HCFA Rulings

Department of Health and Human Services

Health Care Financing Administration

Ruling No. 95-1 Date: December 1995

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This Ruling states the policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provisions, section 1879 of the Social Security Act, to a provider, practitioner, or other supplier for certain services and items for which Medicare payment is denied.

HCFAR 95-1-1

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 CERTAIN SERVICES AND ITEMS FOR WHICH MEDICARE PAYMENT IS DENIED.

PURPOSE: This Ruling states the 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 certain services and items for which Medicare payment is denied.

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

RULING APPLICABLE TO DETERMINING LIMITATION ON LIABILITY OF A MEDICARE BENEFICIARY, PROVIDER, PRACTITIONER, OR OTHER SUPPLIER FOR CERTAIN 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 Medicare program currently pays out millions of dollars each year under 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 to ensure that Medicare payment under the policy is made in an appropriate and consistent manner.

Medicare payment under the limitation on liability provision is dependent upon two primary factors. First, the claims for the services or items furnished must have been denied for one of the following reasons. The services or items were:

- not reasonable and necessary under section 1862(a)(1) of the Act;

- for custodial care and, therefore, not covered under section 1862(a)(9) of the Act;
- denied because the beneficiary was unintentionally, inadvertently, or erroneously placed into a noncertified bed (one that does not meet the requirements of section 1861(e) or (j) of the Act), as referenced by section 1879(e) of the Act; or
- noncovered home health services furnished to a beneficiary who was not "homebound" or who did not require "intermittent skilled nursing care" (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act), as referenced by section 1879(g) of the Act.

The second factor in determining if Medicare payment is made under the limitation on liability provision is whether the beneficiary and/or the provider, practitioner, or other supplier knew or could reasonably have been expected to know that the items or services (for which Medicare payment was denied on one of the bases listed above) were excluded from coverage. A determination of whether the protection under the limitation on liability provision can be afforded for a denied claim is made as a result of a prepayment medical review or a postpayment audit review.

Section 1879(h) of the Act provides for refunds by the supplier to the beneficiary in the case of certain claims for durable medical equipment (DME) 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.

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

A. 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, 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, and before December 31, 1995 (section 1879(g) of the Act).

B. Dependent Services

When it is determined that Medicare payment will be made under the limitation on liability provision for claims for items or services that were denied for one of the reasons specified in section II.A. of this Ruling, the payment determination includes claims for any dependent services that are denied as an indirect result of these

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denials. This longstanding HCFA policy is based on the fact that the cause for denial of payment for the qualifying service is the primary cause for denial of the dependent services. For example, where a particular qualifying service is denied as not reasonable and necessary under section 1862(a) of the Act, lack of medical necessity is the underlying reason for the denial of the dependent services. Therefore, if the limitation on liability protection applies to the denial of the qualifying service, it will also apply to the dependent service.

For example, under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, home health aide services can be covered only if a beneficiary needs intermittent skilled nursing care. When coverage is denied for intermittent skilled nursing services (the qualifying primary services) under section 1862(a)(1) or (9) of the Act, home health

aide services (the dependent services) likewise are not covered. In such cases, if Medicare payment is made under the limitation on liability provision for the primary services, it would be made for the dependent services as well, provided the services are otherwise covered (that is, all other conditions for payment of the dependent services are met including a physician's certification of the need for the dependent services and proof that the services are reasonable and necessary).

C. Reduced Payment Determinations Based on Reasonable and Necessary Levels of Care

The limitation on liability protection may also be applicable if a reduction in the level of payment occurs because the furnished services or items are at a level higher than was reasonable and necessary to meet the needs of the patient. This is because Medicare payment for the difference between reasonable and necessary services and items and those actually furnished is denied on the basis of section 1862(a)(1)(A) of the Act as not reasonable and necessary. For example, if it is determined that the level of care furnished by a hospice (such as continuous home care) was not reasonable and necessary under section 1862(a)(1)(A) because the care could have been given at a lower level (such as routine home care), Medicare payment under the limitation on liability provision may be made for the difference in reimbursement between the denied continuous home care and the approved routine home care if both the beneficiary and provider did not know, or could not reasonably have been expected to know, that payment would not be made for the higher level of care.

