy.

Coverage of parenteral and enteral nutrition therapy is amplified in Medicare Coverage Issues Manual section 65-10. Daily parenteral therapy is "considered reasonable and

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necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition." (Section 65-10.1.) Intradialytic parenteral nutrition therapy is administered to end stage renal disease (ESRD) patients while they are receiving dialysis. ESRD patients typically require hemodialysis three times per week for about three hours. These patients sometimes undergo parenteral therapy to replace fluids and nutrients lost during dialysis (Medicare Carriers Manual section 3329.5). ESRD patients must meet all of the

parenteral nutrition therapy coverage requirements to receive intradialytic parenteral nutrition therapy. Those patients who do not meet all of the parenteral nutrition therapy coverage requirements are ineligible to receive Medicare coverage of intradialytic parenteral nutrition therapy under the prosthetic device benefit, and the statutory basis for the denial of any such claim for payment is section 1861(s)(8).

Any claims for intradialytic parenteral nutrition therapy, or for any form of parenteral and enteral nutrition therapy, from a Medicare beneficiary who does not qualify for the prosthetic device benefit must be denied under section 1861(s)(8). Medicare payment under limitation on liability cannot be made for any parenteral and enteral nutrition therapy, including intradialytic parenteral

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nutrition therapy, denials which are based on section 1861(s)(8).

However, parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items which are **otherwise covered under section 1861(s)(8)** can be denied under section 1862(a)(1) for lack of medical necessity, in which case the protection under the limitation on liability provision can be afforded if all the elements are satisfied. The Medicare beneficiary must qualify for the prosthetic device benefit in order for any services or items to be otherwise covered under section 1861(s)(8).

Example: If a Medicare beneficiary with ESRD, a dialysis patient who meets all of the requirements for coverage of parenteral nutrition therapy, receives intradialytic parenteral nutrition therapy during dialysis and also receives parenteral nutrition therapy on other days of the week when the patient is not on dialysis, it may be determined that the patient is receiving an excessive number of lipids. A claim for Medicare payment which is denied because the patient, who qualifies for parenteral nutrition therapy coverage, is receiving an excessive number of lipids would be denied as not reasonable and necessary under section 1862(a)(1)(A) of the Act

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and the limitation on liability provision, section 1879 of the Act, would be applicable to that denial.

Therefore, the precise statutory basis for the coverage or denial of parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items is crucial and determinative as to whether or not limitation on liability protections can be applied.

Providers have no appeal rights with respect to parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, denials under section 1861(s)(8) of the Act.

IV. **EFFECTIVE DATE**

This Ruling is effective *December 12 , 1996*.

Dated: *12/12/96*

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Bruce C. Vladeck,
Administrator,
Health Care Financing
Administration

Return to Rulings