Major 2016 Stark Law Changes: Hear from CMS About the Final Rule

Presented by the
American Bar Association
Health Law Section and
Center for Professional Development

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This publication accompanies the audio program entitled "Major 2016 Stark Law Changes: Hear from CMS About the Final Rule" broadcast on November 18, 2015 (event code: CE1511SLC).

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   Clinton R. Mikel and Adrienne Dresevic

3. **Federal Register Vol. 80, No. 22 (November 16, 2015)**

Physician Self-referral Updates in the CY 2016 Medicare Physician Fee Schedule Final Rule

Major 2016 Stark Law Changes: Hear from CMS About the Final Rule

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Sponsor: ABA Health Law Section and the Center for Professional Development

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ABA Stark Resources

- Stark Redline – Final PFS CY 2016 Physician Self-Referral (Stark) Changes:
  - http://ow.ly/UfjCY
- Stark Toolkit:
  - http://ow.ly/UNXQu
- eSource Article on Proposed Rule:
  - http://ow.ly/UfjLL
- Lengthy December Health Lawyer Article on Proposed/Final Rule:
  - Article in Peer Review
  - Webinar attendees will be emailed the final article soon (prior to December Health Lawyer print publication)

Disclaimer

- The views expressed today are those of the speakers in their personal capacity and not the official position of the Centers for Medicare & Medicaid Services or any other governmental agency.

Physician Self-referral Law

- Physician self-referral law (section 1877 of the Social Security Act)
  - Unless an exception applies—
    - Prohibits a physician from making referrals for designated health services (DHS) payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship
    - Prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services
- Purpose of the updates to the physician self-referral regulations in the Medicare Physician Fee Schedule for CY 2016 (the "Final Rule"):
  - Accommodate delivery and payment system reform
  - Reduce burden
  - Facilitate compliance

CY 2016 Medicare Physician Fee Schedule Final Rule

- Clarifications
  - Existing policy
  - Additional explanation where it appears stakeholders would benefit from clarification
- New exceptions
  - Assistance to a physician to compensate a nonphysician practitioner
  - Timeshare arrangements
- Revisions to existing definitions, exceptions, and other rules
  - Signature requirements
  - Holdover arrangements
  - Renewing arrangements that qualify for the exception for fair market value compensation
- 80 Fed. Reg. 70886, Nov. 16, 2015

Clarifications

Writing Requirement

- Many exceptions for compensation arrangements require the arrangement to be set out in writing, including the exceptions for:
  - Rental of office space and equipment (§§ 411.357(a) & (b))
  - Personal service arrangements (§ 411.357(d))
  - Fair market value compensation (§ 411.357(l))
- Current regulations: variously use the term "arrangement" and "agreement" in connection with the writing requirement
- Final Rule: removes the term "agreement" from most exceptions and clarifies the requirement that an arrangement be set out in writing

Writing Requirement

- Single "formal contract" not required:
  - Collection of documents may satisfy the writing requirement
  - Collection of documents may include "contemporaneous documents evidencing the course of conduct between the parties" (80 FR 71315)
  - Note: Single signed written contract is the best practice and the best way to ensure compliance
- Standard: "[T]he relevant inquiry is whether the available contemporaneous documents (that is, documents that are contemporaneous with the arrangement) would permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made." (80 FR 71315)

Writing Requirement

- Examples of documents that a party might consider as part of a collection of documents when determining compliance with the writing requirement:
  - Board meeting minutes or other documents authorizing payments for specified services
  - Written communication between the parties, including hard copy and electronic communications
  - Fee schedules for specified services
  - Check requests or invoices identifying items or services provided, relevant dates, and/or rate of compensation
  - Time sheets documenting services performed
  - Call coverage schedules or similar documents providing dates of services to be provided
  - Accounts payable or receivable records documenting the date and rate of payment and the reason for payment
  - Checks issued for items, services, or rent and identified as such

Writing Requirement

- Relationship of documents in a collection:
  - Documents in the collection must clearly relate to one another
  - Document must clearly evidence one and the same arrangement between the parties
- Signature requirement, as applied to a collection of documents:
  - Signature is required on a contemporaneous writing documenting the arrangement
  - Signed writing must clearly relate to the other documents in the collection and to the underlying arrangement

Writing Requirement

- Timing issues:
  - Evidence of the arrangement problem: Contemporaneous documents evidencing the course of conduct between the parties are often generated *after* the arrangement has begun
    - A document produced *after* a referral is made cannot be relied upon to protect referrals that predate the document. (80 FR 71317)
    - However, documents generated over the course of the arrangement can be used to demonstrate compliance for referrals made after the documents have been generated
  - Set in advance problem: If the only documents setting forth the compensation were created after the arrangement began, a party cannot meet the set in advance requirement from the inception of the arrangement.
    - However, "depending on the facts and circumstances, if parties create contemporaneous documents during the course of the arrangement, and the documents set the compensation out in writing, then parties may be able to satisfy the set in advance requirement for referrals made after the contemporaneous documents are created." (80 FR 71317)

Writing Requirement

Documents in chronological order: earliest on top, latest on bottom

TIME

Inception of arrangement

First contemporaneous document produced

Additional contemporaneous documents and records produced

ISSUE:
At what point does the arrangement satisfy the requirements of an applicable exception?

Writing Requirement

- Relation to State law
  - State law principles are not dispositive in determining compliance with the writing and signature requirements of the physician self-referral law
  - Parties may look to state law to INFORM the analysis of whether an arrangement is in writing and signed by the parties
- Clarification of existing policy
  - Guidance regarding the writing requirement is a clarification of existing policy
- Impact on SRDP submissions
  - Parties considering submitting a disclosure to the SRDP for conduct that predates the proposed rule may rely on guidance provided in the proposed rule to determine compliance with the writing requirement
  - Parties that have already submitted disclosures to the SRDP (but not yet settled the matter with CMS) may also rely on guidance provided in the proposed rule regarding the writing requirement; parties may amend or withdraw previously submitted disclosures as appropriate

1-year Term Requirement

- Current regulations: Exceptions for the rental of office space, the rental of equipment, and personal service arrangements require a term of at least 1 year
- Final rule clarification:
  - Formal "term" provision in a contract not required to satisfy requirement
  - Arrangement with a duration of at least 1 year as a matter of fact satisfies the requirement
- Written documentation of the term/duration:
  - Contemporaneous documents establishing that the arrangement lasted for at least 1 year, or
  - If the arrangement is terminated during the 1st year, a party must be able to demonstrate that the parties did not enter into a new arrangement for the same space, equipment, or services during the 1st year

Remuneration and "Split Bill" Arrangements

- "Split bill" arrangements:
  - DHS entity provides examination rooms, nursing personnel, and supplies, and bills appropriate payor for the resources and services it provides to the patient. Physician bills the appropriate payor for his or her professional fees only.
  - Such an arrangement does not "involve[] remuneration between the parties, because the physician and the DHS entity do not provide items, services, or other benefits to one another." (80 FR 71321)
  - Statement in the preamble regarding split bill arrangements was not codified in the regulations in this final rule.

New Exceptions

New Exception: Assistance to Compensate a Nonphysician Practitioner

- New §411.357(x) establishes an exception for remuneration from a hospital to a physician to assist the physician with compensating a nonphysician practitioner (NPP) to furnish services to patients of the physician's practice
  - Applies to federally qualified health centers (FQHCs) and rural health clinics (RHCs) in the same way that it applies to hospitals
- Remuneration provided by a hospital to a physician organization is considered to be provided to each physician who stands in the shoes of the physician organization
  - For this reason, the exception is structured to protect remuneration provided *to a physician.*

NPPs: Requirements for the NPP

- For purposes of the exception, NPP means—
  - Physician assistant
  - Nurse practitioner
  - Clinical nurse specialist
  - Certified nurse midwife
  - Clinical social worker
  - Clinical psychologist
- Substantially all (at least 75 percent) of the services furnished by the NPP to patients of the physician's practice must be—
  - Primary care services
  - Mental health care services
- No unreasonable restriction on the NPP's ability to provide patient care services in the geographic area served (GSA) by the hospital

NPPs: The Arrangement between the NPP and the Physician (or Physician Organization)

- Must be a compensation arrangement
  - Includes an employment, contractual, or other arrangement under which remuneration passes between the NPP and the physician (or physician organization in whose shoes the physician stands under §411.354(c))
  - The exception does not allow a hospital to provide remuneration to assist with conferring an ownership or investment interest in the physician's practice
- May be full-time or part-time
- Exception is not available for a compensation arrangement between a physician (or physician organization) and a staffing company or other entity for the services of the NPP
  - Arrangement must be directly between the physician (or physician organization) and the independent contractor NPP (80 FR 71305)

NPPs: Relocation Requirements

- The NPP may not, within 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under §411.354(c))—
  - Have practiced in the hospital's GSA
  - Have been employed or otherwise engaged to provide patient care services by a physician or physician organization that has a medical practice site located in the hospital's GSA
    - Prohibition applies regardless of whether the NPP furnished services at the medical practice site located in the hospital's GSA

NPPs: Compensation to NPP

- May not exceed fair market value for the patient care services furnished by the NPP to patients of the physician's practice
- Physician may provide remuneration to the NPP other than compensation, signing bonus, and benefits; however, the hospital may not provide assistance for anything other than compensation, signing bonus, and benefits
  - "Benefits" include only health insurance, paid leave, and other routine non-cash benefits offered to similarly situated employees or contractors of the physician's practice (80 FR 71302)
  - Hospital may assist the physician with providing relocation assistance to the NPP if the relocation assistance is included in the calculation of the NPP's "compensation" (80 FR 71309)
    - Caution: total compensation (including any amount associated with relocation costs) must not exceed fair market value

NPPs: The Arrangement between the Hospital and the Physician (or Physician Organization)

- Must be set out in writing and signed by the hospital, physician (or physician organization), and the NPP
- May not be conditioned on the physician's or NPP's referrals to the hospital
- May 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
- Records of the following must be maintained for at least 6 years and made available to the Secretary upon request—
  - The actual amount of remuneration provided by the hospital to the physician (or physician organization)
  - The actual amount of remuneration provided by the physician (or physician organization) to the NPP

NPPs: The Arrangement between the Hospital and the Physician (or Physician Organization)

- Frequency limitation
  - May be used by a hospital only once every 3 years with respect to the same referring physician
    - Applying the "stand in the shoes" provisions limits the use of the exception to once every 3 years with respect to the same physician organization if the physician organization has more than one nontitular owner
    - See discussion of frequency limitation for temporary noncompliance with signature requirements (80 FR 71333)
  - Exception: Frequency limitation is waived if the NPP is replacing a NPP who left the physician's practice within in 1 year of the commencement of his or her employment or contractual arrangement
    - 2-year limit on assistance continues to apply and is measured from the commencement of the original NPP's employment or contractual arrangement (80 FR 71310)

NPPs: Remuneration from the Hospital to the Physician (or Physician Organization)

- May not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the NPP
- Limited to the first 2 consecutive calendar years of the employment or independent contractor arrangement between the NPP and the physician (or the physician organization in whose shoes the physician stands under §411.354(c))
- May not be determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or potential referrals by—
  - The NPP
  - The physician
  - Any other NPP or physician in the physician's practice
- May not take into account any other business generated between the parties

NPPs: Special Definitions

- Referral means a request by a NPP that includes the provision of any DHS for which payment may be made under Medicare, the establishment of any plan of care by a NPP that includes the provision of such DHS, or the certifying or recertifying of the need for such DHS
  - Does not include DHS personally performed by the NPP
- Geographic area served by the hospital, FQHC, or RHC has the same meaning set forth in the exception for physician recruitment
- Compensation arrangement between a physician (or the physician organization in whose shoes the physician stands under §411.354(c)) and a NPP means an employment, contractual, or other arrangement under which remuneration passes (directly) between the parties and does NOT include a NPP's ownership or investment interest in a physician organization

New Exception: Timeshare Arrangements

- New §411.357(y) establishes an exception for timeshare arrangements that include the use of premises, equipment, personnel, items, supplies, or services
- Premises: covers "use" arrangements only
  - Does not cover traditional office space leases
  - The arrangement may not convey a possessory leasehold interest in the office space that is the subject of the arrangement (§411.357(y)(9))
- Equipment excluded from protection under the exception—
  - Advanced imaging equipment
  - Radiation therapy equipment
  - Clinical or pathology laboratory equipment
    - Exception: equipment used to perform CLIA-waived laboratory tests

Timeshares: The Arrangement between the Parties

- Must be set out in writing and signed by the parties
  - Parties must be a physician (or the physician organization in whose shoes the physician stands under §411.354(c)) and—
    - A hospital
    - A physician organization of which the physician is not an owner, employee, or contractor
  - Either party may be the grantor of permission to use the premises, equipment, personnel, items, supplies, and services
- Must specify the premises, equipment, personnel, items, supplies, and services covered by the arrangement
- May not be conditioned on the referral of patients by the physician to the hospital or physician organization that is the other party to the arrangement
- Must be commercially reasonable even if no referrals were made between the parties
- May 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

Timeshares: The Use of the Premises, Equipment, Personnel, Items, Supplies, and Services

- General requirements
  - Predominantly for the provision of evaluation and management (E/M) services to patients
  - Must be used on the same schedule
- Requirements specific to the use of equipment
  - Must be located in the same building where the E/M services are furnished
  - May be used to furnish only DHS incidental to E/M services furnished at the time of the patient's E/M visit

Timeshares: Compensation

- Set in advance
- Consistent with fair market value
- Not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties
- Prohibited compensation formulas—
  - Percentage compensation
  - Per-unit of service fees
    - For example, per-patient or per-use of DHS equipment rates
    - Exception: time-based compensation formulas (e.g., hourly rates or ½-day rates)

Revisions

Temporary Noncompliance with Signature Requirement (§ 411.353(g))

- Final Rule:
  - All parties have 90 days to obtain missing signatures, regardless of whether the failure to obtain the signatures was "inadvertent" or not.
  - Temporary noncompliance rule can be used only once every 3 years with respect to the same referring physician.
- Comments on the signature requirement:
  - "[T]he signature of the parties creates a record of the fact that the parties to an arrangement were aware of and assented to the key terms and conditions of the arrangement." (80 FR 71333)
  - State law principles do not determine compliance with the signature requirement, but "parties may look to State law and other bodies of relevant law, including Federal and State law pertaining to electronic signatures, to inform the analysis of whether a writing is signed for the purposes of the physician self-referral law." (80 FR 71334, emphasis added)
  - "[W]hether an arrangement is signed by the parties depends on the facts and circumstances of the arrangement and the writings that document the arrangement." (80 FR 71334)

Stand in the Shoes: Signature Requirements

- Phase III required all physicians to stand in the shoes of their physician organizations, including owners, employees, and independent contractors
  - Signature requirements in the applicable compensation arrangement exceptions (*i.e.*, the writing must be signed by the "parties") applied to all physicians in the physician organization
  - Prohibition on taking into account the volume or value of referrals or other business generated "between the parties" when determining compensation applied to all physicians in the physician organization
- FY 2009 IPPS Final Rule amended the "stand in the shoes" provisions to require only physicians with a nontitular ownership or investment interest to stand in the shoes of their physician organizations
  - No change to the regulation text that applied the signature requirement and volume or value prohibition to all "parties" (*i.e.*, all physicians in the physician organization)

Stand in the Shoes: Clarifying the Parties

- CY 2016 PFS final rule limits the signature requirement to only those physicians who stand in the shoes of their physician organization
  - Relieves burden on physician organizations imposed by prior rule under the original "stand in the shoes" provisions
- No change to the existing rule that the relevant referrals and other business generated "between the parties" are referrals and other business generated between the DHS entity and the physician organization (including all members, employees, and independent contractor physicians).
  - §411.354(c)(3)(i)
- Revisions effective January 1, 2016

Indefinite Holdover Provisions

- Final Rule: Indefinite "holdover" arrangements permitted under the rental of office space and equipment exceptions (§§ 411.357(a) & (b)) and the personal service arrangements exception (§ 411.357(d)), provided:
  - The expired arrangement satisfied all the requirements of the applicable exception when it expired;
  - The holdover arrangement continues on the same terms and conditions as the immediately preceding arrangement; and
  - The holdover arrangement continues to satisfy all the requirements of the applicable exception during the holdover.