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.A. 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.A. of this Ruling.

Section 1879(a) of the Act provides that Medicare payment will be made under the limitation on liability provision "when a determination is made that, by reason of section 1862(a)(1) or (9) or by reason of a coverage denial described in subsection (g), payment may not be made under Part A or Part B" (Emphasis added) and the conditions described in section 1879(a)(2) are met. The statute thus explicitly restricts the application of the limitation on liability provision to cases that are

decided on one of the statutory grounds we have specified in section II.A. of this Ruling. We believe that, in so providing, the Congress recognized that the issue of medical necessity of a service or item need never be reached if it were determined that the service or item would not otherwise be covered under the statute.

For example, when a Part B claim is submitted for ambulance services, the first step in processing the claim is to determine whether the services meet the requirements of section 1861(s)(7) of the Act (that is, to ascertain that

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other methods of transportation are contraindicated) and, therefore, may be covered services under the Medicare statute. If other methods of transportation are contraindicated (and all other regulatory criteria met), only then must the Medicare contractor determine if the ambulance services are "reasonable and necessary" under section 1862(a)(1). If other methods of transportation are not contraindicated, there is no reason for the Medicare contractor to make a medical necessity determination under section 1862(a)(1) because the services have already been determined to be not otherwise covered under the Medicare statute.

The legislative history also suggests that the Congress excluded other types of cases from the limitation on liability protection because it recognized that beneficiaries and providers, practitioners, and other suppliers are aware or should be aware that Medicare will not pay for those services, as evidenced by the following statement in the Senate Finance Committee Report on the limitation on liability provisions (S. Rep. No. 90-1230, 92nd Cong., 2nd Sess. 294-95(1972)):

"Where expenses were incurred for clearly noncovered services, such as routine physical checkups, eyeglasses or eye examinations to determine the refractive state of the eyes, hearing aids or examination therefor, routine

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dental service or immunizations, there will be a presumption made that the beneficiary and/or the provider were aware, or should have been aware, of the fact that the services were not covered."

In other words, the Congress concluded that there was no need to apply the limitation on liability provision to individuals who had obtained or furnished clearly noncovered services such as those listed in the report. Therefore, it is our position that when items or services are denied for any reason other than one of the specific statutory bases for denial described in section II.A. of this Ruling, limitation on liability cannot be applied.

Examples of circumstances in which Medicare payment under the limitation on liability provision cannot be made because the actual Medicare payment denial is

based on a statutory provision other than section 1862(a)(1) include, but are not limited to, the following:

- Payment for the additional cost of a private room in a hospital or SNF is denied when the privacy accommodations are not required for medical reasons. Medicare payment for the additional cost is denied on the basis of section 1861(v)(2) of the Act.
- Payment for a dressing is denied because it does not meet the definition for "medical and other health services" in section 1861(s)(5) of the Act. Accordingly, Medicare

payment is denied on the basis of section 1861(s)(5) of the Act.

- Payment for ambulance services is denied because transportation by other means is not contraindicated or because regulatory criteria specified in 42 CFR 410.40, such as those relating to destination or nearest appropriate facility, are not met. In such circumstances, Medicare payment is denied on the basis of section 1861(s)(7) of the Act.
- Payment is denied for deluxe features of an item of durable medical equipment and is not based on medical necessity.

Another situation in which the protection under the limitation on liability provision cannot be afforded is if a beneficiary is enrolled under a Medicare contract with a prepaid health care organization (that is, health maintenance organization (HMO), competitive medical plan (CMP), or health care prepayment plan (HCPP)) that assumes financial responsibility for direct payment to a provider, practitioner, or other supplier for items or services furnished to the beneficiary under the terms of its contract. In those situations, since the provider, practitioner, or other supplier is paid directly by the prepaid health care organization, and not by a Medicare fee-for-service contractor, the limitation on liability protection cannot apply because of the inability in that

context to assign liability in ways envisioned under the statute. For example, section 1879 of the Act provides for Medicare payment to be made when the beneficiary and the provider, practitioner, or other supplier did not know, and could not reasonably have been expected to know, that Medicare payment would be denied. However, in the prepaid health care context, the Medicare program is insulated from liability in those situations in which the prepaid health care organization assumes financial responsibility for direct payment of an item or service to the provider, practitioner, or other supplier. Although certain prepaid health care organizations may perform the function of determining Medicare coverage, they do not act strictly as an agent of the Medicare program, as do Medicare contractors. Section 1879 was not intended to assign liability in cases in which a health care organization that authorized or furnished noncovered services under contract with Medicare makes direct payment

to a subcontractor. We, therefore, conclude that the issue of liability in the prepaid health care context is not governed by section 1879.

