

13. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D-1 through 1860D-42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn).

Subpart J--Financial Relationships between Physicians and Entities Furnishing Designated Health Services

14. Section 411.351 is amended by adding the following definition in alphabetical order:

§411.351 Definitions

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Qualified physician organization means a physician organization comprised entirely of physicians participating in the same incentive payment or shared savings program.

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15. Section 411.357 is revised by adding paragraph (x) to read as follows:

§411.357 Exceptions to the referral prohibition related to compensation arrangements.

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(x) Incentive Payment and Shared Savings Programs.
Remuneration in the form of cash or cash equivalent payments, but not including nonmonetary remuneration, provided by a hospital to a physician on the hospital's

medical staff or to a qualified physician organization (as defined at §411.351) pursuant to an arrangement between the hospital and the physician or qualified physician organization, if all of the following conditions are met:

(1) The remuneration is provided as part of a documented incentive payment or shared savings program to achieve --

(i) The improvement of quality of hospital patient care services through changes in physician clinical or administrative practices; or

(ii) Actual cost savings for the hospital resulting from the reduction of waste or changes in physician clinical or administrative practices, without an adverse affect on or diminution in the quality of hospital patient care services.

(2) The incentive payment or shared savings program identifies patient care quality measures or cost saving measures (for purposes of this paragraph, collectively, "performance measures") or both that --

(i) Use an objective methodology, are verifiable, are supported by credible medical evidence, and are individually tracked;

(ii) Are reasonably related to the hospital's or comparable hospitals' practices and patient population;

(iii) With respect to patient care quality measures, are listed in CMS' Specification Manual for National Hospital Quality Measures; and

(iv) Are monitored throughout the term of the arrangement to protect against inappropriate reductions or limitations in patient care services.

(3) The incentive payment or shared savings program establishes --

(i) Baseline levels for the performance measures using the hospital's historical and clinical data; and

(ii) Target levels for the performance measures that are developed by comparing historical data for the hospital's practices and patient population to national or regional data for comparable hospitals' practices and patient populations; and

(iii) Thresholds above or below which no payments will accrue to physicians.

(4) At least five physicians participate in each performance measure (the "participating physician pool"). Physicians participating in the incentive payment or shared savings program ("participating physicians") must be on the medical staff of the hospital at the commencement of the program, and may not be selected in a manner that takes into account the volume or value of referrals or other

business generated between the parties. A hospital may elect to make an incentive payment or shared savings program available to physicians in a particular department or specialty, provided that the hospital offers the opportunity to participate in the incentive payment or shared savings program to all physicians in the department or specialty on the same terms and conditions.

(5) The incentive payment or shared savings program requires independent medical review of the program's impact on the quality of patient care services provided at the hospital and corrective action if the independent medical review indicates a diminution in the quality of hospital patient care services. The independent medical review must be completed prior to the commencement of the incentive payment or shared savings program (with respect to the program's potential impact on the quality of patient care services provided at the hospital) and at least annually thereafter. For purposes of this paragraph, "independent medical review," means written review by an individual or organization that is--

- (i) Not affiliated with the hospital;
- (ii) Not affiliated with any participating physician or any physician organization to which any participating physician belongs; and

(iii) At the time of the review, not participating in any incentive payment or shared savings program at the hospital.

(6) Under the incentive payment or shared savings program--

(i) Physicians must have access to the same selection of items, supplies or devices as was available at the hospital prior to the commencement of the program, and must not be restricted in their ability to make medically appropriate decisions for their patients, including, but not limited to, decisions about tests, treatments, procedures, services, supplies or discharge;

(ii) The hospital may not make a payment to a participating physician or a qualified physician organization for the use of an item, supply or device if the physician or qualified physician organization has an ownership or investment interest in, or a compensation arrangement with, the manufacturer, distributor or group purchasing organization that arranges for the purchase of the item, supply or device; and

(iii) The hospital may not limit the availability of new technology that--

(A) Is linked through objective evidence to improved outcomes and is clinically appropriate for a particular patient; and

(B) Meets the same Federal regulatory standards as technology available under the incentive payment or shared savings program (for example, approval by the Food and Drug Administration and Medicare or Medicaid coverage decisions).

(7) The hospital provides effective prior written notice to patients affected by the incentive payment or shared savings program that--

(i) Identifies the physicians participating in the program;

(ii) Discloses that participating physicians receive payments for meeting targets for performance measures; and

(iii) Describes the performance measures in a manner reasonably designed to inform patients about the program.

(8) The arrangement is set out in writing, is signed by the parties, and specifies the remuneration (or a formula for the remuneration) in detail sufficient to be independently verified, including a comprehensive description of the incentive payment or shared savings program in which the physician is participating, the applicable baseline measures, and the targets for

performance measures to be achieved by the participating physician. To satisfy this requirement, each specific performance measure and the resulting payment (or a formula for the resulting payment) to the participating physician or qualified physician organization must be clearly and separately identified.

(9) The performance measures provided for under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law and, in the aggregate, are reasonable and necessary for the legitimate business purposes of the arrangement.

(10) The term of the arrangement is for no less than 1 year and no more than 3 years.

(11) Payments must take into account previous payments made for performance measures already achieved to ensure that the participating physician or qualified physician organization does not receive payment related to patient care quality improvements or cost savings that were achieved during a prior period of the arrangement. No payment may be made for the achievement of cost savings that results in a diminution in hospital patient care quality with respect to that performance measure.

(12) Payments are limited in duration and amount. For purposes of calculating the actual payments to the physician, cost savings are measured by comparing the hospital's actual acquisition costs for the items and supplies or costs of providing the specified services that are subject to the shared savings program to the hospital's baseline costs for the same items, supplies or services during the 1-year period immediately preceding the commencement of the program.

(13) The remuneration to be paid over the term of the arrangement (or the formula for the remuneration) is --

(i) Set in advance, does not vary during the term of the arrangement, and is not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties;

(ii) Not based in whole or in part on a reduction in the length of stay for a particular patient or in the aggregate for the hospital;

(iii) Distributed to the physicians in each participating physician pool or in each qualified physician organization if the qualified physician organization consists of at least five participating physicians on a per capita basis with respect to each performance measure; and

(iv) Paid directly to participating physicians or qualified physician organizations.

(14) The remuneration paid to a participating physician or qualified physician organization may not include any amount that takes into account the provision of a greater volume of Federal health care patient procedures or services than the volume provided by the participating physician or qualified physician organization during the period of the same length immediately preceding the commencement of the program as that covered by the payment.

(15) The hospital maintains accurate and contemporaneous documentation of the incentive payment or shared savings program and makes such documentation available to the Secretary upon request, including, but not limited to, the following:

(i) The written agreement between the parties;

(ii) The basis for the selection of the performance measures;

(iii) The selection and qualifications of the individual or organization designated as the independent medical reviewer;

(iv) The written findings of the independent medical reviewer;

(v) Corrective actions taken by the hospital based on the written findings of the independent medical reviewer (or any other review indicating that corrective action was needed);

(vi) The amount and calculation of payments made under the incentive payment or shared savings program, including the hospital's projected and actual acquisition costs where relevant;

(vii) The re-basing of performance measures; and

(viii) The written notification provided to hospital patients.

(16) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Social Security Act) or any Federal or State law or regulation governing billing or claims submission.

PART 414--PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

16. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

Subpart B--Physicians and Other Practitioners