Indefinite Holdover Provisions

- Fair market value requirement must be met during the holdover: "[A]s soon as a holdover arrangement ceases to meet all the requirements of an applicable exception, including the fair market value requirement, referrals for DHS by the physician to the entity that is a party to the arrangement are no longer permissible." (80 FR 71320)
- Amendments not permitted during the holdover: "If parties were permitted to amend the terms and conditions of an arrangement in the course of the holdover, then parties would be able to frequently renegotiate the terms of the arrangement during the holdover in a manner that could take into account the volume or value of referrals." (80 FR 71320)

Indefinite Holdover Provisions

- Application of Final Rule to current "holdover" arrangements:
  - Arrangements in a valid holdover under the current 6-month holdover provisions on January 1, 2016 (the effective date of the final rule) may qualify for the indefinite holdover
    - Arrangements expiring by their own terms on or after July 1, 2015
  - Expired arrangements that are no longer in a valid holdover under the current 6-month holdover provisions may not make use of the indefinite holdover provisions
    - Arrangements that expired on their own terms prior to July 1, 2015
- Intersection of writing requirement and holdover provisions:
  - However, "even without a holdover provision, an arrangement that continued after a contract expired on its own terms could potentially satisfy the writing requirement of an applicable exception, provided that the parties had sufficient contemporaneous documentation of the arrangement." (80 FR 71319)

Renewals – Exception for Fair Market Value Compensation (§ 411.357(l))

- Final Rule: Arrangements with any timeframe, including 1-year or more, may be renewed any number of times under the exception for fair market value compensation, provided:
  - The terms of the arrangement and the compensation for the same items or services do not change, and
  - The arrangement continues to satisfy all the requirements of the exception during the renewal period
- Renewal need not be in writing: "We note that nothing in the exception requires parties to renew the arrangement in writing. However, the parties must have written documentation establishing that the renewed arrangement was on the same terms and conditions as the original arrangement." (80 FR 71320)

Physician-owned Hospitals

- Preventing Conflicts of Interest: Public Website and Public Advertising Disclosure Requirement
  - Advertising: New §411.362(a) defines "public advertising for the hospital" as any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital.
  - Website: Any language that would put a reasonable person on notice that hospital may be physician-owned is deemed a sufficient statement of physician ownership or investment
    - A public website for the hospital does not include, by way of example—
      - Social media websites
      - Electronic patient payment portals
      - Electronic patient care portals
      - Electronic health information exchanges

Website or Advertising Noncompliance

- SRDP is the appropriate means for reporting overpayments in the event that a physician-owned hospital discovers that it failed to satisfy the public website or public advertising disclosure requirements.
  - For noncompliance with the public website disclosure requirement, the period of noncompliance is the period during which the physician-owned hospital failed to satisfy the requirement, the earliest possible date being September 23, 2011, the date by which a physician-owned hospital had to be in compliance with the public website and advertising disclosure requirements.
  - For noncompliance with the public advertising disclosure requirement, the period of noncompliance is the duration of the applicable advertisement's predetermined initial circulation, unless the hospital amends the advertisement to satisfy the requirement at an earlier date.

Physician-owned Hospitals

- Determining the *bona fide* investment level
  - Goal of the revision is to better align the prohibition set forth at §411.362(b)(4)(i) with the statutory definition of "physician owner or investor" in a hospital
  - Attempted not to unsettle long-standing definitions in the physician self-referral regulations
    - Currently use the term "referring physician" in the general ownership definitions
- Solely for the purposes of §411.362 (including for the purposes of determining the baseline bona fide investment level and the bona fide investment level thereafter), CMS established a definition of ownership or investment interest that applies to all types of owners or investors, regardless of their status as a referring or non-referring physician.
- The effective date of the revised definition is January 1, 2017.
  - Provides time for hospitals to come into compliance with the new policy.
  - Parties that have considered all physicians in their determination of the ownership level (and not just referring physicians) are in compliance.

Bona Fide Investment Levels: §411.362(a)

- A "direct" ownership or investment interest in a hospital exists if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor.
- An "indirect" ownership or investment interest in a hospital exists if:
  (1) between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and,
  (2) the hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital.
- An indirect ownership or investment interest in a hospital exists even though the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

Other Issues

- Clarified single "volume or value" standard by using uniform language throughout the regulations
- Updated the exception for ownership of publicly traded securities
- Clarified "carve out" from definition of remuneration
  - Separately listed the purposes for which items, devices, or supplies must be used solely in order not to be considered remuneration
  - Clarified that the use of the items, devices, or supplies for more than one of the enumerated purposes is permissible, provided that they are used solely for such purposes
- Established definitions for the geographic area served by a FQHC or RHC
- Amended definition of *locum tenens* physician
- Clarified formula for calculating the maximum retention payment when based on a written certification
- Replaced "Web site" with "website" (or at least CMS tried)

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Final PFS CY 2016 Physician Self-Referral (Stark) Changes[1]

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Blue Underline = Insertion; ~~Red Strikethrough~~ = Deletion

[1] 80 Fed. Reg. 70886 (2015), Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, available at: https://federalregister.gov/a/2015-28005.

See, also, July 8, 2015, Proposed Rule, 80 Fed. Reg. 41685 (2015), available at: http://www.gpo.gov/fdsys/pkg/FR-2015-07-15/pdf/2015-16875.pdf. An ABA Health Law Section eSource Article regarding the proposed rule is available at: http://www.americanbar.org/publications/aba_health_esource/2015-2016/october/starklaw.html.

An upcoming ABA Health Lawyer article will address the changes made by the Final Rule.

The Final Rule will *generally* be effective as of January 1, 2016. However, the definition of "ownership or investment interest" in 42 C.F.R. §411.362(a), related to physician-owned-hospitals, has a delayed effective date of January 1, 2017. Note that, regardless of the effective date(s), CMS views many of the Final Rule revisions as "clarifications" of "existing policy", with the attendant implication that the changes can arguably be effectively relied upon immediately/retroactively.

Stark Regulations

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42 C.F.R. Part 411

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411.351	Definitions	6	No
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	Clinical laboratory services	6	No
	Consultation	7	No
	Designated health services (DHS)	7	No
	Does not violate the anti-kickback statue	7	No
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	Durable medical equipment (DME) and supplies	8	No
	Electronic health record	8	No
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	Entity	8	Yes
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	Hospital	9	No
	HPSA	9	No
	Immediate family member or member of a physician's immediate family	9	No
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	Inpatient hospital services	10	No
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	Outpatient hospital services	11	No
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	Physician	12	No

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42 C.F.R. Section	Heading	Redline Page	Rule Change?
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	(b) Ownership or investment interest [defined]	22	No
	(c) Compensation arrangement [defined]	24	Yes
	(d) Special rules on compensation	26	Yes
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	(a) Physician services	27	No
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	(c) Services furnished to enrollees [of prepaid health plans]	30	No
	(d) [Reserved]	31	No
	(e) Academic medical centers	31	No
	(f) Implants furnished by an ASC	32	No
	(g) EPO and other dialysis-related drugs furnished by an ESRD facility	33	No
	(h) Preventative screening tests, immunizations, and vaccines	33	No
	(i) Eyeglasses and contact lenses following cataract surgery	33	No
	(j) Intra-family rural referrals	34	No

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42 C.F.R. Section	Heading	Redline Page	Rule Change?
411.356	Exceptions to the referral prohibition related to ownership or investment interests	34	Yes
	(a) Publicly-traded securities	34	Yes
	(b) Mutual funds	35	No
	(c) Specific providers [rural providers, Puerto Rico hospitals, and whole hospital]	35	No
411.357	Exceptions to the referral prohibition related to compensation arrangements	35	Yes
	(a) Rental of office space	35	Yes
	(b) Rental of equipment	36	Yes
	(c) Bona fide employment relationships	37	Yes
	(d) Personal service arrangements	38	Yes
	(e) Physician recruitment	39	Yes
	(f) Isolated transactions	42	Yes
	(g) Certain arrangements with hospitals	42	No
	(h) Group practice arrangements with hospital [billed by hospital]	42	No
	(i) Payments by a physician	43	No
	(j) Charitable donations by a physician	43	No
	(k) Non-monetary compensation up to $300	43	No
	(l) Fair market value compensation	44	Yes
	(m) Medical staff incidental benefits	45	Yes
	(n) Risk-sharing arrangements	45	No
	(o) Compliance training	46	No
	(p) Indirect compensation arrangements	46	Yes
	(q) Referral services	46	No
	(r) Obstetrical malpractice insurance subsidies	46	Yes
	(s) Professional courtesy	48	Yes
	(t) Retention payments in underserved areas	48	Yes
	(u) Community-wide health information systems	50	No
	(v) E-prescribing items and services	51	No
	(w) Electronic health records	52	No
	(x) Assistance to compensate a nonphysician practitioner	53	Yes
	(y) Timeshare arrangements	55	Yes
411.361	Reporting requirements	56	No
411.362	Additional requirements concerning physician ownership and investment in hospitals	58	Yes
§411.370	Advisory opinions relating to physician referrals.	64	No
§411.372	Procedure for submitting a request	65	No
§411.373	Certification	66	No

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42 C.F.R. Section	Heading	Redline Page	Rule Change?
§411.375	Fees for the cost of advisory opinions	67	No
§411.377	Expert opinions from outside sources.	68	No
§411.378	Withdrawing a request.	68	No
§411.379	When CMS accepts a request.	68	No
§411.380	When CMS issues a formal advisory opinion.	69	No
§411.382	CMS's right to rescind advisory opinions.	69	No
§411.384	Disclosing advisory opinions and supporting information.	70	No
§411.386	CMS's advisory opinions as exclusive.	70	No
§411.387	Parties affected by advisory opinions.	70	No
§411.388	When advisory opinions are not admissible evidence.	70	No
§411.389	Range of the advisory opinion	70	No

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§411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered services under Medicare report information concerning ownership, investment, or compensation arrangements in the form, in the manner, and at the times specified by CMS.

(d) This subpart does not alter an individual's or entity's obligations under—

(1) The rules regarding reassignment of claims (§424.80);

(2) The rules regarding purchased diagnostic tests (§414.50);

(3) The rules regarding payment for services and supplies incident to a physician's professional services (§410.26); or

(4) Any other applicable Medicare laws, rules, or regulations.

[72 FR 51079, Sept. 5, 2007]

§411.351 Definitions.

As used in this subpart, unless the context indicates otherwise:

Centralized building means all or part of a building, including, for purposes of this subpart only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. Space in a building or a mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider or supplier (for example, a diagnostic imaging facility) is not a centralized building for purposes of this subpart. This provision does not preclude a group practice from providing services to other providers or suppliers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.

Clinical laboratory services means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, including procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body, as specifically identified by the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are clinical laboratory services for purposes of this subpart. Any service not specifically identified as a clinical laboratory service on the List of CPT/HCPCS

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Codes is not a clinical laboratory service for purposes of this subpart.

Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:

(1) The physician's opinion or advice regarding evaluation or management or both of a specific medical problem is requested by another physician.

(2) The request and need for the consultation are documented in the patient's medical record.

(3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided that the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:

(1)

(i) Clinical laboratory services.

(ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services.

(iii) Radiology and certain other imaging services.

(iv) Radiation therapy services and supplies.

(v) Durable medical equipment and supplies.

(vi) Parenteral and enteral nutrients, equipment, and supplies.

(vii) Prosthetics, orthotics, and prosthetic devices and supplies.

(viii) Home health services.

(ix) Outpatient prescription drugs.

(x) Inpatient and outpatient hospital services.

(2) Except as otherwise noted in this subpart, the term "designated health services" or **DHS** means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS).

Does not violate the anti-kickback statute, as used in this subpart only, means that the particular arrangement—

(1)

(i) Meets a safe harbor under the anti-kickback statute, as set forth at §1001.952 of this title, "Exceptions";

(ii) Has been specifically approved by the OIG in a favorable advisory opinion issued to a party to the

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particular arrangement (for example, the entity furnishing DHS) with respect to the particular arrangement (and not a similar arrangement), provided that the arrangement is conducted in accordance with the facts certified by the requesting party and the opinion is otherwise issued in accordance with part 1008 of this title, "Advisory Opinions by the OIG"; or

(iii) Does not violate the anti-kickback provisions in section 1128B(b) of the Act.

(2) For purposes of this definition, a **favorable advisory opinion** means an opinion in which the OIG opines that—

(i) The party's specific arrangement does not implicate the anti-kickback statute, does not constitute prohibited remuneration, or fits in a safe harbor under §1001.952 of this title; or

(ii) The party will not be subject to any OIG sanctions arising under the anti-kickback statute (for example, under sections 1128A(a)(7) and 1128(b)(7) of the Act) in connection with the party's specific arrangement.

Downstream contractor means a "first tier contractor" as defined at §1001.952(t)(2)(iii) or a "downstream contractor" as defined at §1001.952(t)(2)(i).

Durable medical equipment (**DME**) and supplies has the meaning given in section 1861(n) of the Act and §414.202 of this chapter.

Electronic health record means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

Employee means any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)-1(c).)

Entity means—

(1) A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it—

(i) Is the person or entity that has performed services that are billed as DHS; or

(ii) Is the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned in accordance with §424.80(b)(1) (employer) or (b)(2) (payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at §1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).

(2) A health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier under §424.80(b)(1) and (b)(2) of this chapter, with respect to any DHS provided by that supplier.

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(3) For purposes of this subpart, "entity" does not include a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with §414.50 of this chapter and ~~section 30.2.9 of the CMS Internet-only Manual, p~~Pub.~~lication~~ 100-04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.9 ~~(general billing requirements)~~.

