

(ii) If no such hospitals exist within the same local region, by comparable hospitals in comparable regions.

(6) The compensation is of low value (that is, less than \$25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value).

(7) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(8) The compensation arrangement does not violate the Federal anti-kickback provisions in section 1128B(b) of the Act.

(n) *Risk sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physicians association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the Federal anti-kickback statute, section 1128B(b) of the Act, or any law or regulation governing billing or claims submission. For purposes of this paragraph (n), “health plan” and “enrollees” have the meanings ascribed to those terms in § 1001.952(1) of this title.

(o) *Compliance training.* Compliance training provided by a hospital to a physician (or the physician’s immediate family member) who practices in the hospital’s local community or service area, provided the training is held in the local community or service area. For purposes of this paragraph (o), “compliance training” means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, reporting) or specific training regarding the requirements of Federal health care programs (for example, billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements).

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined in § 411.354(c)(2), if all

of the following conditions are satisfied:

(1) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided not taking into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

[60 FR 41978, Aug. 14, 1995, as amended at 66 FR 961, Jan. 4, 2001]

§ 411.360 Group practice attestation.

(a) Except as provided in paragraph (b) of this section, a group practice (as defined in section 1877(h)(4) of the Act and § 411.351) must submit a written statement to its carrier annually to attest that, during the most recent 12-month period (calendar year, fiscal year, or immediately preceding 12-month period) 75 percent of the total patient care services of group practice members was furnished through the group, was billed under a billing number assigned to the group, and the amounts so received were treated as receipts of the group.

(b) A newly-formed group practice (one in which physicians have recently begun to practice together) or any group practice that has been unable in the past to meet the requirements of section 1877(h)(4) of the Act must—

(1) Submit a written statement to attest that, during the next 12-month period (calendar year, fiscal year, or next 12 months), it expects to meet the 75-percent standard and will take measures to ensure the standard is met; and

(2) At the end of the 12-month period, submit a written statement to attest that it met the 75-percent standard during that period, billed for those services under a billing number assigned to the group, and treated amounts received for those services as receipts of the group. If the group did not meet the standard, any Medicare payments made for clinical laboratory services furnished by the group during the 12-month period that were conditioned upon the standard being met are overpayments.

(c) Once any group has chosen whether to use its fiscal year, the calendar year, or some other 12-month period, the group practice must adhere to this choice.

(d) The attestation must contain a statement that the information furnished in the attestation is true and accurate and must be signed by a group representative.

(e) A group that intends to meet the definition of a group practice in order to qualify for an exception described in §§411.355 through 411.357, must submit the attestation required by paragraph (a) or paragraph (b)(1) of this section, as applicable, to its carrier no later than 60 days after receipt of the attestation instructions from its carrier.

[60 FR 41978, Aug. 14, 1995, as amended at 60 FR 63440, Dec. 11, 1995]

§411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing items or services for which payment may be made under Medicare must submit information to CMS concerning their financial relationships (as defined in paragraph (d) of this section), in such form, manner, and at such times as CMS specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that provide 20 or fewer Part A and Part B items and services during a calendar year, or to designated health services provided outside the United States.

(c) *Required information.* The information submitted to CMS under paragraph (a) of this section must include at least the following:

(1) The name and unique physician identification number (UPIN) of each

physician who has a financial relationship with the entity;

(2) The name and UPIN of each physician who has an immediate relative (as defined in §411.351) who has a financial relationship with the entity;

(3) The covered items and services provided by the entity; and

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement, if requested by CMS).

(d) *Reportable financial relationships.* For purposes of this section, a financial relationship is any ownership or investment interest or any compensation arrangement, as described in section 1877 of the Act.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information on a CMS-prescribed form within the time period specified by the servicing carrier or intermediary. Entities are given at least 30 days from the date of the carrier's or intermediary's request to provide the initial information. Thereafter, an entity must provide updated information within 60 days from the date of any change in the submitted information. Entities must retain documentation sufficient to verify the information provided on the forms and, upon request, must make that documentation available to CMS or the OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to \$10,000 for each day of the period beginning on the day following the applicable deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to CMS under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.