There are situations, however, where Medicare enrollees of HCPPs and cost HMOs/CMPs may receive services and have Medicare payment made through Medicare contractors, instead of the prepaid health care organization making direct payment to the provider, practitioner, or other supplier. In these situations, the limitation on liability protection

may apply to the enrollee if services are denied on one of the specific statutory bases described in section II.A. of this Ruling. These situations include the following:

- The HMO/CMP is a cost-reimbursed HMO with a contract under section 1876 of the Act, and the service in question is a provider service which, although it is being arranged for through the HMO/CMP, is a service that the HMO/CMP has opted to have paid by a Medicare contractor under the provisions of section 1876(h)(2)(A);
- The service is one that a Medicare enrollee of an HCPP or a cost HMO/CMP chooses to receive "out of plan" (that is, without having arranged for the service through the HMO/CMP), and the service is, therefore, being billed through the Medicare contractor; or
- The provider, practitioner, other supplier, or beneficiary submits a claim for the service through the Medicare contractor as a result of the HCPP or cost HMO/CMP's refusal to pay for the service.

Medicare enrollees of "risk" HMOs/CMPs under section 1876 of the Act are prohibited from having Medicare program payments made through Medicare contractors. For these enrollees, the only program payment is the capitation payable to the HMO/CMP for each enrolled Medicare beneficiary. Therefore, the limitation on liability provision is never extended to enrollees of the "risk" HMOs/CMPs.

IV. **DETERMINING KNOWLEDGE**

For the protection under the limitation on liability provision to be afforded, lack of prior knowledge that Medicare payment for the item or service would be denied must first be established. Two determinations must be made to establish knowledge: (1) Whether and when the beneficiary knew or should have known that Medicare payment for the item or service would be denied, and (2) whether and when the provider, practitioner, or other supplier knew or should have known that Medicare payment for the item or service would likely be denied. The principles for determining knowledge described below apply to determinations of knowledge with respect to denials under section 1879(a) through (g) of the Act for which Medicare

payment may be made, as well as to those under section 1879(h) of the Act, for which refunds may be required.

A. Criteria For Determining Beneficiary Knowledge

Section 1879(a)(2) of the Act requires that the beneficiary "did not know, and could not reasonably have been expected to know, that payment would not be made* * *," for items or services that are excluded from coverage as not reasonable and necessary or as custodial care, in order for the limitation on liability protection to be afforded. This includes knowledge based on written notice having been provided to the beneficiary, as well as any other means from

which it is determined that the beneficiary knew, or should have known, that payment would not be made.

Our regulations at 42 CFR 411.404 (Criteria for determining that a beneficiary knew that services or items were excluded from coverage as custodial care or as not reasonable and necessary) provide one basis for determining beneficiary knowledge that payment would not be made for items or services that are excluded from coverage as not reasonable and necessary or as custodial care. These regulations provide that a beneficiary will be considered to know, based on written notice, that services or items were excluded from coverage as not reasonable and necessary or as custodial care. Under these regulations, there is a presumption that he or she knew, or could reasonably have been expected to know, that Medicare payment for a service or item would be denied if advance written notice has been given either to the beneficiary or to someone acting on his or her behalf that the items or services were not covered.

In accordance with §411.404, a written notice of Medicare denial of payment must contain sufficient information to enable the beneficiary to understand the basis for the denial. Such notice constitutes sufficient documentation to show that the beneficiary had prior knowledge of the likelihood of denial of that claim, and of all future claims filed by on or behalf of the beneficiary that involve that same or a similar item or service. In

addition, a written notice of Medicare denial of payment from a Medicare contractor for a previous claim for a particular service or item received by the beneficiary serves as prior written notice for all future claims filed by or on behalf of the beneficiary that involve that same or a similar service or item.