Fair market value means the value in arm's-length transactions, consistent with the general market value. **"General market value"** means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. With respect to rentals and leases described in §411.357(a), (b), and (l) (as to equipment leases only), "**fair market value**" means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

Home health services means the services described in section 1861(m) of the Act and part 409, subpart E of this chapter.

Hospital means any entity that qualifies as a "hospital" under section 1861(e) of the Act, as a "psychiatric hospital" under section 1861(f) of the Act, or as a "critical access hospital" under section 1861(mm)(1) of the Act, and refers to any separate legally organized operating entity plus any subsidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills. However, a "hospital" does not include entities that perform services for hospital patients "under arrangements" with the hospital.

HPSA means, for purposes of this subpart, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in part 5 of this title).

Immediate family member or member of a physician's immediate family means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

"Incident to" services or services "incident to" means those services and supplies that meet the requirements of section 1861(s)(2)(A) of the Act, §410.26 of this chapter, and ~~sections 60, 60.1, 60.2, and 60.3 of the CMS Internet-only Manual, p~~Pub.~~lication~~ 100-02, Medicare Benefit

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Policy Manual, Chapter 15 ~~(covered medical and other health services), as amended or replaced from time to time~~, Sections 60, 60.1, 60.2, 60.3, and 60.4.

Inpatient hospital services means those services defined in section 1861(b) of the Act and §409.10(a) and (b) of this chapter and include inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient critical access hospital services, as defined in section 1861(mm)(2) of the Act. "Inpatient hospital services" do not include emergency inpatient services provided by a hospital located outside of the U.S. and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H of this chapter, or emergency inpatient services provided by a nonparticipating hospital within the U.S., as authorized by section 1814(d) of the Act and described in part 424, subpart G of this chapter. "Inpatient hospital services" also do not include dialysis furnished by a hospital that is not certified to provide end-stage renal dialysis (ESRD) services under subpart U of part 405 of this chapter. "Inpatient hospital services" include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. "Inpatient hospital services" do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists if Medicare reimburses the services independently and not as part of the inpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Interoperable means able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually, as published in the Federal Register, and is posted on the CMS Web site at http://www.cms.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp#TopOfPage.

Locum tenens physician (or substitute physician) ~~mean~~is a physician who substitutes ~~(that is, "stands in the shoes")~~ in exigent circumstances for another physician, in accordance with section 1842(b)(6)(D) of the Act ~~applicable reassignment rules~~ and ~~regulations, including section 30.2.11 of the CMS Internet-only Manual, p~~Pub.~~lication~~ 100-04, Medicare Claims Processing Manual, Chapter 1, ~~(general billing requirements), as amended or replaced from time to time~~ Section 30.2.11.

Member of the group or member of a group practice means, for purposes of this subpart, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a

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physician employed by his or her individual professional corporation that has an equity interest in the group practice), a locum tenens physician (as defined in this section), or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes "patient care services" to the group as defined in this section. An independent contractor or a leased employee is not a member of the group (unless the leased employee meets the definition of an "employee" under this §411.351).

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (s)(2)(C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient critical access hospital services, as defined in section 1861(mm)(3) of the Act. "Outpatient hospital services" do not include emergency services furnished by nonparticipating hospitals and covered under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. "Outpatient hospital services" include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. "Outpatient hospital services" do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the outpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Outpatient prescription drugs means all drugs covered by Medicare Part B or D, except for those drugs that are "covered ancillary services," as defined at §416.164(b) of this chapter, for which separate payment is made to an ambulatory surgical center.

Parenteral and enteral nutrients, equipment, and supplies means the following services (including all HCPCS level 2 codes for these services):

(1) Parenteral nutrients, equipment, and supplies, meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in Pub. 100-03,~~section 108.2 of the~~ Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2, as amended or replaced from time to time; and

(2) Enteral nutrients, equipment, and supplies, meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in Pub. 100-03, ~~section 108.2 of the~~ Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2~~as amended or replaced from time to time~~.

Patient care services means any task(s) performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters or generally benefit a particular practice. Patient care services can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.

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Physical therapy, occupational therapy, and outpatient speech-language pathology services means those particular services so identified on the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this subpart. Any service not specifically identified as physical therapy, occupational therapy or outpatient speech-language pathology on the List of CPT/HCPCS Codes is not a physical therapy, occupational therapy, or outpatient speech-language pathology service for purposes of this subpart. The list of codes identifying physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this regulation includes the following:

(1) Physical therapy services, meaning those outpatient physical therapy services described in section 1861(p) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Assessments, function tests, and measurements of strength, balance, endurance, range of motion, and activities of daily living;

(ii) Therapeutic exercises, massage, and use of physical medicine modalities, assistive devices, and adaptive equipment; or

(iii) Establishment of a maintenance therapy program for an individual whose restoration potential has been reached; however, maintenance therapy itself is not covered as part of these services.

(2) **Occupational therapy services**, meaning those services described in section 1861(g) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities;

(ii) Evaluation of an individual's level of independent functioning;

(iii) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; or

(iv) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

(3) **Outpatient speech-language pathology services**, meaning those services as described in section 1861(ll)(2) of the Act that are for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation

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that apply to members of the group practice under §411.352(g) (or the contract must satisfy the requirements of the personal service arrangements exception in §411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules in §424.80(b)(2) of this chapter (see also ~~section 30.2.11 of the CMS Internet-only Manual, p~~Pub.~~lication~~ 100-04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.7 ~~(general billing requirements)~~, as amended or replaced from time to time). Referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals in §411.353(a), and the group practice is subject to the limitation on billing for those referrals in §411.353(b).

Physician incentive plan means any compensation arrangement between an entity (or downstream contractor) and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

Physician organization means a physician, a physician practice, or a group practice that complies with the requirements of §411.352.

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of services.

Professional courtesy means the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these items and services that are covered by Medicare):

(1) **Orthotics**, meaning leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.

(2) **Prosthetics**, meaning artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

(3) **Prosthetic devices**, meaning devices (other than a dental device) listed in section 1861(s)(8) of the Act that replace all or part of an internal body organ, including colostomy bags, and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(4) **Prosthetic supplies**, meaning supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

Radiation therapy services and supplies means those particular services and supplies, including (effective January 1, 2007) therapeutic nuclear medicine services and supplies, so identified on the List of CPT/HCPCS Codes. All services and supplies so identified on the List of CPT/HCPCS Codes are radiation therapy services and supplies for purposes of this subpart. Any service or supply not specifically identified as radiation therapy services or supplies on the List of CPT/HCPCS Codes is not a radiation therapy service or supply for purposes of this subpart. The list of codes identifying radiation therapy services and supplies is based on section 1861(s)(4) of the Act and §410.35 of this chapter.

Radiology and certain other imaging services means those particular services so identified on the List of CPT/HCPCS Codes. All services identified on the List of CPT/HCPCS Codes are radiology and certain other imaging services for purposes of this subpart. Any service not specifically identified as radiology and certain

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other imaging services on the List of CPT/HCPCS Codes is not a radiology or certain other imaging service for purposes of this subpart. The list of codes identifying radiology and certain other imaging services includes the professional and technical components of any diagnostic test or procedure using x-rays, ultrasound, computerized axial tomography, magnetic resonance imaging, nuclear medicine (effective January 1, 2007), or other imaging services. All codes identified as radiology and certain other imaging services are covered under section 1861(s)(3) of the Act and §§410.32 and 410.34 of this chapter, but do not include—

(1) X-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;

(2) Radiology or certain other imaging services that are integral to the performance of a medical procedure that is not identified on the list of CPT/HCPCS codes as a radiology or certain other imaging service and is performed—

(i) Immediately prior to or during the medical procedure; or

(ii) Immediately following the medical procedure when necessary to confirm placement of an item placed during the medical procedure.

(3) Radiology and certain other imaging services that are "covered ancillary services," as defined at §416.164(b), for which separate payment is made to an ASC.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy, if—

(i) The request results from a consultation initiated by another physician (whether the request for a consultation was made

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to a particular physician or to an entity with which the physician is affiliated); and

(ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist.

(3) Can be in any form, including, but not limited to, written, oral, or electronic.

Referring physician means a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made by another person or entity. A referring physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely for one or more of the following purposes:~~to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies or are used solely to order or communicate the results of tests or procedures for the entity.~~

(i) Collecting specimens for the entity furnishing the items, devices or supplies;

(ii) Transporting specimens for the entity furnishing the items, devices or supplies;

(iii) Processing specimens for the entity furnishing the items, devices or supplies;

(iv) Storing specimens for the entity furnishing the items, devices or supplies;

(v) Ordering tests or procedures for the entity furnishing the items, devices or supplies; or

(vi) Communicating the results of tests or procedures for the entity furnishing the items, devices or supplies.

(3) A payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or self-insured plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the self-insured plan (or a subcontractor of the insurer or self-insured plan) and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.

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Rural area means an area that is not an urban area as defined at §412.62(f)(1)(ii) of this chapter.

Same building means a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (for example, lawns, courtyards, driveways, parking lots) and interior loading docks or parking garages. For purposes of this section, the "same building" does not include a mobile vehicle, van, or trailer.

Specialty hospital means a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act) that is primarily or exclusively engaged in the care and treatment of one of the following:

(1) Patients with a cardiac condition;

(2) Patients with an orthopedic condition;

(3) Patients receiving a surgical procedure; or

(4) Any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital. A "specialty hospital" does not include any hospital—

(1) Determined by the Secretary to be in operation before or under development as of November 18, 2003;

(2) For which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

(3) For which the type of categories described above is no different at any time on or after such date than the type of such categories as of such date;

(4) For which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

(5) That meets such other requirements as the Secretary may specify.

Transaction means an instance or process of two or more persons or entities doing business. An **isolated financial transaction** means one involving a single payment between two or more persons or entities or a transaction that involves integrally related installment payments provided that—

(1) The total aggregate payment is fixed before the first payment is made and does not take into account, directly or indirectly, the volume or value of referrals or other business generated by the referring physician; and

(2) The payments are immediately negotiable or are guaranteed by a third party, or secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

[72 FR 51080, Sept. 5, 2007, as amended at 72 FR 66400, 66930, Nov. 27, 2007; 73 FR 48751, Aug. 19, 2008; 73 FR 69934, Nov. 19, 2008]

§411.352 Group practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

(a) ***Single legal entity***. The group practice must consist of a single legal entity operating primarily

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for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). The single legal entity may be organized or owned (in whole or in part) by another medical practice, provided that the other medical practice is not an operating physician practice (and regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this subpart, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a single legal entity may itself own subsidiary entities. A group practice operating in more than one State will be considered to be a single legal entity notwithstanding that it is composed of multiple legal entities, provided that—

(1) The States in which the group practice is operating are contiguous (although each State need not be contiguous to every other State);

(2) The legal entities are absolutely identical as to ownership, governance, and operation; and

(3) Organization of the group practice into multiple entities is necessary to comply with jurisdictional licensing laws of the States in which the group practice operates.

(b) ***Physicians***. The group practice must have at least two physicians who are members of the group (whether employees or direct or indirect owners), as defined at §411.351.

(c) ***Range of care***. Each physician who is a member of the group, as defined at §411.351, must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(d) ***Services furnished by group practice members***. (1) Except as otherwise provided in paragraphs (d)(3), (d)(4), (d)(5), and (d)(6) of this section, substantially all of the patient care services of the physicians who are members of the group (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. Patient care services must be measured by one of the following:

(i) The total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). (For example, if a physician practices 40 hours a week and spends 30 hours a week on patient care services for a group practice, the physician has spent 75 percent of his or her time providing patient care services for the group.)

(ii) Any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

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(2) The data used to calculate compliance with this substantially all test and related supportive documentation must be made available to the Secretary upon request.

(3) The substantially all test set forth in paragraph (d)(1) of this section does not apply to any group practice that is located solely in a HPSA, as defined at §411.351.

(4) For a group practice located outside of a HPSA (as defined at §411.351), any time spent by a group practice member providing services in a HPSA should not be used to calculate whether the group practice has met the substantially all test, regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.

(5) During the start up period (not to exceed 12 months) that begins on the date of the initial formation of a new group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the substantially all test requirement set forth in paragraph (d)(1) of this section as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This paragraph (d)(5) does not apply when an existing group practice admits a new member or reorganizes.

(6)(i) If the addition to an existing group practice of a new member who would be considered to have relocated his or her medical practice under §411.357(e)(2) would result in the existing group practice not meeting the substantially all test set forth in paragraph (d)(1) of this section, the group practice will have 12 months following the addition of the new member to come back into full compliance, provided that—

(A) For the 12-month period the group practice is fully compliant with the substantially all test if the new member is not counted as a member of the group for purposes of §411.352; and

(B) The new member's employment with, or ownership interest in, the group practice is documented in writing no later than the beginning of his or her new employment, ownership, or investment.

(ii) This paragraph (d)(6) does not apply when an existing group practice reorganizes or admits a new member who is not relocating his or her medical practice.

(e) ***Distribution of expenses and income***. The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Nothing in this section prevents a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from DHS under §411.352(i).

(f) ***Unified business***.

(1) The group practice must be a unified business having at least the following features:

(i) Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries); and

(ii) Consolidated billing, accounting, and financial reporting.

(2) Location and specialty-based compensation practices are permitted with respect to revenues derived from services that are not DHS and may be permitted with respect to revenues derived from DHS under §411.352(i).

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(g) ***Volume or value of referrals***. No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in §411.352(i).

(h) ***Physician-patient encounters***. Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(i) ***Special rule for productivity bonuses and profit shares***.

(1) A physician in the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. A physician in the group practice may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).

(2) **Overall profits** means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. Overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(i) The group's profits are divided per capita (for example, per member of the group or per physician in the group).

(ii) Revenues derived from DHS are distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group.

(3) A productivity bonus must be calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. A productivity bonus will be deemed not to relate directly to the volume or value of referrals of DHS if one of the following conditions is met:

(i) The bonus is based on the physician's total patient encounters or relative value units (RVUs). (The methodology for establishing RVUs is set forth in §414.22 of this chapter.)

(ii) The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group practice.

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(4) Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(2) and (i)(3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

[72 FR 51084, Sept. 5, 2007]

§411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) ***Prohibition on referrals***. Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff. However, a referral made by a physician's group practice, its members, or its staff may be imputed to the physician if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) ***Limitations on billing***. An entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.

(c) ***Denial of payment for services furnished under a prohibited referral***.

(1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral. The period during which referrals are prohibited is the period of disallowance. For purposes of this section, with respect to the following types of noncompliance, the period of disallowance begins at the time the financial relationship fails to satisfy the requirements of an applicable exception and ends no later than—

(i) Where the noncompliance is unrelated to compensation, the date that the financial relationship satisfies all of the requirements of an applicable exception;

(ii) Where the noncompliance is due to the payment of excess compensation, the date on which all excess compensation is returned by the party that received it to the party that paid it and the financial relationship satisfies all of the requirements of an applicable exception; or

(iii) Where the noncompliance is due to the payment of compensation that is of an amount insufficient to satisfy the requirements of an applicable exception, the date on which all additional required compensation is paid by the party that owes it to the party to which it is owed and the financial relationship satisfies all of the requirements of an applicable exception.

