

§411.382

42 CFR Ch. IV (10–1–99 Edition)

considered confidential information or trade secrets within the meaning of 18 U.S.C. 1095.

(c)(1) HCFA issues an advisory opinion, in accordance with the provisions of this part, within 90 days after it has formally accepted the request for an advisory opinion, or, for requests that HCFA determines, in its discretion, involve complex legal issues or highly complicated fact patterns, within a reasonable time period.

(2) If the 90th day falls on a Saturday, Sunday, or Federal holiday, the time period ends at the close of the first business day following the weekend or holiday;

(3) The 90-day period is suspended from the time HCFA—

(i) Notifies the requestor that the costs have reached or are likely to exceed the triggering amount as described in §411.375(c)(2) until HCFA receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until HCFA receives the additional information;

(iii) Notifies the requestor of the full amount due until HCFA receives payment of this amount; and

(iv) Notifies the requestor of the need for expert advice until HCFA receives the expert advice.

(d) After HCFA has notified the requestor of the full amount owed and has received full payment of that amount, HCFA issues the advisory opinion and promptly mails it to the requestor by regular first class U.S. mail.

[63 FR 1657, Jan. 9, 1998]

§411.382 HCFA's right to rescind advisory opinions.

Any advice HCFA gives in an opinion does not prejudice its right to reconsider the questions involved in the opinion and, if it determines that it is in the public interest, to rescind or revoke the opinion. HCFA provides notice to the requestor of its decision to rescind or revoke the opinion so that the requestor and the parties involved in the requestor's arrangement may discontinue any course of action they have taken in accordance with the advisory opinion. HCFA does not proceed

against the requestor with respect to any action the requestor and the involved parties have taken in good faith reliance upon HCFA's advice under this part, provided—

(a) The requestor presented to HCFA a full, complete and accurate description of all the relevant facts; and

(b) The parties promptly discontinue the action upon receiving notice that HCFA had rescinded or revoked its approval, or discontinue the action within a reasonable "wind down" period, as determined by HCFA.

[63 FR 1657, Jan. 9, 1998]

§411.384 Disclosing advisory opinions and supporting information.

(a) Advisory opinions that HCFA issues and releases in accordance with the procedures set forth in this subpart are available to the public.

(b) Promptly after HCFA issues an advisory opinion and releases it to the requestor, HCFA makes available a copy of the advisory opinion for public inspection during its normal hours of operation and on the DHHS/HCFA web site.

(c) Any predecisional document, or part of such predecisional document, that is prepared by HCFA, the Department of Justice, or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part is exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to HCFA in connection with a request for an advisory opinion are available to the public to the extent they are required to be made available by 5 U.S.C. 552, through procedures set forth in 45 CFR part 5.

(e) Nothing in this section limits HCFA's obligation, under applicable laws, to publicly disclose the identity of the requesting party or parties, and the nature of the action HCFA has taken in response to the request.

[63 FR 1657, Jan. 9, 1998]

§411.386 HCFA's advisory opinions as exclusive.

The procedures described in this subpart constitute the only method by

which any individuals or entities can obtain a binding advisory opinion on the subject of a physician's referrals, as described in § 411.370. HCFA 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.

[63 FR 1658, Jan. 9, 1998]

§ 411.387 Parties affected by advisory opinions.

An advisory opinion issued by HCFA does not apply in any way to any individual or entity that does not join in the request for the opinion. Individuals or entities other than the requestor(s) may not rely on an advisory opinion.

[63 FR 1658, Jan. 9, 1998]

§ 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.

[63 FR 1658, Jan. 9, 1998]

§ 411.389 Range of the advisory opinion.

(a) An advisory opinion states only HCFA'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, HCFA's advisory opinion cannot be read to indicate HCFA's views on the legal or factual issues that may be raised before that agency.

(b) An advisory opinion that HCFA 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.

[63 FR 1658, Jan. 9, 1998]

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 PRO or the intermediary determines that the additional period of one day is necessary for planning post-discharge care. If the PRO 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.