Generally, the required written notice of the likelihood of denial must be furnished to the beneficiary (or the person acting on his or her behalf) by:

- A provider, practitioner, or other supplier before the service or item was furnished.
- The provider, after the Medicare contractor, during the course of the patient's stay, advised the provider that covered care had ceased.
- A provider utilization review committee that, on admission or during the patient's stay, advised that the patient no longer required covered care.
- The Medicare contractor.

While §411.404 provides criteria for beneficiary knowledge based on written notice, section 1879(a)(2) of the Act specifies only that knowledge must not exist in order to apply the limitation on liability protection. If it is clear and obvious that a beneficiary in fact did know, prior to receiving a service or item, that Medicare payment for that service or item would be denied, the administrative presumption favorable to the beneficiary referred to in

§411.404, is rebutted. For example, if the beneficiary admits that he or she had prior knowledge that payment for a service or item would be denied, no further evidence is required; the absence of a written notice is moot.

The failure of any provider, practitioner, or other supplier to furnish to a beneficiary proper advance notice of the likelihood of denial is not sufficient to afford the beneficiary the protection of the limitation on liability provision if the contractor has proof that the beneficiary, nonetheless, had the requisite knowledge that the service would be denied. In any case in which the contractor has such evidence of prior knowledge on the beneficiary's part, the beneficiary must be held liable under the limitation on liability provision.

B. Determining Provider, Practitioner, or Other Supplier Knowledge

1. General

The Medicare contractors determine, based on the information they maintain and/or disseminate to a particular provider, practitioner, or other supplier, whether the provider, practitioner, or other supplier actually had prior knowledge that services or items would likely be denied or whether knowledge reasonably could have been expected. The determination of actual or expected knowledge is based on all the relevant facts pertaining to each particular denial.

2. Criteria For Determining Practitioner and Other Supplier Knowledge

In accordance with 42 CFR 411.406 (Criteria for determining that a provider, practitioner, or other supplier knew that items or services were excluded from coverage as custodial care or as not reasonable and necessary) and §7300.5 of the Medicare Carriers Manual, evidence that the practitioner or other supplier did, in fact,

know or should have known that Medicare would not pay for a service or item includes:

- A Medicare contractor's prior written notice to the practitioner or other supplier of Medicare denial of payment for similar or reasonably comparable services or items;
- Our general notices to the medical community of Medicare payment denial of services and items under all or certain circumstances. (Our notices include, but are not limited to, manual instructions, bulletins, carriers' written guides, and directives); and
- Provision of the services and items was inconsistent with acceptable standards of practice in the local medical community (refer to section V. of this Ruling).

If any of the circumstances described above exists, a practitioner or other supplier is held to have knowledge.

The practitioner or other supplier is presumed liable for denied services or items at the initial determination, with one exception. If a practitioner or other supplier

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gives the beneficiary proper written advance notice that Medicare will likely deny payment for the service or item to be furnished, and so documents the claim, the beneficiary is held liable for the denied services or items at the initial determination. The advance notice must clearly identify the particular service or item, must state that the practitioner or other supplier believes Medicare is likely to deny payment as not reasonable and necessary for the particular service or item, and must give the basis for the practitioner or other supplier's belief that Medicare is likely to deny payment for the service or item, in order to protect the practitioner or other supplier from liability. The beneficiary must be told why the practitioner or supplier is predicting Medicare denial of payment so that the beneficiary can make an informed decision whether to receive the service or item and to pay for it out-of-pocket. Such a notice constitutes proof that the beneficiary had prior knowledge that Medicare payment would be denied for the service or item in question.

In our program instructions (Medicare Carriers Manual §7300.5(A)), we suggest that the practitioner or supplier have the beneficiary sign the agreement. If a beneficiary's signature is absent, in case of a dispute as to the agreement, the beneficiary's allegations regarding the notice will be given credence.

In summary, if the practitioner or other supplier can show that (1) the beneficiary received proper written advance notice, or (2) the practitioner or other supplier did not know, and could not reasonably have been expected to know, that Medicare would not pay for the service or item, then, absent evidence to the contrary, the

medical review entity (in this case the carrier) must find that the practitioner or other supplier is not liable.