(2) When payment for a designated health service is denied on the basis that the service was furnished pursuant to a prohibited referral, and such payment denial is appealed—

(i) The ultimate burden of proof (burden of persuasion) at each level of appeal is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral (and not on CMS or its contractors to establish that the service was furnished pursuant to a prohibited referral); and

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(ii) The burden of production on each issue at each level of appeal is initially on the claimant, but may shift to CMS or its contractors during the course of the appellate proceeding, depending on the evidence presented by the claimant.

(d) ***Refunds***. An entity that collects payment for a designated health service that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis, as defined at §1003.101 of this title.

(e) ***Exception for certain entities***. Payment may be made to an entity that submits a claim for a designated health service if—

(1) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity; and

(2) The claim otherwise complies with all applicable Federal and State laws, rules, and regulations.

(f) ***Exception for certain arrangements involving temporary noncompliance***.

(1) Except as provided in paragraphs (f)(2), (f)(3), and (f)(4) of this section, an entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The financial relationship between the entity and the referring physician fully complied with an applicable exception under §411.355, §411.356, or §411.357 for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception;

(ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance; and

(iii) The financial relationship does not violate the anti-kickback statute (section 1128B(b) of the Act), and the claim or bill otherwise complies with all applicable Federal and State laws, rules, and regulations.

(2) Paragraph (f)(1) of this section applies only to DHS furnished during the period of time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant with an exception.

(3) Paragraph (f)(1) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) Paragraph (f)(1) does not apply if the exception with which the financial relationship previously complied was §411.357(k) or (m).

(g) ***Special rule for certain arrangements involving temporary noncompliance with signature requirements***.

(1) An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in §411.355, §411.356, or §411.357, except with respect to the signature requirement in §411.357(a)(1), ~~§411.357~~(b)(1), ~~§411.357~~(d)(1)(i), ~~§411.357~~(e)(1)(i), ~~§411.357~~(e)(4)(i), ~~§411.357~~(l)(1), ~~§411.357~~(p)(2), ~~§411.357~~(q) (incorporating the requirement contained in §1001.952(f)(4) of this title), ~~§411.357~~(r)(2)(ii), ~~§411.357~~(t)(1)(ii) or (t)(2)(iii)

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(both incorporating the requirements contained in §411.357(e)(1)(i)), ~~§411.357~~(v)(7)(i), ~~or §411.357~~(w)(7)(i), (x)(1)(i), or (y)(1); and

(ii) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant (without regard to whether any referrals occur or compensation is paid during such 90-day period) and the compensation arrangement otherwise complies with all criteria of the applicable exception. ~~failure to comply with the signature requirement was—~~

~~(A) Inadvertent and the parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant (without regard to whether any referrals occur or compensation is paid during such 90-day period) and the compensation arrangement otherwise complies with all criteria of the applicable exception; or~~

~~(B) Not inadvertent and the parties obtain the required signature(s) within 30 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant (without regard to whether any referrals occur or compensation is paid during such 30-day period) and the compensation arrangement otherwise complies with all criteria of the applicable exception.~~

(2) Paragraph (g)(1) of this section may be used by an entity only once every 3 years with respect to the same referring physician.

[72 FR 51086, Sept. 5, 2007, as amended at 73 FR 48751, Aug. 19, 2008; 73 FR 57543, Oct. 3, 2008]

§411.354 Financial relationship, compensation, and ownership or investment interest.

(a) ***Financial relationships***.

(1) **Financial relationship** means—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) **Types of financial relationships**.

(i) A direct financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between the entity furnishing DHS and the referring physician (or a member of his or her immediate family).

(ii) An indirect financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

(b) ***Ownership or investment interest***. An ownership or investment interest in the entity may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS.

(1) An ownership or investment interest includes, but is not limited to, stock, stock options other than those described in §411.354(b)(3)(ii), partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are

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secured with an entity's property or revenue or a portion of that property or revenue.

(2) An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. It may, however, be part of an indirect financial relationship.

(3) Ownership and investment interests do not include, among other things—

(i) An interest in an entity that arises from a retirement plan offered by that entity to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that entity;

(ii) Stock options and convertible securities received as compensation until the stock options are exercised or the convertible securities are converted to equity (before this time the stock options or convertible securities are compensation arrangements as defined in paragraph (c) of this section);

(iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section);

(iv) An "under arrangements" contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS "under arrangements" with the hospital (such a contract is a compensation arrangement as defined in paragraph (c) of this section); or

(v) A security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital (such an interest is a compensation arrangement as defined in paragraph (c) of this section).

(4) An ownership or investment interest that meets an exception set forth in §411.355 or §411.356 need not also meet an exception for compensation arrangements set forth in §411.357 with respect to profit distributions, dividends, or interest payments on secured obligations.

(5)(i) An indirect ownership or investment interest exists if—

(A) Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(B) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

(ii) An indirect ownership or investment interest exists even though the entity furnishing DHS does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

(iii) Notwithstanding anything in this paragraph (b)(5), common ownership or investment in an entity does not, in and of itself, establish an indirect ownership or investment interest by one common owner or investor in another common owner or investor.

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(iv) An indirect ownership or investment interest requires an unbroken chain of ownership interests between the referring physician and the entity furnishing DHS such that the referring physician has an indirect ownership or investment interest in the entity furnishing DHS.

(c) ***Compensation arrangement***. A compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. An "under arrangements" contract between a hospital and an entity providing DHS "under arrangements" to the hospital creates a compensation arrangement for purposes of these regulations. A compensation arrangement does not include the portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term "remuneration" at §411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(1)(i) A direct compensation arrangement exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities.

(ii) Except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to "stand in the shoes" of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if—

(A) The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and

(B) The physician has an ownership or investment interest in the physician organization.

(iii) A physician (other than a physician described in paragraph (c)(1)(ii)(B) of this section) is permitted to "stand in the shoes" of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization.

(2) An indirect compensation arrangement exists if—

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or takes

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into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(iv)(A) For purposes of paragraph (c)(2)(i) of this section, except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to "stand in the shoes" of his or her physician organization if the physician has an ownership or investment interest in the physician organization.

(B) For purposes of paragraph (c)(2)(i) of this section, a physician (other than a physician described in paragraph (c)(2)(iv)(A) of this section) is permitted to "stand in the shoes" of his or her physician organization.

(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv) of this section, a physician who "stands in the shoes" of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. When applying the exceptions in §§411.355 and ~~§~~411.357 ~~of this part~~ to arrangements in which a physician stands in the shoes of his or her physician organization, the "parties to the arrangements" are considered to be~~relevant referrals and other business generated "between the parties" are referrals and other business generated between the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians).~~ —

(A) With respect to a signature requirement, the physician organization and any physician who "stands in the shoes" of the physician organization as required under paragraph (c)(1)(ii) or (c)(2)(iv)(A) of this section; and

(B) With respect to all other requirements of the exception, including the relevant referrals and other business generated between the parties, the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians).

(ii) The provisions of paragraphs (c)(1)(ii) and (c)(2)(iv)(A) of this section—

(A) Need not apply during the original term or current renewal term of an arrangement that satisfied the requirements of §411.357(p) as of September 5, 2007 (see 42 CFR parts 400-413, revised as of October 1, 2007);

(B) Do not apply to an arrangement that satisfies the requirements of §411.355(e); and

(C) Do not apply to a physician whose ownership or investment interest is titular only. A titular ownership or investment interest is an ownership or

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investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment.

(iii) An arrangement structured to comply with an exception in §411.357 (other than §411.357(p)), but which would otherwise qualify as an indirect compensation arrangement under this paragraph as of August 19, 2008, need not be restructured to satisfy the requirements of §411.357(p) until the expiration of the original term or current renewal term of the arrangement.

(d) ***Special rules on compensation***. The following special rules apply only to compensation under section 1877 of the Act and subpart J of this part:

(1) Compensation is considered "set in advance" if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing~~an agreement between the parties~~ before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the arrangement~~agreement~~ in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(2) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account "the volume or value of referrals" if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of DHS.

(3) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account "other business generated between the parties," provided that the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which are not considered "other business generated" by the referring physician).

(4) A physician's compensation from a bona fide employer or under a managed care contract or other ~~contract~~ arrangement for personal services may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets all of the following conditions. The compensation arrangement:

(i) Is set in advance for the term of the ~~agreement~~arrangement.

(ii) Is consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of anticipated or required referrals).

(iii) Otherwise complies with an applicable exception under §411.355 or §411.357.

(iv) Complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set ~~forth~~ out in ~~a~~

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~~written agreement~~writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(v) The required referrals relate solely to the physician's services covered by the scope of the employment, the arrangement for personal services, or the contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, arrangement for personal services, or contract.

[72 FR 51086, Sept. 5, 2007; 72 FR 68076, Dec. 4, 2007, as amended at 73 FR 48751, Aug. 19, 2008; 73 FR 57543, Oct. 3, 2008; 74 FR 62006, Nov. 25, 2009]

§411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in §411.353 does not apply to the following types of services:

(a) ***Physician services***.

(1) **Physician services** as defined in §410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at §411.351) as the referring physician; or

(ii) Under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at §411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of paragraph (a) of this section, "**physician services**" include only those "incident to" services (as defined at §411.351) that are physician services under §410.20(a) of this chapter.

(b) ***In-office ancillary services.*** Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN)), that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) An individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services.

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(2) They are furnished in one of the following locations:

(i) The same building (as defined at §411.351), but not necessarily in the same space or part of the building, in which all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), or (b)(2)(i)(C) of this section are satisfied:

(A)(1) The referring physician or his or her group practice (if any) has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; and

(2) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 30 hours per week. The 30 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(B)(1) The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any);

(2) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(3) The referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(C)(1) The referring physician is present and orders the DHS during a patient visit on the premises as set forth in paragraph (b)(2)(i)(C)(2) of this section or the referring physician or a member of the referring physician's group practice (if any) is present while the DHS is furnished during occupancy of the premises as set forth in paragraph (b)(2)(i)(C)(2) of this section;

(2) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(3) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS.

(ii) A centralized building (as defined at §411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A centralized building (as defined at §411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

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(4) They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a "physician in the group practice" (as defined at §411.351) under a billing number assigned to the group practice.

(iv) An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (b)(3)(iv) of this section under a billing number assigned to the physician, group practice, or entity, provided that the billing arrangement meets the requirements of §424.80(b)(5) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) For purposes of paragraph (b) of this section, **DME covered by the in-office ancillary services exception** means canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purpose of ambulating, a patient uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(ii) The item is furnished in a building that meets the "same building" requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(iii) The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards set forth in §424.57(c) of this chapter.

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

(vi) All other requirements of the in-office ancillary services exception in paragraph (b) of this section are met.

(5) A designated health service is "**furnished**" for purposes of paragraph (b) of this section in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) **Special rule for home care physicians**. In the case of a referring physician whose principal medical practice consists of

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treating patients in their private homes, the "same building" requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a designated health service provided by the referring physician to the patient in the patient's private home. For purposes of paragraph (b)(5) of this section only, a private home does not include a nursing, long-term care, or other facility or institution, except that a patient may have a private home in an assisted living or independent living facility.

(7) **Disclosure requirement for certain imaging services**. (i) With respect to magnetic resonance imaging, computed tomography, and positron emission tomography services identified as "radiology and certain other imaging services" on the List of CPT/HCPCS Codes, the referring physician must provide written notice to the patient at the time of the referral that the patient may receive the same services from a person other than one described in paragraph (b)(1) of this section. Except as set forth in paragraph (b)(7)(ii) of this section, the written notice must include a list of at least 5 other suppliers (as defined in §400.202 of this chapter) that provide the services for which the individual is being referred and which are located within a 25-mile radius of the referring physician's office location at the time of the referral. The notice should be written in a manner sufficient to be reasonably understood by all patients and should include for each supplier on the list, at a minimum, the supplier's name, address, and telephone number.

(ii) If there are fewer than 5 other suppliers located within a 25-mile radius of the physician's office location at the time of the referral, the physician must list all of the other suppliers of the imaging service that are present within a 25-mile radius of the referring physician's office location. Provision of the written list of alternate suppliers will not be required if no other suppliers provide the services for which the individual is being referred within the 25-mile radius.

(c) ***Services furnished by an organization (or its contractors or subcontractors) to enrollees***. Services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization):

(1) An HMO or a CMP in accordance with a contract with CMS under section 1876 of the Act and part 417, subparts J through M of this chapter.

(2) A health care prepayment plan in accordance with an agreement with CMS under section 1833(a)(1)(A) of the Act and part 417, subpart U of this chapter.

(3) An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 note).

(4) A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(6) A MCO contracting with a State under section 1903(m) of the Act.

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(7) A prepaid inpatient health plan (PIHP) or prepaid ambulance health plan (PAHP) contracting with a State under part 438 of this chapter.

(8) A health insuring organization (HIO) contracting with a State under part 438, subpart D of this chapter.

(9) An entity operating under a demonstration project under sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.

(d) [Reserved]

(e) ***Academic medical centers***. (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician—

(A) Is a bona fide employee of a component of the academic medical center on a full-time or substantial part-time basis. (**A "component" of an academic medical center** means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center.) The components need not be separate legal entities;

(B) Is licensed to practice medicine in the State(s) in which he or she practices medicine;

(C) Has a bona fide faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital (as defined at §411.355(e)(3)); and

(D) Provides either substantial academic services or substantial clinical teaching services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services) is not precluded from qualifying under this paragraph (e)(1)(i)(D).

(ii) The compensation paid to the referring physician must meet all of the following conditions:

(A) The total compensation paid by each academic medical center component to the referring physician is set in advance.

(B) In the aggregate, the compensation paid by all academic medical center components to the referring physician does not exceed fair market value for the services provided.

(C) The total compensation paid by each academic medical center component is not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center.

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(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in one or more written agreements or other written documents that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components.

(C) All money paid to a referring physician for research must be used solely to support bona fide research or teaching and must be consistent with the terms and conditions of the grant.

(iv) The referring physician's compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(2) The "**academic medical center**" for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate) or an accredited academic hospital (as defined at §411.355(e)(3));

(ii) One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and

(iii) One or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions is made by physicians who are faculty members. The hospital for purposes of this paragraph (e)(2)(iii) may be the same hospital that satisfies the requirement of paragraph (e)(2)(i) of this section. For purposes of this paragraph, a faculty member is a physician who is either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. In meeting this paragraph (e)(2)(iii), faculty from any affiliated medical school or accredited academic hospital education program may be aggregated, and residents and non-physician professionals need not be counted. Any faculty member may be counted, including courtesy and volunteer faculty. For purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all individual physicians with the same class of privileges at the affiliated hospital (for example, physicians holding courtesy privileges).

