

§ 411.387

obtain a binding advisory opinion on the subject of a physician's referrals, as described in § 411.370. CMS has not and does not issue a binding advisory opinion on the subject matter in § 411.370, in either oral or written form, except through written opinions it issues in accordance with this subpart.

[69 FR 57230, Sept. 24, 2004]

§ 411.387 Effect of an advisory opinion.

(a) An advisory opinion is binding on the Secretary, and a favorable advisory opinion shall preclude imposition of sanctions under section 1877(g) of the Act with respect to:

(1) The individuals or entities requesting the opinion; and

(2) Individuals or entities that are parties to the specific arrangement with respect to which such advisory opinion has been issued.

(b) The Secretary will not pursue sanctions under section 1877(g) of the Act against any party to an arrangement that CMS determines is indistinguishable in all its material aspects from an arrangement with respect to which CMS issued a favorable advisory opinion.

(c) Individuals and entities may rely on an advisory opinion as non-binding guidance that illustrates the application of the physician self-referral law and regulations to the specific facts and circumstances described in the advisory opinion.

[84 FR 63193, Nov. 15, 2019]

§ 411.388 When advisory opinions are not admissible evidence.

The failure of a party to seek or to receive an advisory opinion may not be introduced into evidence to prove that the party either intended or did not intend to violate the provisions of sections 1128, 1128A or 1128B of the Act.

[69 FR 57230, Sept. 24, 2004]

§ 411.389 Range of the advisory opinion.

(a) An advisory opinion states only CMS's opinion regarding the subject matter of the request. If the subject of an advisory opinion is an arrangement that must be approved by or is regulated by any other agency, CMS's advisory opinion cannot be read to indicate

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CMS's views on the legal or factual issues that may be raised before that agency.

(b) An advisory opinion that CMS issues under this part does not bind or obligate any agency other than the Department. It does not affect the requestor's, or anyone else's, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.

[69 FR 57230, Sept. 24, 2004]

Subpart K—Payment for Certain Excluded Services

§ 411.400 Payment for custodial care and services not reasonable and necessary.

(a) *Conditions for payment.* Notwithstanding the exclusions set forth in § 411.15 (g) and (k). Medicare pays for “custodial care” and “services not reasonable and necessary” if the following conditions are met:

(1) The services were furnished by a provider or by a practitioner or supplier that had accepted assignment of benefits for those services.

(2) Neither the beneficiary nor the provider, practitioner, or supplier knew, or could reasonably have been expected to know, that the services were excluded from coverage under § 411.15 (g) or (k).

(b) *Time limits on payment*—(1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, payment may not be made for inpatient hospital care, posthospital SNF care, or home health services furnished after the earlier of the following:

(i) The day on which the beneficiary has been determined, under § 411.404, to have knowledge, actual or imputed, that the services were excluded from coverage by reason of § 411.15(g) or § 411.15(k).

(ii) The day on which the provider has been determined, under § 411.406 to have knowledge, actual or imputed, that the services are excluded from coverage by reason of § 411.15(g) or § 411.15(k).

(2) *Exception.* Payment may be made for services furnished during the first day after the limit established in paragraph (b)(1) of this section, if the QIO

or the intermediary determines that the additional period of one day is necessary for planning post-discharge care. If the QIO or the intermediary determines that yet another day is necessary for planning post-discharge care, payment may be made for services furnished during the second day after the limit established in paragraph (b)(1) of this section.

§ 411.402 Indemnification of beneficiary.

(a) *Conditions for indemnification.* If Medicare payment is precluded because the conditions of § 411.400(a)(2) are not met, Medicare indemnifies the beneficiary (and recovers from the provider, practitioner, or supplier), if the following conditions are met:

(1) The beneficiary paid the provider, practitioner, or supplier some or all of the charges for the excluded services.

(2) The beneficiary did not know and could not reasonably have been expected to know that the services were not covered.

(3) The provider, practitioner, or supplier knew, or could reasonably have been expected to know that the services were not covered.

(4) The beneficiary files a proper request for indemnification before the end of the sixth month after whichever of the following is later:

(i) The month in which the beneficiary paid the provider, practitioner, or supplier.

(ii) The month in which the intermediary or carrier notified the beneficiary (or someone on his or her behalf) that the beneficiary would not be liable for the services.

For good cause shown by the beneficiary, the 6-month period may be extended.

(b) *Amount of indemnification.*¹ The amount of indemnification is the total that the beneficiary paid the provider, practitioner, or supplier.

(c) *Effect of indemnification.* The amount of indemnification is considered an overpayment to the provider,

practitioner, or supplier, and as such is recoverable under this part or in accordance with other applicable provisions of law.

§ 411.404 Criteria for determining that a beneficiary knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A beneficiary who receives services that constitute custodial care under § 411.15(g) or that are not reasonable and necessary under § 411.15(k), is considered to have known that the services were not covered if the criteria of paragraphs (b) and (c) of this section are met.

(b) *Written notice.* (1) Written notice is given to the beneficiary, or to someone acting on his or her behalf, that the services were not covered because they did not meet Medicare coverage guidelines.