3. Criteria For Determining Provider Knowledge

(a) Favorable Presumption

(1) Background

Administrative presumptions ("favorable presumptions") are used for certain categories of providers in determining whether a provider had prior knowledge that Medicare payment for services or items would be denied. We established favorable presumptions in July 1973 because, when the Congress passed the limitation on liability provisions in section 1879 of the Act (section 213 of the Social Security Amendments of 1972, Public Law 92-603), providers were not as knowledgeable about Medicare coverage rules as they later became. In addition, written guidelines were not as explicit as they are now. Therefore, we developed formulas, using statistical denial rate criteria, that allowed providers who usually made correct coverage determinations to be paid for their few incorrect coverage determinations under the presumption that they did not have prior knowledge

that Medicare payment for the services or items would be denied.

The basis for applying the favorable presumption mechanism, based on the statistical denial rate criteria, was established in our regulations at 42 CFR 405.195 and 405.196. These regulations specified, in part, that a favorable presumption would be allowed if we found that, on the basis of bills submitted, the provider effectively distinguished between cases in which the services or items furnished by the provider were covered under Medicare and cases in which they were excluded from coverage. The favorable presumption mechanism applied from July 1973 until February 1986 to hospitals, SNFs, and home health agencies (HHAs).

On February 21, 1986, we published a final rule in the ***Federal Register***, 51 FR 6222, which added a new 42 CFR 405.336 and removed 42 CFR 405.195 and 405.196. These changes to the regulations revised the way we applied limitation on liability for providers and removed the administrative mechanism of favorable presumption in determining whether a hospital, SNF, or HHA should be held liable for furnishing a service or item for which Medicare payment is denied.

In April 1986, sections 9126(c) and 9205 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99-272, reinstated the use of a

favorable presumption for SNFs (including SNF swing beds) and HHAs, but not for hospitals. Under COBRA, a statistical denial rate criterion remained in effect, which was to be applied in the same manner as under the regulations in effect as of July 1, 1985 (42 CFR 405.195 and 405.196).

In October 1986, section 9305(f) of the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Public Law 99-509, extended the favorable presumption mechanism to the hospice program. Section 9305(g) of OBRA '86 extended the limitation on liability provision to HHA denials if Medicare payment for home health services a beneficiary received is denied 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). This provision was applicable only to services furnished from July 1, 1987, to October 1, 1989 (section 9305(g)(3) of OBRA '86).

(2) Extended Application of Favorable Presumptions

Under statutory provisions, favorable presumptions were extended to apply to HHAs, hospices, and SNFs (including SNF swing beds). The following provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) extended the application of favorable presumptions until December 31, 1995:

- Section 4008(a)(1) amended section 9126(c) of COBRA for SNFs (including SNF swing beds);

- Section 4008(a)(2) amended section 9305(f) of OBRA '86 for hospices; and
- Section 4207(b)(3) amended section 9305(g) of OBRA '86 for claims for home health services that are denied 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).

(OBRA '90 inadvertently omitted a favorable presumption extension for HHA medical necessity denials by failing to amend section 9205 of COBRA. Therefore, we issued a Program Memorandum (Transmittal No. AB-91-6, July 1991) that administratively extended the HHAs' favorable presumption for medical necessity denials until section 4207(b)(3) of OBRA '90 could be appropriately amended. Section 158(b) of the Social Security Act Amendments of 1994 made this amendment.)

(3) Criteria For Determining If an HHA, SNF, or Hospice Merits a Favorable Presumption

As a means of determining whether an HHA, SNF, or hospice merits a favorable presumption, we established and implemented two statistical formulas that provide a measure of the SNF's, HHA's, or hospice's accuracy in assessing whether services

and items are covered or noncovered, in accordance with the regulations that existed under 42 CFR 405.195 and 405.196. The first formula calculates the "denial rate," which is a quarterly measurement used to

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indicate whether the SNF, HHA, or hospice can generally make correct judgments concerning the coverage of services and items. Denial of very few claims billed as covered is held to demonstrate a provider's ability to make correct coverage assessments under most circumstances. Thus, when a provider does not exceed the denial rate established under COBRA (5 percent of claims submitted for SNFs (including SNF swing beds) and 2.5 percent of claims submitted for HHAs and hospices), a favorable presumption is employed.