(3) An **accredited academic hospital** for purposes of this section means a hospital or a health system that sponsors four or more approved medical education programs.

(f) ***Implants furnished by an ASC***. Implants furnished by an ASC, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices, and implanted DME that meet the following conditions:

(1) The implant is implanted by the referring physician or a member of the referring physician's group practice in an ASC that is certified by Medicare under part 416 of this chapter and with which the referring physician has a financial relationship.

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(2) The implant is implanted in the patient during a surgical procedure paid by Medicare to the ASC as an ASC procedure under §416.65 of this chapter.

(3) The arrangement for the furnishing of the implant does not violate the anti-kickback statute (section 1128B(b) of the Act).

(4) All billing and claims submission for the implants does not violate any Federal or State law or regulation governing billing or claims submission.

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to, and implanted in, the patient.

(g) ***EPO*** and other ***dialysis-related drugs***. EPO and other dialysis-related drugs that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph, "**EPO and other dialysis-related drugs"** means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes; and "**furnished**" means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home.

(2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the EPO and other dialysis-related drugs does not violate any Federal or State law or regulation governing billing or claims submission.

(4) The exception set forth in this paragraph does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) ***Preventive screening tests, immunizations, and vaccines***. Preventive screening tests, immunizations, and vaccines that meet the following conditions:

(1) The preventive screening tests, immunizations, and vaccines are subject to CMS-mandated frequency limits.

(2) The arrangement for the provision of the preventive screening tests, immunizations, and vaccines does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the preventive screening tests, immunizations, and vaccines does not violate any Federal or State law or regulation governing billing or claims submission.

(4) The preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be listed as eligible for this exception on the List of CPT/HCPCS Codes.

(i) ***Eyeglasses and contact lenses following cataract surgery***. Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in

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§§410.36(a)(2)(ii) and 414.228 of this chapter, respectively.

(2) The arrangement for the furnishing of the eyeglasses or contact lenses does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the eyeglasses or contact lenses does not violate any Federal or State law or regulation governing billing or claims submission.

(j) ***Intra-family rural referrals***. (1) Services provided pursuant to a referral from a referring physician to his or her immediate family member or to an entity furnishing DHS with which the immediate family member has a financial relationship, if all of the following conditions are met:

(i) The patient who is referred resides in a rural area as defined at §411.351 of this subpart;

(ii) Except as provided in paragraph (j)(1)(iii) of this section, in light of the patient's condition, no other person or entity is available to furnish the services in a timely manner within 25 miles of or 45 minutes transportation time from the patient's residence;

(iii) In the case of services furnished to patients where they reside (for example, home health services or DME), no other person or entity is available to furnish the services in a timely manner in light of the patient's condition; and

(iv) The financial relationship does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(2) The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. However, neither the referring physician nor the immediate family member has any obligation to inquire as to the availability of persons or entities located farther than 25 miles of or 45 minutes transportation time from (whichever test the referring physician utilized for purposes of paragraph (j)(1)(ii)) the patient's residence.

[72 FR 51088, Sept. 5, 2007; 72 FR 68076, Dec. 4, 2007, as amended at 75 FR 73616, Nov. 29, 2010]

§411.356 Exceptions to the referral prohibition related to ownership or investment interests.

For purposes of §411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) ***Publicly-traded securities***. Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and ~~(a)~~(2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; ~~or~~

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers; or

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(iii) Listed for trading on an electronic stock market or over-the-counter quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.

(2) They are in a corporation that had stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. "Stockholder equity" is the difference in value between a corporation's total assets and total liabilities.

(b) ***Mutual funds***. Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

(c) ***Specific providers***. Ownership or investment interest in the following entities, for purposes of the services specified:

(1) A rural provider, in the case of DHS furnished in a rural area (as defined at §411.351 of this subpart) by the provider. A "rural provider" is an entity that furnishes substantially all (not less than 75 percent) of the DHS that it furnishes to residents of a rural area and, for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), is not a specialty hospital, and in the case where the entity is a hospital, the hospital meets the requirements of §411.362 no later than September 23, 2011.

(2) A hospital that is located in Puerto Rico, in the case of DHS furnished by such a hospital.

(3) A hospital that is located outside of Puerto Rico, in the case of DHS furnished by such a hospital, if—

(i) The referring physician is authorized to perform services at the hospital;

(ii) Effective for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), the hospital is not a specialty hospital;

(iii) The ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital; and

(iv) The hospital meets the requirements described in §411.362 not later than September 23, 2011.

[72 FR 51091, Sept. 5, 2007, as amended at 75 FR 72260, Nov. 24, 2010]

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

For purposes of §411.353, the following compensation arrangements do not constitute a financial relationship:

(a) ***Rental of office space***. Payments for the use of office space made by a lessee to a lessor if the~~re is a rental or lease agreement that~~ arrangement meets the following requirements:

(1) The lease arrangement ~~agreement~~ is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The ~~term~~ duration of the ~~agreement~~ lease arrangement is at least 1 year. To meet this requirement, if the ~~agreement~~ lease arrangement is terminated ~~during the term~~ with or without

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cause, the parties may not enter into a new ~~agreement~~ lease arrangement for the same space during the first year of the original ~~term of the agreement~~lease arrangement.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement~~or rental~~ and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the ~~agreement~~ lease arrangement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the ~~agreement~~ lease arrangement are not determined—

(i) In a manner that takes into account the volume or value of any referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(6) The ~~agreement~~ lease arrangement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) If the lease arrangement expires after a term of at least 1 year,~~A~~ a holdover lease arrangement ~~month-to-month rental for up to 6 months~~ immediately following the expiration of ~~an agreement~~the lease arrangement ~~of at least 1 year that met the conditions of paragraphs (a)(1) through (a)(6) of this section~~ satisfies the requirements of paragraph (a) of this section if the following conditions are met~~, provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.~~:

(i) The lease arrangement met the conditions of paragraphs (a)(1) through (6) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (a)(1) through (6) of this section.

(b) ***Rental of equipment***. Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) ~~A rental or~~The lease ~~agreement~~ arrangement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment ~~rented or~~ leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease ~~or rental~~arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor).

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(3) The ~~agreement provides for a term of rental or~~duration of the lease ~~of~~ arrangement is at least 1 year. To meet this requirement, if the ~~agreement~~ lease arrangement is terminated ~~during the term~~ with or without cause, the parties may not enter into a new ~~agreement~~ lease arrangement for the same equipment during the first year of the original ~~term of the agreement~~lease arrangement.

(4) The rental charges over the term of the ~~agreement~~ lease arrangement are set in advance, are consistent with fair market value, and are not determined—

(i) In a manner that takes into account the volume or value of any referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(5) The ~~agreement~~ lease arrangement would be commercially reasonable even if no referrals were made between the parties.

(6) ~~A holdover month-to-month rental for up to 6 months immediately following the expiration of an agreement~~If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies ~~that met~~ the ~~conditions of~~ requirements of paragraph~~s~~ (b)~~(1) through (b)(5)~~ of this section ~~satisfies the requirements of paragraph (b) of this section, provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.~~ if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (b)(1) through (5) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding lease arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (b)(1) through (5) of this section.

(c) ***Bona fide employment relationships***. Any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

(3) The remuneration is provided under an ~~agreement~~ arrangement that would be commercially reasonable even if no referrals were made to the employer.

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(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(d) ***Personal service arrangements***. (1) General—Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member can "furnish" services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through locum tenens physicians (as defined at §411.351, except that the regular physician need not be a member of a group practice).

(iii) The aggregate services ~~contracted for~~covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The ~~term~~ duration of each arrangement is for at least 1 year. To meet this requirement, if an arrangement is terminated ~~during the term~~ with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original ~~term of the~~ arrangement.

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at §411.351 of this subpart), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(vi) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.

(vii) If the arrangement expires after a term of at least 1 year, ~~A~~a holdover ~~personal service~~ arrangement ~~for up to 6 months~~immediately following the expiration of ~~an agreement~~the arrangement satisfies the requirements ~~of at least 1 year that met the conditions~~ of paragraph (d) of this section ~~satisfies the requirements of paragraph (d) of this section, provided that the holdover personal service arrangement is on the same terms and conditions as the immediately preceding agreement.~~if the following conditions are met:

(A) The arrangement met the conditions of paragraphs (d)(1)(i) through (vi) of this section when the arrangement expired;

(B) The holdover arrangement is on the same terms and conditions as the immediately preceding arrangement; and

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(C) The holdover arrangement continues to satisfy the conditions of paragraphs (d)(1)(i) through (vi) of this section.

(2) Physician incentive plan exception. In the case of a physician incentive plan (as defined at §411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled with the entity.

(ii) Upon request of the Secretary, the entity provides the Secretary with access to information regarding the plan (including any downstream contractor plans), in order to permit the Secretary to determine whether the plan is in compliance with paragraph (d)(2) of this section.

(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as defined at §422.208, the entity or any downstream contractor (or both) complies with the requirements concerning physician incentive plans set forth in §422.208 and §422.210 of this chapter.

(e) ***Physician recruitment***. (1) Remuneration provided by a hospital to recruit a physician that is paid directly to the physician and that is intended to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by both parties;

(ii) The arrangement is not conditioned on the physician's referral of patients to the hospital;

(iii) The ~~hospital does not determine (directly or indirectly) the~~ amount of ~~the~~ remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly)~~to the physician based on~~ the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties; and

(iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment or services ~~contract~~ arrangement that complies with §411.354(d)(4)).

(2)(i) The "geographic area served by the hospital" is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. The geographic area served by the hospital may include one or more zip codes from which the hospital draws no inpatients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the hospital draws at least 75 percent of its inpatients.

(ii) With respect to a hospital that draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the "geographic area served by the hospital" will be deemed to be the area composed of all of the contiguous zip codes from which the hospital draws its inpatients.

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(iii) Special optional rule for rural hospitals. In the case of a hospital located in a rural area (as defined at §411.351), the "geographic area served by the hospital" may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the "geographic area served by the hospital" may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the hospital's inpatients resides, and continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients.

(iv) A physician will be considered to have relocated his or her medical practice if the medical practice was located outside the geographic area served by the hospital and—

(A) The physician moves his or her medical practice at least 25 miles and into the geographic area served by the hospital; or

(B) The physician moves his medical practice into the geographic area served by the hospital, and the physician's new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years, measured on an annual basis (fiscal or calendar year). For the initial "start up" year of the recruited physician's practice, the 75 percent test in the preceding sentence will be satisfied if there is a reasonable expectation that the recruited physician's medical practice for the year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years.

(3) The recruited physician will not be subject to the relocation requirement of this paragraph, provided that he or she establishes his or her medical practice in the geographic area served by the recruiting hospital, if—

(i) He or she is a resident or physician who has been in practice 1 year or less;

(ii) He or she was employed on a full-time basis for at least 2 years immediately prior to the recruitment arrangement by one of the following (and did not maintain a private practice in addition to such full-time employment):

(A) A Federal or State bureau of prisons (or similar entity operating one or more correctional facilities) to serve a prison population;

(B) The Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or

(C) A facility of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service; or

(iii) The Secretary has deemed in an advisory opinion issued under section 1877(g) of the Act that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.

(4) In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician practice, or directly to a physician who joins a

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physician practice, the following additional conditions must be met:

(i) The ~~written agreement~~writing in paragraph (e)(1) of this section is also signed by the physician practice.

(ii) Except for actual costs incurred by the physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.

(iii) In the case of an income guarantee of any type made by the hospital to a recruited physician who joins a physician practice, the costs allocated by the physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician. With respect to a physician recruited to join a physician practice located in a rural area or HPSA, if the physician is recruited to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, the costs allocated by the physician practice to the recruited physician do not exceed either—

(A) The actual additional incremental costs attributable to the recruited physician; or

(B) The lower of a per capita allocation or 20 percent of the practice's aggregate costs.

(iv) Records of the actual costs and the passed-through amounts are maintained for a period of at least ~~5~~6 years and made available to the Secretary upon request.

(v) The remuneration from the hospital under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.

(vi) The physician practice may not impose on the recruited physician practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital.

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

(5) Recruitment of a physician by a hospital located in a rural area (as defined at §411.351) to an area outside the geographic area served by the hospital is permitted under this exception if the Secretary determines in an advisory opinion issued under section 1877(g) of the Act that the area has a demonstrated need for the recruited physician and all other requirements of this paragraph (e) are met.

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(ii) The "**geographic area served**" by a federally qualified health center or a rural health clinic is the area composed of the lowest number of contiguous or noncontiguous zip codes from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center or rural health clinic may include one or more zip codes

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from which the federally qualified health center or rural health clinic draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients.

(f) ***Isolated transactions***. Isolated financial transactions, such as a one-time sale of property or a practice, if all of the following conditions are met:

(1) The amount of remuneration under the isolated transaction is—

(i) Consistent with the fair market value of the transaction; and

(ii) Not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician or other business generated between the parties.

(2) The remuneration is provided under an ~~agreement~~ arrangement that would be commercially reasonable even if the physician made no referrals to the entity.

(3) There are no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under the other provisions in §411.355 through §411.357 and except for commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician.

(g) ***Certain arrangements with hospitals***. Remuneration provided by a hospital to a physician if the remuneration does not relate, directly or indirectly, to the furnishing of DHS. To qualify as "unrelated," remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. Remuneration relates to the furnishing of DHS if it—

(1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles;

(2) Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or

(3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

(h) ***Group practice arrangements with a hospital***. An arrangement between a hospital and a group practice under which DHS are furnished by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services furnished to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before, and has continued in effect without interruption since, December 19, 1989.

(3) With respect to the DHS covered under the arrangement, at least 75 percent of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with a written agreement that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

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(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(i) ***Payments by a physician***. Payments made by a physician (or his or her immediate family member)—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for any other items or services that are furnished at a price that is consistent with fair market value, and that are not specifically excepted by another provision in §§411.355 through 411.357 (including, but not limited to, §411.357(l)). "**Services**" in this context means services of any kind (not merely those defined as "services" for purposes of the Medicare program in §400.202 of this chapter).

(j) ***Charitable donations by a physician***. Bona fide charitable donations made by a physician (or immediate family member) to an entity if all of the following conditions are satisfied:

(1) The charitable donation is made to an organization exempt from taxation under the Internal Revenue Code (or to a supporting organization);

(2) The donation is neither solicited, nor offered, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity; and

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

(k) ***Nonmonetary compensation***. (1) Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of $300 per calendar year, as adjusted for inflation in accordance with paragraph (k)(2) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(ii) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

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

(2) The annual aggregate nonmonetary compensation limit in this paragraph (k) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral Web site at: http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.