(2) A notice concerning similar or reasonably comparable services furnished on a previous occasion also meets this criterion.

(3) After a beneficiary is notified that there is no Medicare payment for a service that is not covered by Medicare, he or she is presumed to know that there is no Medicare payment for any form of subsequent treatment for the non-covered condition.

(c) *Source of notice.* The notice was given by one of the following:

(1) The QIO, intermediary, or carrier.

(2) The group or committee responsible for utilization review for the provider that furnished the services.

(3) The provider, practitioner, or supplier that furnished the service.

[54 FR 41734, Oct. 11, 1989, as amended at 69 FR 66423, Nov. 15, 2004]

§ 411.406 Criteria for determining that a provider, practitioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A provider, practitioner, or supplier that furnished services which constitute custodial care under § 411.15(g) or that are not reasonable and necessary under § 411.15(k) is considered to have known that the services were not covered if any one of the conditions specified in paragraphs (b) through (e) of this section is met.

¹ For services furnished before 1988, the indemnification amount was reduced by any deductible or coinsurance amounts that would have been applied if the services had been covered.

(b) *Notice from the QIO, intermediary or carrier.* The QIO, intermediary, or carrier had informed the provider, practitioner, or supplier that the services furnished were not covered, or that similar or reasonably comparable services were not covered.

(c) *Notice from the utilization review committee or the beneficiary's attending physician.* The utilization review group or committee for the provider or the beneficiary's attending physician had informed the provider that these services were not covered.

(d) *Notice from the provider, practitioner, or supplier to the beneficiary.* Before the services were furnished, the provider, practitioner or supplier informed the beneficiary that—

- (1) The services were not covered; or
- (2) The beneficiary no longer needed covered services.

(e) *Knowledge based on experience, actual notice, or constructive notice.* It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:

(1) Its receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or QIOs, including notification of QIO 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 a QIO.

(2) FEDERAL REGISTER publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.

(3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

[54 FR 41734, Oct. 11, 1989, as amended at 60 FR 48425, Sept. 19, 1995]

§ 411.408 Refunds of amounts collected for physician services not reasonable and necessary, payment not accepted on an assignment-related basis.

(a) *Basic rule.* Except as provided in paragraph (d) of this section, a physician who furnishes a beneficiary services for which the physician does not

undertake to claim payment on an assignment-related basis must refund any amounts collected from the beneficiary for services otherwise covered if Medicare payment is denied because the services are found to be not reasonable and necessary under § 411.15(k).

(b) *Time limits for making refunds.* A timely refund of any incorrectly collected amounts of money must be made to the beneficiary to whom the services were furnished. A refund is timely if—

(1) A physician who does not request a review within 30 days after receipt of the denial notice makes the refund within that time period; or

(2) A physician who files a request for review within 30 days after receipt of the denial notice makes the refund within 15 days after receiving notice of an initial adverse review determination, whether or not the physician further appeals the initial adverse review determination.

(c) *Notices and appeals.* If payment is denied for nonassignment-related claims because the services are found to be not reasonable and necessary, a notice of denial will be sent to both the physician and the beneficiary. The physician who does not accept assignment will have the same rights as a physician who submits claims on an assignment-related basis, as detailed in subpart H of part 405 and subpart B of part 473, to appeal the determination, and will be subject to the same time limitations.

(d) *When a refund is not required.* A refund of any amounts collected for services not reasonable and necessary is not required if—

(1) The physician did not know, and could not reasonably have been expected to know, that Medicare would not pay for the service; or

(2) Before the service was provided—

(i) The physician informed the beneficiary, or someone acting on the beneficiary's behalf, in writing that the physician believed Medicare was likely to deny payment for the specific service; and

(ii) The beneficiary (or someone eligible to sign for the beneficiary under § 424.36(b) of this chapter) signed a statement agreeing to pay for that service.

(e) *Criteria for determining that a physician knew that services were excluded as not reasonable and necessary.* A physician will be determined to have known that furnished services were excluded from coverage as not reasonable and necessary if one or more of the conditions in §411.406 of this subpart are met.

(f) *Acceptable evidence of prior notice to a beneficiary that Medicare was likely to deny payment for a particular service.* To qualify for waiver of the refund requirement under paragraph (d)(2) of this section, the physician must inform the beneficiary (or person acting on his or her behalf) that the physician believes Medicare is likely to deny payment.

(1) The notice must—

(i) Be in writing, using approved notice language;

(ii) Cite the particular service or services for which payment is likely to be denied; and

(iii) Cite the physician's reasons for believing Medicare payment will be denied.

(2) The notice is not acceptable evidence if—

(i) The physician routinely gives this notice to all beneficiaries for whom he or she furnishes services; or

(ii) The notice is no more than a statement to the effect that there is a possibility that Medicare may not pay for the service.

(g) *Applicability of sanctions to physicians who fail to make refunds under this section.* A physician who knowingly and willfully fails to make refunds as required by this section may be subject to sanctions as provided for in chapter V, parts 1001, 1002, and 1003 of this title.

[55 FR 24568, June 18, 1990; 55 FR 35142, 35143, Aug. 28, 1990]

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