The second formula calculates the demand bill "reversal rate," which is a quarterly measurement used to indicate whether the SNF, HHA, or hospice can generally make correct judgments concerning the noncoverage of services and items. A demand bill is a claim for services or items that the provider believes are not covered but which the provider must submit at the demand of the beneficiary or the beneficiary's representative. If the Medicare contractor determines that one or more services or items on such a claim actually do qualify for Medicare payment, the provider's assessment that the service or item is not covered is reversed. Like the denial rate, reversal of very few claims billed as noncovered is held to demonstrate a provider's ability to make correct noncoverage judgments under most circumstances. Thus, when a provider does not exceed the established reversal rate criterion (for SNFS (including SNF swing beds), less than 20 reversals out of

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100 or fewer demand bills submitted, or no more than 20 percent if more than 100 demand bills are submitted; for HHAs and hospices, less than 10 reversals out of 100 or fewer demand bills submitted, or no more than 10 percent if more than 100 demand bills are submitted), a favorable presumption is employed.

As long as an SNF, HHA, or hospice remains within both the denial rate threshold and the demand bill reversal rate threshold, all of its denied claims will be processed as if the provider had no prior knowledge that the claims would be denied. However, such a favorable presumption is rebutted and no Medicare payment will be made if it is clear and obvious that the provider knew that particular services or items would be denied (see section IV.B.3.(b) of this Ruling).

We note that a favorable presumption can be employed for purposes of determining a provider's limitation on liability under section 1879 only during a prepayment review of the claim. A favorable presumption amounts to an automatic decision that a provider did not have knowledge that payment would be denied, without a further review of the case to see if there is evidence to the contrary. Therefore, there is no longer a need for a presumption when a postpayment audit

review is conducted, because the claim is being reviewed and the reviewer will know, based on the specific facts of the case, whether the provider had

knowledge that payment would be denied on the basis that services and items were not reasonable and necessary. Therefore, a favorable presumption is not relevant for purposes of a postpayment audit review.

In addition, for appeal purposes, the existence/non-existence of a favorable presumption is determined based on a provider's statistical standing at the time the initial claim determination is made, not at the time of the appeal hearing.

(b) When a Provider Is Always Considered To Have Prior Knowledge

No Medicare payment will be made to any provider for any claim if previous notification was given or if for any other reason the provider clearly should have known that the claim would be denied. This includes providers that have a favorable presumption, since the presumption is rebutted where there is clear and obvious evidence that the provider knew or should have known that the services or items at issue would be denied.

Sections 9126(c) and 9205 of COBRA and section 9305(f) of OBRA '86, which reinstated the use of a favorable presumption, require application of the presumption in the manner provided in regulations in effect as of July 1, 1985 (42 CFR 405.195 and 405.196). Section 405.195(a) explicitly provided for a rebuttable presumption. General legal principles provide that a rebuttable (or "disputable")

presumption controls unless and until it is invalidated by proof of evidence contrary to the presumption. If evidence contrary to the presumption is found, the presumption disappears and the case stands upon the facts and the reasonable inferences to be drawn therefrom. Therefore, in all cases in which there is evidence that a provider had knowledge or should have had knowledge that services or items would be denied, the favorable presumption is rebutted.

Criteria for determining whether a provider had knowledge or should have had knowledge that services or items would be denied are in regulations at 42 CFR 411.406 and in 3439.B. through 3439.G. of the Medicare Intermediary Manual. These sources cite various forms and methods of notification that provide sufficient evidence that the provider knew or should have known that the services or items would be denied. Such notices are sufficient notice for all subsequent claims involving that same service or item under similar or reasonably comparable conditions. In general, notification often is provided by one of the following sources:

- The provider's utilization review committee informed the provider in writing that the services were not covered;
- The provider previously submitted a no-payment claim (i.e., a pro forma filing in which no payment is sought, rather, only a formal payment denial determination is

requested), or submitted a claim for Medicare payment only at the request of the beneficiary;

- The provider issued a written notice of the likelihood of Medicare payment denial for a service or item to the beneficiary;
- We have issued manuals, bulletins, memoranda, etc., advising providers of the noncoverage of a particular service or category of services;
- A Medicare contractor previously issued a written notice to the provider that Medicare payment for a particular service or item is denied. This also includes notification of PRO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by the PRO;
- The provider was previously notified by telephone and/or in writing that care is not covered or that covered care has ended; or
- A general bulletin or newsletter was issued to providers advising that a specific service or item is not considered reasonable and necessary.