(3) Where an entity has inadvertently provided nonmonetary compensation to a

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physician in excess of the limit (as set forth in paragraph (k)(1) of this section), such compensation is deemed to be within the limit if—

(i) The value of the excess nonmonetary compensation is no more than 50 percent of the limit; and

(ii) The physician returns to the entity the excess nonmonetary compensation (or an amount equal to the value of the excess nonmonetary compensation) by the end of the calendar year in which the excess nonmonetary compensation was received or within 180 consecutive calendar days following the date the excess nonmonetary compensation was received by the physician, whichever is earlier.

(iii) Paragraph (k)(3) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) In addition to nonmonetary compensation up to the limit described in paragraph (k)(1) of this section, an entity that has a formal medical staff may provide one local medical staff appreciation event per year for the entire medical staff. Any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the limit in paragraph (k)(1).

(l) ***Fair market value compensation***. Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in §411.352) for the provision of items or services (other than the rental of office space) by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement ~~is set forth in an agreement that~~ meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in writing~~the agreement~~.

(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement ~~made for less than 1 year~~ may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

(3) The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of equipment may not be determined using a formula based on—

(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated through the use of the equipment; or

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(4) The arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.

(5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the

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Act), or any Federal or State law or regulation governing billing or claims submission.

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

(m) ***Medical staff incidental benefits***. Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) ~~without regard to~~and is not offered in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(2) Except with respect to identification of medical staff on a hospital ~~w~~Web- site or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital ~~w~~Web -site or in hospital advertising, meets the "on campus" requirement of this paragraph (m) ~~of this section~~.

(4) The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.

(5) 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). The $25 limit in this paragraph (m)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-I for the 12 month period and the new limits on the physician self-referral ~~web~~ Web site at~~:~~ http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.

(6) 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.

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

(8) Other facilities and health care clinics (including, but not limited to, federally qualified health centers) that have bona fide medical staffs may provide compensation under this paragraph (m) on the same terms and conditions applied to hospitals under this paragraph (m).

(n) ***Risk-sharing arrangements***. Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a MCO or an IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the

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arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. For purposes of this paragraph (n), "health plan" and "enrollees" have the meanings set forth in §1001.952(l) of this title.

(o) ***Compliance training***. Compliance training provided by an entity to a physician (or to the physician's immediate family member or office staff) who practices in the entity's local community or service area, provided that 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, or reporting); specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangements); or training regarding other Federal, State, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided. For purposes of this paragraph, "compliance training" includes programs that offer continuing medical education credit, provided that compliance training is the primary purpose of the program.

(p) ***Indirect compensation arrangements***. Indirect compensation arrangements, as defined at §411.354(c)(2), if all of the following conditions are satisfied:

(1)(i) 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 and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.

(ii) Compensation for the rental of office space or equipment may not be determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed ~~on~~ or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(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~~ writing~~ten 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 (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(q) ***Referral services***. Remuneration that meets all of the conditions set forth in §1001.952(f) of this title.

(r) ***Obstetrical malpractice insurance subsidies***. Remuneration that meets all of the conditions of paragraph (r)(1) or (2) of this section.

(1) Remuneration that meets all of the conditions set forth in §1001.952(o) of this title.

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(2) A payment from a hospital, federally qualified health center, or rural health clinic that is used to pay for some or all of the costs of malpractice insurance premiums for a physician who engages in obstetrical practice as a routine part of his or her medical practice, if all of the following conditions are met:

(i)(A) The physician's medical practice is located in a rural area, a primary care HPSA, or an area with demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician's obstetrical patients reside in a medically underserved area or are members of a medically underserved population.

(ii) The arrangement is set out in writing, is signed by the physician and the hospital, federally qualified health center, or rural health clinic providing the payment, and specifies the payment to be made by the hospital, federally qualified health center, or rural health clinic and the terms under which the payment is to be provided.

(iii) The arrangement is not conditioned on the physician's referral of patients to the hospital, federally qualified health center, or rural health clinic providing the payment.

(iv) The hospital, federally qualified health center, or rural health clinic does not determine ~~(directly or indirectly)~~ the amount of the payment in a manner that takes into account (directly or indirectly) ~~based on~~ the volume or value of any actual or anticipated referrals by the physician or any other business generated between the parties.

(v) The physician is allowed to establish staff privileges at any hospital(s), federally qualified health center(s), or rural health clinic(s) and to refer business to any other entities (except as referrals may be restricted under an employment arrangement or services ~~contract~~ arrangement that complies with §411.354(d)(4)).

(vi) The payment is made to a person or organization (other than the physician) that is providing malpractice insurance (including a self-funded organization).

(vii) The physician treats obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(viii) The insurance is a bona fide malpractice insurance policy or program, and the premium, if any, is calculated based on a bona fide assessment of the liability risk covered under the insurance.

(ix)(A) For each coverage period (not to exceed 1 year), at least 75 percent of the physician's obstetrical patients treated under the coverage of the obstetrical malpractice insurance during the prior period (not to exceed 1 year)—

(1) Resided in a rural area, HPSA, medically underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(2) Were part of a medically underserved population.

(B) For the initial coverage period (not to exceed 1 year), the requirements of paragraph (r)(2)(ix)(A) of this section will be satisfied if the physician certifies that he or she has a reasonable expectation that at least 75 percent of the physician's obstetrical

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patients treated under the coverage of the malpractice insurance will—

(1) Reside in a rural area, HPSA, medically underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(2) Be part of a medically underserved population.

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

(3) For purposes of paragraph (r)(2) of this section**, costs of malpractice insurance premiums** means:

(i) For physicians who engage in obstetrical practice on a full-time basis, any costs attributable to malpractice insurance; or

(ii) For physicians who engage in obstetrical practice on a part-time or sporadic basis, the costs attributable exclusively to the obstetrical portion of the physician's malpractice insurance, and related exclusively to obstetrical services provided—

(A) In a rural area, primary care HPSA, or an area with demonstrated need for the physician's obstetrical services, as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) In any area, provided that at least 75 percent of the physician's obstetrical patients treated in the coverage period (not to exceed 1 year) resided in a medically underserved area or were part of a medically underserved population.

(s) ***Professional courtesy***. Professional courtesy (as defined at §411.351) offered by an entity with a formal medical staff to a physician or a physician's immediate family member or office staff if all of the following conditions are met:

(1) The professional courtesy is offered to all physicians on the entity's bona fide medical staff or in such entity's local community or service area, and the offer does not take into account~~without regard to~~ the volume or value of referrals or other business generated between the parties;

(2) The health care items and services provided are of a type routinely provided by the entity;

(3) The entity has a professional courtesy policy that is set out in writing and approved in advance by the entity's governing body;

(4) The professional courtesy is not offered to a physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need; and

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

(t) ***Retention payments in underserved areas***—
(1) **Bona fide written offer**. Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician has a bona fide firm, written recruitment offer or offer of

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employment from a hospital, academic medical center (as defined at §411.355(e)), or physician organization (as defined at §411.351) that is not related to the hospital making the payment, and the offer specifies the remuneration being offered and requires the physician to move the location of his or her medical practice at least 25 miles and outside of the geographic area served by the hospital making the retention payment.

(ii) The requirements of §411.357(e)(1)(i) through §411.357(e)(1)(iv) are satisfied.

(iii) Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the written recruitment offer or offer of employment.

(iv) The retention payment does not exceed the lower of—

(A) The amount obtained by subtracting the physician's current income from physician and related services from the income the physician would receive from comparable physician and related services in the written recruitment or employment offer, provided that the respective incomes are determined using a reasonable and consistent methodology, and that they are calculated uniformly over no more than a 24-month period; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) are satisfied.

(2) **Written certification from physician**. Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician furnishes to the hospital before the retention payment is made a written certification that the physician has a bona fide opportunity for future employment by a hospital, academic medical center (as defined at §411.355(e)), or physician organization (as defined at §411.351) that requires the physician to move the location of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The certification contains at least the following—

(A) Details regarding the steps taken by the physician to effectuate the employment opportunity;

(B) Details of the physician's employment opportunity, including the identity and location of the physician's future employer or employment location or both, and the anticipated income and benefits (or a range for income and benefits);

(C) A statement that the future employer is not related to the hospital making the payment;

(D) The date on which the physician anticipates relocating his or her medical practice outside of the geographic area served by the hospital; and

(E) Information sufficient for the hospital to verify the information included in the written certification.

(ii) The hospital takes reasonable steps to verify that the physician has a

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bona fide opportunity for future employment that requires the physician to relocate outside the geographic area served by the hospital.

(iii) The requirements of §411.357(e)(1)(i) through §411.357(e)(1)(iv) are satisfied.

(iv) The retention payment does not exceed the lower of—

(A) An amount equal to 25 percent of the physician's current annual income (~~measured over no more than~~ averaged over the previous 24 months~~ period~~), using a reasonable and consistent methodology that is calculated uniformly; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) are satisfied.

(3) Remuneration provided under paragraph (t)(1) or (t)(2) must meet the following additional requirements:

(i)(A) The physician's current medical practice is located in a rural area or HPSA (regardless of the physician's specialty) or is located in an area with demonstrated need for the physician as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician's patients reside in a medically underserved area or are members of a medically underserved population.

(ii) The hospital does not enter into a retention arrangement with a particular referring physician more frequently than once every 5 years.

(iii) The amount and terms of the retention payment are not altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician.

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

(4) The Secretary may waive the relocation requirement of paragraphs (t)(1) and (t)(2) of this section for payments made to physicians practicing in a HPSA or an area with demonstrated need for the physician through an advisory opinion issued in accordance with section 1877(g)(6) of the Act, if the retention payment arrangement otherwise complies with all of the conditions of this paragraph.

(5) This paragraph (t) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(u) ***Community-wide health information systems***. Items or services of information technology provided by an entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health, provided that—

(1) The items or services are available as necessary to enable the physician to participate in a community-wide health information system, are

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principally used by the physician as part of the community-wide health information system, and are not provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician;

(2) The community-wide health information systems are available to all providers, practitioners, and residents of the community who desire to participate; and

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

(v) ***Electronic prescribing items and services.*** Nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to a physician who is a member of its medical staff;

(ii) Group practice (as defined at §411.352) to a physician who is a member of the group (as defined at §411.351); or

(iii) PDP sponsor or MA organization to a prescribing physician.

(2) The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.

(4) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided and the donor's cost of the items and services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

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(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(w) ***Electronic health records items and services.*** Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records, if all of the following conditions are met:

(1) The items and services are provided to a physician by an entity (as defined at §411.351) that is not a laboratory company.

(2) The software is interoperable (as defined in §411.351) at the time it is provided to the physician. For purposes of this paragraph, software is deemed to be interoperable if, on the date it is provided to the physician, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services).

(4) Before receipt of the items and services, the physician pays 15 percent of the donor's cost for the items and services. The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph, the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

(i) The determination is based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);

(ii) The determination is based on the size of the physician's medical practice (for example, total patients, total patient encounters, or total relative value units);

(iii) The determination is based on the total number of hours that the physician practices medicine;

(iv) The determination is based on the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

(v) The determination is based on whether the physician is a member of the

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donor's medical staff, if the donor has a formal medical staff;

(vi) The determination is based on the level of uncompensated care provided by the physician; or

(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided, the donor's cost of the items and services, and the amount of the physician's contribution; and

(iii) Covers all of the electronic health records items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(9) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(10) The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice.

(11) [Reserved]

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

(13) The transfer of the items or services occurs and all conditions in this paragraph (w) are satisfied on or before December 31, 2021.

(x) ***Assistance to compensate a nonphysician practitioner***. (1) Remuneration provided by a hospital to a physician to compensate a nonphysician practitioner to provide patient care services, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner.

(ii) The arrangement is not conditioned on—

(A) The physician's referrals to the hospital; or

(B) The nonphysician practitioner's referrals to the hospital.

(iii) The remuneration from the hospital—

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(A) Does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); and

(B) Is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by—

(1) The physician (or any physician in the physician's practice) or other business generated between the parties; or

(2) The nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.

(iv) The compensation, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the patient care services furnished by the nonphysician practitioner to patients of the physician's practice.

(v) The nonphysician practitioner has not, within 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under §411.354(c))—

(A) Practiced in the geographic area served by the hospital; or

(B) Been employed or otherwise engaged to provide patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished services at the medical practice site located in the geographic area served by the hospital.

(vi)(A) The nonphysician practitioner has a compensation arrangement with the physician or the physician organization in whose shoes the physician stands under §411.354(c); and

(B) Substantially all of the services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services.

(vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide patient care services in the geographic area served by the hospital.

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

(2) Records of the actual amount of remuneration provided under paragraph (x)(1) of this section by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(3) For purposes of this paragraph (x), "nonphysician practitioner" means a physician assistant as defined in section 1861(aa)(5) of the Act, a nurse practitioner or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, a certified nurse-midwife as defined in section 1861(gg) of the Act, a clinical social worker as defined in section 1861(hh) of the Act,

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or a clinical psychologist as defined in §410.71(d) of this subchapter.

(4) For purposes of paragraphs (x)(1)(ii)(B) and (x)(1)(iii)(B)(2) of this section, "referral" means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the nonphysician practitioner.

(5) For purposes of paragraph (x)(1) of this section, "geographic area served by the hospital" has the meaning set forth in paragraph (e)(2) of this section.

(6) For purposes of paragraph (x)(1) of this section, a "compensation arrangement" between a physician (or the physician organization in whose shoes the physician stands under §411.354(c) and a nonphysician practitioner—

(i) Means an employment, contractual, or other arrangement under which remuneration passes between the parties; and

(ii) Does not include a nonphysician practitioner's ownership or investment interest in a physician organization.

(7)(i) This paragraph (x) may be used by a hospital, federally qualified health center, or rural health clinic only once every 3 years with respect to the same referring physician.

(ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, or rural health clinic to a physician to compensate a nonphysician practitioner to provide patient care services if—

(A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide patient care services with the physician (or the physician organization in whose shoes the physician stands) within 1 year of the commencement of the employment or contractual arrangement; and

(B) The remuneration provided to the physician is provided during a period that does not exceed 2 consecutive years as measured from the commencement of the compensation arrangement between the nonphysician practitioner who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

(8)(i) This paragraph (x) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(ii) The "**geographic area served**" by a federally qualified health center or a rural health clinic has the meaning set forth in paragraph (e)(6)(ii) of this section.

(y) ***Timeshare arrangements***. Remuneration provided under an arrangement for the use of premises, equipment, personnel, items, supplies, or services if the following conditions are met:

(1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement.

(2) The arrangement is between a physician (or the physician organization in whose

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shoes the physician stands under §411.354(c) and—

(i) A hospital; or

(ii) Physician organization of which the physician is not an owner, employee, or contractor.

(3) The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used—

(i) Predominantly for the provision of evaluation and management services to patients; and

(ii) On the same schedule.

(4) The equipment covered by the arrangement is—

(i) Located in the same building where the evaluation and management services are furnished;

(ii) Not used to furnish designated health services other than those incidental to the evaluation and management services furnished at the time of the patient's evaluation and management visit; and

(iii) Not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).

(5) The arrangement is not conditioned on the referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.