The provider is accountable for information contained in the patient's medical records, such as the patient's medical chart, attending physicians' notes, or similar records, since these are provider records. Evidence based upon medical records, such as that described in the

following list, clearly indicates knowledge that Medicare payment for services or items would be denied:

- A physician clearly indicated in the patient's medical record that the patient no longer needed the services or the level of care provided;
- The physician indicated the patient could be discharged; or
- The attending physician refused to certify or recertify the patient's need for a particular level of care covered by Medicare because he/she determined that the patient does not require a covered level of care.

V. ACCEPTABLE STANDARDS OF PRACTICE--APPLICATION

In situations in which services or items furnished do not meet locally acceptable standards of practice, the provider, practitioner, or other supplier is considered to have known that Medicare payment for the services or items would be denied. Providers, practitioners, and other suppliers are always responsible for knowing

locally acceptable standards of practice; their local licensure is premised on the assumption that they have such knowledge. Medicare payment to providers, practitioners, or other suppliers is premised on the presumption that they have such knowledge, as evidenced by their licensure. No other evidence of knowledge of local medical standards of practice is necessary.

Medicare contractors, in determining what "acceptable standards of practice" exist within the local medical community, rely on published medical literature, a consensus of expert medical opinion, and consultations with their medical staff, medical associations, including local medical societies, and other health experts. "Published medical literature" refers generally to scientific data or research studies that have been published in peer-reviewed medical journals or other specialty journals that are well recognized by the medical profession, such as the "New England Journal of Medicine" and the "Journal of the American Medical Association." By way of example, consensus of expert medical opinion might include recommendations that are derived from technology assessment processes conducted by organizations such as the Blue Cross and Blue Shield Association or the American College of Physicians, or findings published by the Institute of Medicine.

VI. FRAUD AND ABUSE--APPLICATION

Generally, the protection under the limitation on liability provision cannot be afforded to providers, practitioners, or other suppliers if a formal finding of fraud or abuse has been made with regard to a provider's, practitioner's, or other supplier's billing practices. In cases in which a formal finding of fraud or abuse is made, an immediate finding of liability for the provider, practitioner, or other supplier results.

VII. PAYMENT UNDER LIMITATION ON LIABILITY

A. Beneficiary Is Determined To Be Not Liable

For claims denied solely on the basis of one of the provisions listed in section II.A of this Ruling and it has been determined that the beneficiary did not know and could not reasonably have been expected to know that the service or item would be denied, the following are the effects:

- Under section 1879(a)(2) of the Act and the accompanying regulations at 42 CFR 411.400(a)(2), the Medicare program must make payment when the provider, practitioner, or other supplier did not know and could not reasonably have been expected to know that the services or items would be denied. In these instances, the usual deductible and coinsurance amounts apply. The number of days or visits paid for under the limitation on liability provision is charged to the beneficiary's utilization record. Medicare payment may also be made under section 1154(a)(2)(B) of the Act and 42 CFR 411.400(b)(2) for a 1-day "grace period" after the date of notice to the provider or to the beneficiary, whichever is earlier, if additional time is needed to arrange for post-discharge care. If it is determined thereafter by a

PRO or the Medicare contractor that even more time is required in order to arrange post-discharge care, 1 additional "grace period" day is paid. Initial approval of 2 or more "grace period" days is not permitted. The "grace period" is applicable

only if circumstances would have permitted Medicare program payment under section 1879(a)(1) and (2) of the Act and 42 CFR 411.400(b)(2), that is, protection under the limitation on liability provision was afforded both to the beneficiary and the provider;

- Under section 1879(b) of the Act and 42 CFR 411.402, Medicare does not make payment when it is determined that the provider, practitioner, or other supplier had prior knowledge that Medicare would deny payment for services or items or could reasonably have been expected to have had this knowledge. In these instances, the beneficiary is not responsible for paying the deductible and coinsurance charges related to the denied claim and the beneficiary's Medicare utilization record is not charged for the services and items furnished, effective for all services or items furnished on or after January 1, 1988.

In addition, under section 1879(b) and 42 CFR 411.402 et seq., if the provider, practitioner, or other supplier is considered to be liable and requests and receives payment from the beneficiary or any person(s) who assumed financial responsibility for payment of the beneficiary's expenses, the Medicare program indemnifies the beneficiary or other person(s) for any amounts paid by the beneficiary. This includes any deductible or coinsurance charges paid by or on behalf of the beneficiary. Further, these indemnification

payments are considered an overpayment to the provider, practitioner, or other supplier.

B. Beneficiary Is Determined To Be Liable

Under section 1879(c) of the Act and 42 CFR 411.404, the beneficiary is held to be liable when it is determined that he or she had prior knowledge that Medicare payment for the service or item would be denied or could reasonably have been expected to have had such knowledge. In these instances, the beneficiary is held responsible for expenses incurred for services or items for which Medicare payment is denied, regardless of whether the provider, practitioner, or other supplier had knowledge. The Medicare program makes no payment to the beneficiary, provider, practitioner, or other supplier.

VIII. **APPEALS**

A. Beneficiary's Right To Appeal

If the Medicare contractor determines that the beneficiary knew or could reasonably have been expected to know that Medicare payment for the services or items furnished would be denied, the beneficiary has appeal rights for both the determination holding him or her liable for the cost of the denied services or items and the substantive coverage determination. In addition, if Medicare pays the claim in accordance with section 1879 of the Act (that is, the Medicare contractor determines that neither the beneficiary nor the provider, practitioner, or other

supplier knew or could reasonably have been expected to know that the services or items would be denied), the beneficiary may still appeal the coverage determination.

B. Provider's Right to Appeal

If the Medicare contractor finds (1) that the beneficiary or the provider (or both) knew or could reasonably have been expected to know that Medicare payment for the services or items furnished would be denied, or (2) that the beneficiary did not know and could not reasonably have been expected to know that Medicare payment for the services or items furnished would be denied, and the beneficiary chooses not to exercise his or her appeal rights, the provider may appeal both the coverage and the liability determinations. However, if Medicare pays the claim in accordance with section 1879 of the Act, the provider may not appeal the coverage determination.

C. Practitioner's and Other Supplier's Right to Appeal

When it is determined by the Medicare contractor that a practitioner who accepts assignment or an other supplier who accepts assignment knew or could reasonably have been expected to know that Medicare payment for the services or items furnished would be denied, the practitioner or other supplier may appeal both the coverage and the liability determinations. In addition, if Medicare pays the claim in accordance with section 1879 of the Act, the practitioner

who accepts assignment or the other supplier who accepts assignment may still appeal the coverage determination.

D. PRO Determinations

Under title XI of the Act, when a PRO determines that a provider or practitioner is liable for payment of denied services and items furnished a beneficiary, the provider or practitioner may appeal the coverage determination and/or the liability determination only through the reconsideration or review level of appeal. At any appeal beyond the reconsideration or review level, the provider or practitioner may challenge only the PRO's liability determination, not the substantive coverage determination.

Medicare Part A limitation on liability determinations are governed by procedures in 42 CFR part 405, subpart G. Medicare Part B limitation on liability determinations are governed by procedures in 42 CFR part 405, subpart H, and 42 CFR part 473. When the PRO makes a limitation on liability determination on a Part B claim, which is governed by subpart H of 42 CFR part 405, either the PRO or the carrier may conduct the fair hearing. Part B ALJ hearings and Appeals Council review are conducted pursuant to the procedures outlined in HCFA and SSA's ***Federal Register*** notice of June 1, 1988, 53 FR 20023 (June 1, 1988), unless superseded by subsequent regulations.

IX. **EFFECTIVE DATE**

This Ruling is effective *December 31* , 1995.

Dated: *12/22/95*

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Bruce C. Vladeck,
Administrator,
Health Care Financing
Administration

Return to Rulings