(6) The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined—

(i) In a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(7) The arrangement would be commercially reasonable even if no referrals were made between the parties.

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

(9) The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

[72 FR 51091, Sept. 5, 2007; 72 FR 68076, Dec. 4, 2007, as amended at 73 FR 48752, Aug. 19, 2008; 73 FR 57543, Oct. 3, 2008; 78 FR 78768, Dec. 27, 2013]

§411.361 Reporting requirements.

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

(b) ***Exception***. The requirements of paragraph (a) of this section do not apply to entities that furnish 20 or fewer Part A and Part B services during a calendar year, or to any Medicare covered services furnished outside the United States.

(c) ***Required information***. The information requested by CMS or OIG can include the following:

(1) The name and unique physician identification number (UPIN) or the national provider identifier (NPI) of each physician who has a reportable financial relationship with the entity.

(2) The name and UPIN or NPI of each physician who has an immediate family member (as defined at §411.351) who has a reportable financial relationship with the entity.

(3) The covered services furnished by the entity.

(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 or value of the ownership or investment interest or the compensation arrangement) as evidenced in records that the entity knows or should know about in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain to comply with the rules of the Internal Revenue Service and the Securities and Exchange Commission and other rules of the Medicare and Medicaid programs.

(d) ***Reportable financial relationships***. For purposes of this section, a reportable financial relationship is any ownership or investment interest, as defined at §411.354(b) or any compensation arrangement, as defined at §411.354(c), except for ownership or investment interests that satisfy the exceptions set forth in §411.356(a) or §411.356(b) regarding publicly-traded securities and mutual funds.

(e) ***Form and timing of reports***. Entities that are subject to the requirements of this section must submit the required information, upon request, within the time period specified by the request. Entities are given at least 30 days from the date of the request to provide the information. Entities must retain the information, and documentation sufficient to verify the information, for the length of time specified by the applicable regulatory requirements for the information, and, upon request, must make that information and documentation available to CMS or 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 following the 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 or OIG under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

[72 FR 51098, Sept. 5, 2007]

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§411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) ***Definitions***. For purposes of this section—

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement).

External data source means a data source that—

(1) Is generated, maintained, or under the control of a State Medicaid agency;

(2) Is reliable and transparent;

(3) Maintains data that, for purposes of the process described in paragraph (c) of this section, are readily available and accessible to the requesting hospital, comparison hospitals, and CMS; and

(4) Maintains or generates data that, for purposes of the process described in paragraph (c) of this section, are accurate, complete, and objectively verifiable.

Main campus of the hospital means "campus" as defined at §413.65(a)(2).

Ownership or **investment interest** means for purposes of this section, a direct or indirect ownership or investment interest in a hospital.

(1) A direct ownership or investment interest in a hospital exists if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor.

(2) An indirect ownership or investment interest in a hospital exists if—

(i) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(ii) The hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital.

(3) An indirect ownership or investment interest in a hospital exists even though the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

Physician owner or investor means a physician (or immediate family member of the physician) with a direct or an indirect ownership or investment interest in the hospital.

Procedure room means a room in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include an emergency room or department (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).

Public advertising for the hospital means any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital.

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(b) ***General requirements***. (1) **Physician ownership and provider agreement**. The hospital had physician ownership or investment on December 31, 2010; and a provider agreement under section 1866 of the Act in effect on that date.

(2) **Prohibition on facility expansion**. The hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital is licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless an exception is granted pursuant to paragraph (c) of this section.

(3) **Disclosure of conflicts of interest**. (i) At such time and in such manner as specified by CMS, the hospital must submit an annual report to CMS containing a detailed description of the identity of each owner or investor in the hospital and the nature and extent of all ownership and investment interests in the hospital.

(ii) The hospital must—

(A) Require each referring physician owner or investor who is a member of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to provide written disclosure of his or her ownership or investment interest in the hospital (and, if applicable, the ownership or investment interest of any treating physician) to all patients whom the physician refers to the hospital. Disclosure must be required by a time that permits the patient to make a meaningful decision regarding the receipt of care.

(B) Not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

(C) Disclose on any public Web site for the hospital and in any public advertising for the hospital that the hospital is owned or invested in by physicians. Any language that would put a reasonable person on notice that the hospital may be physician-owned would be deemed a sufficient statement of physician ownership or investment. For purposes of this section, a public Web site for the hospital does not include, by way of example: social media Web sites; electronic patient payment portals; electronic patient care portals; and electronic health information exchanges.

(4) **Ensuring bona fide investment**. The hospital satisfies the following criteria:

(i) The percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate does not exceed such percentage as of March 23, 2010.

(ii) Any ownership or investment interests that the hospital offers to a physician owner or investor are not offered on more favorable terms than the terms offered to a person who is not a physician owner or investor.

(iii) The hospital (or any owner or investor in the hospital) does not directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor.

(iv) The hospital (or any owner or investor in the hospital) does not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any individual physician owner or investor or group of physician owners or investors that is

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related to acquiring any ownership or investment interest in the hospital.

(v) Ownership or investment returns are distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital.

(vi) Physician owners and investors do not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.

(vii) The hospital does not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to an individual who is not a physician owner or investor.

(5) **Patient safety**. The hospital satisfies the following criteria:

(i) If the hospital does not have a physician available on the premises to provide services during all hours in which the hospital is providing services to the patient, the hospital must disclose this information to the patient. Before providing services to the patient, the hospital must receive a signed acknowledgment from the patient stating that the patient understands that a physician may not be present during all hours services are furnished to the patient.

(ii) The hospital must have the capacity to provide assessment and initial treatment for all patients, and the ability to refer and transfer patients to hospitals with the capability to treat the needs of the patient that the hospital is unable to address. For purposes of this paragraph, the hospital inpatient stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or an outpatient service.

(6) **Prohibition on conversion from an ambulatory surgery center**. The hospital must not have been converted from an ambulatory surgical center to a hospital on or after March 23, 2010.

(c) ***Criteria for an individual hospital seeking an exception to the prohibition on facility expansion***—(1) **General**. An applicable hospital or high Medicaid facility may request an exception from the prohibition on facility expansion up to once every 2 years from the date of a CMS decision on the hospital's most recent request.

(2) **Criteria for applicable hospital**. An applicable hospital is a hospital that satisfies all of the following criteria:

(i) **Population increase**. Is located in a county that has a percentage increase in population that is at least 150 percent of the percentage increase in population of the State in which the hospital is located during the most recent 5-year period for which data are available as of the date that the hospital submits its request. To calculate State and county population growth, a hospital must use Bureau of the Census estimates.

(ii) **Medicaid inpatient admissions**. Has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located during the most recent 12-month period

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for which data are available as of the date that the hospital submits its request. For purposes of this paragraph, the most recent **12-month period for which data are available** means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each hospital located in the same county as the requesting hospital.

(A) Until such time that the Healthcare Cost Report Information System (HCRIS) contains sufficiently complete inpatient Medicaid discharge data, a hospital may use filed Medicare hospital cost report data or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located.

(B) On or after such date that the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data, a hospital may use only filed Medicare hospital cost report data to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located.

(iii) **Nondiscrimination**. Does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(iv) **Average bed capacity**. Is located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine a State's average bed capacity and the national average bed capacity. CMS will provide on its Web site State average bed capacities and the national average bed capacity. For purposes of this paragraph (c)(2)(iv), "**sufficient number**" means the number of hospitals, as determined by CMS~~,~~ that would ensure that the determination under this paragraph (c)(2)(iv) would not materially change after additional hospital data are reported.

(v) **Average bed occupancy**. Has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate. A hospital must use filed hospital cost report data to determine its average bed occupancy rate. CMS will provide on its Web site State average bed occupancy rates. For purposes of this paragraph (c)(2)(v), "**sufficient number**" means the number of hospitals, as determined by CMS~~,~~ that would ensure that the determination under this paragraph (c)(2)(v) would not materially change after additional hospital data are reported.

(3) **Criteria for high Medicaid facility**. A high Medicaid facility is a hospital that satisfies all of the following criteria:

(i) **Sole hospital**. Is not the sole hospital in the county in which the hospital is located.

(ii) **Medicaid inpatient admissions**. With respect to each of the 3 most recent 12-month periods for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such

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admissions for any other hospital located in the county in which the hospital is located. For purposes of this paragraph, **the most recent 12-month period for which data are available** means the most recent 12-month period for which the data source used contains all data from the requesting hospital and every hospital located in the same county as the requesting hospital.

(A) Until such time that the Healthcare Cost Report Information System (HCRIS) contains sufficiently complete inpatient Medicaid discharge data, a hospital may use filed Medicare hospital cost report data or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located.

(B) On or after such date that the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data, a hospital may use only filed Medicare hospital cost report data to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located.

(iii) **Nondiscrimination**. Does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(4) **Procedure for submitting a request**.

(i) A hospital must either mail an original and one copy of the written request to CMS or submit the request electronically to CMS. If a hospital submits the request electronically, the hospital must mail an original hard copy of the signed certification set forth in paragraph (c)(4)(iii) of this section to CMS.

(ii) A request must include the following information:

(A) The name, address, National Provider Identification number(s) (NPI), Tax Identification Number(s) (TIN), and CMS Certification Number(s) (CCN) of the hospital requesting an exception.

(B) The county in which the hospital requesting an exception is located.

(C) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the hospital.

(D) A statement identifying the hospital as an applicable hospital or high Medicaid facility and a detailed explanation with supporting documentation regarding whether and how the hospital satisfies each of the criteria for an applicable hospital or high Medicaid facility. The request must state that the hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(E) Documentation supporting the hospital's calculations of its baseline number of operating rooms, procedure rooms, and beds; the hospital's number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits a request for an exception; and the additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

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(iii) A request must include the following certification signed by an authorized representative of the hospital: "With knowledge of the penalties for false statements provided by 18 U.S.C. 1001, I certify that all of the information provided in the request and all of the documentation provided with the request is true and correct to the best of my knowledge and belief." An authorized representative is the chief executive officer, chief financial officer, or other comparable officer of the hospital.

(5) **Community input and timing of complete request**. Upon submitting a request for an exception and until the hospital receives a CMS decision, the hospital must disclose on any public Web site for the hospital that it is requesting an exception and must also provide actual notification that it is requesting an exception, in either electronic or hard copy form, directly to hospitals whose data are part of the comparisons in paragraphs (c)(2)(ii) and (c)(3)(ii) of this section. Individuals and entities in the hospital's community may provide input with respect to the hospital's request no later than 30 days after CMS publishes notice of the hospital's request in the Federal Register. Such input must take the form of written comments. The written comments must be either mailed or submitted electronically to CMS. If CMS receives written comments from the community, the hospital has 30 days after CMS notifies the hospital of the written comments to submit a rebuttal statement.

(i) If only filed Medicare hospital cost report data are used in the hospital's request, the written comments, and the hospital's rebuttal statement—

(A) A request will be deemed complete at the end of the 30-day comment period if CMS does not receive written comments from the community.

(B) A request will be deemed complete at the end of the 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(ii) If data from an external data source are used in the hospital's request, the written comments, or the hospital's rebuttal statement—

(A) A request will be deemed complete no later than 180 days after the end of the 30-day comment period if CMS does not receive written comments from the community.

(B) A request will be deemed complete no later than 180 days after the end of the 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(6) **A permitted increase under this section**—

(i) May not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and

(ii) May occur only in facilities on the hospital's main campus.

(7) **Publication of final decisions**. Not later than 60 days after receiving a complete request, CMS will publish the final decision in the Federal Register.

(8) **Limitation on review**. There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the process under this section (including the establishment of such process).

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[75 FR 72260, Nov. 24, 2010, as amended at 76 FR 74581, Nov. 30, 2011; 79 FR 67029, Nov. 10, 2014]

§411.370 Advisory opinions relating to physician referrals.

(a) ***Period during which CMS accepts requests***. The provisions of §411.370 through §411.389 apply to requests for advisory opinions that are submitted to CMS during any time period in which CMS is required by law to issue the advisory opinions described in this subpart.

(b) ***Matters that qualify for advisory opinions and who may request one***. Any individual or entity may request a written advisory opinion from CMS concerning whether a physician's referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. In the advisory opinion, CMS determines whether a business arrangement described by the parties to that arrangement appears to constitute a "financial relationship" (as defined in section 1877(a)(2) of the Act) that could potentially restrict a physician's referrals, and whether the arrangement or the designated health services at issue appear to qualify for any of the exceptions to the referral prohibition described in section 1877 of the Act.

(1) The request must involve an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. CMS does not consider, for purposes of an advisory opinion, requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties.

(2) The requestor must be a party to the existing or proposed arrangement.

(c) Matters not subject to advisory opinions. CMS does not address through the advisory opinion process—

(1) Whether the fair market value was, or will be, paid or received for any goods, services, or property; and

(2) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

(d) ***Facts subject to advisory opinions***. CMS considers requests for advisory opinions that involve applying specific facts to the subject matter described in paragraph (b) of this section. Requestors must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in §411.372.

(e) ***Requests that will not be accepted***. CMS does not accept an advisory opinion request or issue an advisory opinion if—

(1) The request is not related to a named individual or entity;

(2) CMS is aware that the same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(3) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry.

(f) ***Effects of an advisory opinion on other Governmental authority***. Nothing in this part

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limits the investigatory or prosecutorial authority of the OIG, the Department of Justice, or any other agency of the Government. In addition, in connection with any request for an advisory opinion, CMS, the OIG, or the Department of Justice may conduct whatever independent investigation it believes appropriate.

[69 FR 57227, Sept. 24, 2004, as amended at 72 FR 51098, Sept. 5, 2007]

§411.372 Procedure for submitting a request.

(a) ***Format for a request***. A party or parties must submit a request for an advisory opinion to CMS in writing, including an original request and 2 copies. The request must be addressed to: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Office of Financial Management, Division of Premium Billing and Collections, Mail Stop C3-09-27, Attention: Advisory Opinions, 7500 Security Boulevard, Baltimore, MD 21244-1850.

(b) ***Information CMS requires with all submissions***. The request must include the following:

(1) The name, address, telephone number, and Taxpayer Identification Number of the requestor.

(2) The names and addresses, to the extent known, of all other actual and potential parties to the arrangement that is the subject of the request.

(3) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the requestor.

(4) A complete and specific description of all relevant information bearing on the arrangement, including—

(i) A complete description of the arrangement that the requestor is undertaking, or plans to undertake, including: the purpose of the arrangement; the nature of each party's (including each entity's) contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement (or their immediate family members who are involved) and any entities that provide designated health services; the types of services for which a physician wishes to refer, and whether the referrals will involve Medicare or Medicaid patients;

(ii) Complete copies of all relevant documents or relevant portions of documents that affect or could affect the arrangement, such as personal services or employment contracts, leases, deeds, pension or insurance plans, financial statements, or stock certificates (or, if these relevant documents do not yet exist, a complete description, to the best of the requestor's knowledge, of what these documents are likely to contain);

(iii) Detailed statements of all collateral or oral understandings, if any; and

(iv) Descriptions of any other arrangements or relationships that could affect CMS's analysis.

(5) Complete information on the identity of all entities involved either directly or indirectly in the arrangement, including their names, addresses, legal form, ownership structure, nature of the business (products and services) and, if relevant, their Medicare and Medicaid provider numbers. The requestor must also include a brief description of any other entities that could affect the outcome of the

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opinion, including those with which the requestor, the other parties, or the immediate family members of involved physicians, have any financial relationships (either direct or indirect, and as defined in section 1877(a)(2) of the Act and §411.351), or in which any of the parties holds an ownership or control interest as defined in section 1124(a)(3) of the Act.

(6) A discussion of the specific issues or questions the requestor would like CMS to address including, if possible, a description of why the requestor believes the referral prohibition in section 1877 of the Act might or might not be triggered by the arrangement and which, if any, exceptions to the prohibition the requestor believes might apply. The requestor should attempt to designate which facts are relevant to each issue or question raised in the request and should cite the provisions of law under which each issue or question arises.

(7) An indication of whether the parties involved in the request have also asked for or are planning to ask for an advisory opinion on the arrangement in question from the OIG under section 1128D(b) of the Act (42 U.S.C. 1320a-7d(b)) and whether the arrangement is or is not, to the best of the requestor's knowledge, the subject of an investigation.

(8) The certification(s) described in §411.373. The certification(s) must be signed by—

(i) The requestor, if the requestor is an individual;

(ii) The chief executive officer, or comparable officer, of the requestor, if the requestor is a corporation;

(iii) The managing partner of the requestor, if the requestor is a partnership; or

(iv) A managing member, if the requestor is a limited liability company.

(9) A check or money order payable to CMS in the amount described in §411.375(a).

(c) ***Additional information CMS might require.*** If the request does not contain all of the information required by paragraph (b) of this section, or, if either before or after accepting the request, CMS believes it needs more information in order to render an advisory opinion, it may request whatever additional information or documents it deems necessary. Additional information must be provided in writing, signed by the same person who signed the initial request (or by an individual in a comparable position), and be certified as described in §411.373.

[69 FR 57227, Sept. 24, 2004]

§411.373 Certification.

(a) Every request must include the following signed certification: "With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief."

(b) If the advisory opinion relates to a proposed arrangement, in addition to the certification required by paragraph (a) of this section, the following certification must be included and signed by the requestor: "The arrangement described in this request for an advisory opinion is one into which [the requestor], in good faith, plans to enter." This statement may be made contingent on a favorable advisory opinion, in

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which case the requestor should add one of the following phrases to the certification:

(1) "if CMS issues a favorable advisory opinion."

(2) "if CMS and the OIG issue favorable advisory opinions."

[69 FR 57227, Sept. 24, 2004]

§411.375 Fees for the cost of advisory opinions.

(a) ***Initial payment***. Parties must include with each request for an advisory opinion submitted through December 31, 1998, a check or money order payable to CMS for $250. For requests submitted after this date, parties must include a check or money order in this amount, unless CMS has revised the amount of the initial fee in a program issuance, in which case, the requestor must include the revised amount. This initial payment is nonrefundable.

(b) ***How costs are calculated***. Before issuing the advisory opinion, CMS calculates the costs the Department has incurred in responding to the request. The calculation includes the costs of salaries, benefits, and overhead for analysts, attorneys, and others who have worked on the request, as well as administrative and supervisory support for these individuals.

(c) ***Agreement to pay all costs***. (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (c)(3) of this section, to pay all costs the Department incurs in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If CMS estimates that the costs of processing the advisory opinion request have reached or are likely to exceed the designated triggering dollar amount, CMS notifies the requestor.

(3) If CMS notifies the requestor that the actual or estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, CMS stops processing the request until the requestor makes a written request for CMS to continue. If CMS is delayed in processing the request for an advisory opinion because of this procedure, the time within which CMS must issue an advisory opinion is suspended until the requestor asks CMS to continue working on the request.

(4) If the requestor chooses not to pay for CMS to complete an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs CMS has identified as costs it incurred in processing the request for an advisory opinion, up to that point.

(5) If the costs CMS has incurred in responding to the request are greater than the amount the requestor has paid, CMS, before issuing the advisory opinion, notifies the requestor of any additional amount that is due. CMS does not issue an advisory opinion until the requestor has paid the full amount that is owed. Once the requestor has paid CMS the total amount due for the costs of processing the request, CMS issues the advisory opinion. The time period CMS has for issuing advisory opinions is suspended from the time CMS notifies the requestor of the amount owed until the time CMS receives full payment.

(d) ***Fees for outside experts***. (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in §411.377.

(2) The time period for issuing an advisory opinion is suspended from the time that

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CMS notifies the requestor that it needs an outside expert opinion until the time CMS receives that opinion.

[69 FR 57228, Sept. 24, 2004]

§411.377 Expert opinions from outside sources.

(a) CMS may request expert advice from qualified sources if CMS believes that the advice is necessary to respond to a request for an advisory opinion. For example, CMS may require the use of accountants or business experts to assess the structure of a complex business arrangement or to ascertain a physician's or immediate family member's financial relationship with entities that provide designated health services.

(b) If CMS determines that it needs to obtain expert advice in order to issue a requested advisory opinion, CMS notifies the requestor of that fact and provides the identity of the appropriate expert and an estimate of the costs of the expert advice. As indicated in §411.375(d), the requestor must pay the estimated cost of the expert advice.

(c) Once CMS has received payment for the estimated cost of the expert advice, CMS arranges for the expert to provide a prompt review of the issue or issues in question. CMS considers any additional expenses for the expert advice, beyond the estimated amount, as part of the costs CMS has incurred in responding to the request, and the responsibility of the requestor, as described in §411.375(c).

[69 FR 57229, Sept. 24, 2004]

§411.378 Withdrawing a request.

The party requesting an advisory opinion may withdraw the request before CMS issues a formal advisory opinion. This party must submit the withdrawal in writing to the same address as the request, as indicated in §411.372(a). Even if the party withdraws the request, the party must pay the costs the Department has expended in processing the request, as discussed in §411.375. CMS reserves the right to keep any request for an advisory opinion and any accompanying documents and information, and to use them for any governmental purposes permitted by law.

[69 FR 57229, Sept. 24, 2004]

§411.379 When CMS accepts a request.

(a) Upon receiving a request for an advisory opinion, CMS promptly makes an initial determination of whether the request includes all of the information it will need to process the request.

(b) Within 15 working days of receiving the request, CMS—

(1) Formally accepts the request for an advisory opinion;

(2) Notifies the requestor about the additional information it needs; or

(3) Declines to formally accept the request.

(c) If the requestor provides the additional information CMS has requested, or otherwise resubmits the request, CMS processes the resubmission in accordance with paragraphs (a) and (b) of this section as if it were an initial request for an advisory opinion.

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(d) Upon accepting the request, CMS notifies the requestor by regular U.S. mail of the date that CMS formally accepted the request.

(e) The 90-day period that CMS has to issue an advisory opinion set forth in §411.380(c) does not begin until CMS has formally accepted the request for an advisory opinion.

[69 FR 57229, Sept. 24, 2004]

§411.380 When CMS issues a formal advisory opinion.

(a) CMS considers an advisory opinion to be issued once it has received payment and once the opinion has been dated, numbered, and signed by an authorized CMS official.

(b) An advisory opinion contains a description of the material facts known to CMS that relate to the arrangement that is the subject of the advisory opinion, and states CMS's opinion about the subject matter of the request based on those facts. If necessary, CMS includes in the advisory opinion material facts that could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1095.

(c)(1) CMS 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 CMS 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 CMS'

(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 CMS receives written notice from the requestor to continue processing the request;

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

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

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

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

[69 FR 57229, Sept. 24, 2004]

§411.382 CMS's right to rescind advisory opinions.

Any advice CMS 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. CMS 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. CMS does not proceed against the requestor with respect to any action the requestor and the involved parties have taken in good faith reliance upon CMS's advice under this part, provided—

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

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

[69 FR 57229, Sept. 24, 2004]

§411.384 Disclosing advisory opinions and supporting information.

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

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

(c) Any predecisional document, or part of such predecisional document, that is prepared by CMS, 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 CMS 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 CMS's obligation, under applicable laws, to publicly disclose the identity of the requesting party or parties, and the nature of the action CMS has taken in response to the request.

[69 FR 57230, Sept. 24, 2004]

§411.386 CMS'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. 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 Parties affected by advisory opinions.

An advisory opinion issued by CMS 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.

[69 FR 57230, Sept. 24, 2004]

§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

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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 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]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 425, and 495

[CMS–1631–FC]

RIN 0938–AS40

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This major final rule with comment period addresses changes to the physician fee schedule, and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.

DATES: *Effective date:* The provisions of this final rule with comment period are effective on January 1, 2016, except the definition of ''ownership or investment interest'' in § 411.362(a), which has an effective date of January 1, 2017.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 29, 2015. (See the **SUPPLEMENTARY INFORMATION** section of this final rule with comment period for a list of provisions open for comment.)

ADDRESSES: In commenting, please refer to file code CMS–1631–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *www.regulations.gov*. Follow the instructions for ''submitting a comment.''

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1631–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1631–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT:

Donta Henson, (410) 786–1947 for issues related to pathology and ophthalmology services or any physician payment issues not identified below.

Abdihakin Abdi, (410) 786–4735, for issues related to portable X-ray transportation fees.

Gail Addis, (410) 786–4522, for issues related to the refinement panel.

Lindsey Baldwin, (410) 786–1694, for issues related to valuation of moderate sedation and colonoscopy services.

Jessica Bruton, (410) 786–5991, for issues related to potentially misvalued code lists.

Roberta Epps, (410) 786–4503, for issues related to PAMA section 218(a) policy.

Ken Marsalek, (410) 786–4502, for issues related to telehealth services.

Ann Marshall, (410) 786–3059, for issues related to advance care planning, and for primary care and care management services.

Geri Mondowney, (410) 786–4584, for issues related to geographic practice cost indices, malpractice RVUs, target, and phase-in provisions.

Chava Sheffield, (410) 786–2298, for issues related to the practice expense methodology, impacts, and conversion factor.

Michael Soracoe, (410) 786–6312, for issues related to the practice expense methodology and the valuation and coding of the global surgical packages.

Regina Walker-Wren, (410) 786–9160, for issues related to the ''incident to'' proposals.

Pamela West, (410) 786–2302, for issues related to therapy caps.

Emily Yoder, (410) 786–1804, for issues related to valuation of radiation treatment services.

Amy Gruber, (410) 786–1542, for issues related to ambulance payment policy.

Corinne Axelrod, (410) 786–5620, for issues related to rural health clinics or federally qualified health centers and payment to grandfathered tribal FQHCs.

Simone Dennis, (410) 786–8409, for issues related to rural health clinics HCPCS reporting.

Edmund Kasaitis (410) 786–0477, for issues related to Part B drugs, biologicals, and biosimilars.

Alesia Hovatter, (410) 786–6861, for issues related to Physician Compare.

Deborah Krauss, (410) 786–5264 and Alexandra Mugge, (410) 786–4457, for issues related to the physician quality reporting system and the merit-based incentive payment system.

Alexandra Mugge, (410) 786–4457, for issues related to EHR Incentive Program.

Sarah Arceo, (410) 786–2356 or Patrice Holtz, (410786–5663 for issues related to EHR Incentive Program-Comprehensive Primary Care (CPC) initiative and Medicare EHR Incentive Program aligned reporting.

Rabia Khan or Terri Postma, (410) 786–8084 or *ACO@cms.hhs.gov*, for issues related to Medicare Shared Savings Program.

Kimberly Spalding Bush, (410) 786–3232, or Sabrina Ahmed (410) 786–7499, for issues related to value-based Payment Modifier and Physician Feedback Program.

Frederick Grabau, (410) 786–0206, for issues related to changes to opt-out regulations.

Lisa Ohrin Wilson (410) 786–8852, or Matthew Edgar (410) 786–0698, for issues related to physician self-referral updates.

Christiane LaBonte, (410) 786–7234, for issues related to Comprehensive Primary Care (CPC) initiative.

JoAnna Baldwin (410) 786–7205, or Sarah Fulton (410) 786–2749, for issues

related to appropriate use criteria for advanced diagnostic imaging services.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Provisions open for comment: We will consider comments that are submitted as indicated above in the **DATES** and **ADDRESSES** sections on the following subject areas discussed in this final rule with comment period: Interim final work, practice expense (PE), and malpractice (MP) RVUs (including applicable work time, direct PE inputs, and MP crosswalks) for CY 2016; interim final new, revised, potentially misvalued HCPCS codes as indicated in the Preamble text and listed in Addendum C to this final rule with comment period; and the additions and deletions to the physician self-referral list of HCPCS/CPT codes found on tables 50 and 51.

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Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order below:

AAA Abdominal aortic aneurysms
ACO Accountable care organization
AMA American Medical Association
ASC Ambulatory surgical center
ATA American Telehealth Association
ATRA American Taxpayer Relief Act (Pub. L. 112–240)
AWV Annual wellness visit
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
CAD Coronary artery disease
CAH Critical access hospital
CBSA Core-Based Statistical Area
CCM Chronic care management
CEHRT Certified EHR technology
CF Conversion factor
CG–CAHPS Clinician and Group Consumer Assessment of Healthcare Providers and Systems
CLFS Clinical Laboratory Fee Schedule
CNM Certified nurse-midwife
CP Clinical psychologist
CPC Comprehensive Primary Care
CPEP Clinical Practice Expert Panel
CPT [Physicians] Current Procedural Terminology (*CPT codes, descriptions and other data only are copyright 2014 American Medical Association. All rights reserved.*)
CQM Clinical quality measure
CSW Clinical social worker
CT Computed tomography
CY Calendar year
DFAR Defense Federal Acquisition Regulations
DHS Designated health services
DM Diabetes mellitus
DSMT Diabetes self-management training
eCQM Electronic clinical quality measures
EHR Electronic health record
E/M Evaluation and management
EP Eligible professional
eRx Electronic prescribing
ESRD End-stage renal disease
FAR Federal Acquisition Regulations
FFS Fee-for-service
FQHC Federally qualified health center
FR Federal Register
GAF Geographic adjustment factor
GAO Government Accountability Office

GPCI Geographic practice cost index
GPO Group purchasing organization
GPRO Group practice reporting option
GTR Genetic Testing Registry
HCPCS Healthcare Common Procedure Coding System
HHS [Department of] Health and Human Services
HOPD Hospital outpatient department
HPSA Health professional shortage area
IDTF Independent diagnostic testing facility
IPPE Initial preventive physical exam
IPPS Inpatient Prospective Payment System
IQR Inpatient Quality Reporting
ISO Insurance service office
IT Information technology
IWPUT Intensity of work per unit of time
LCD Local coverage determination
MA Medicare Advantage
MAC Medicare Administrative Contractor
MAP Measure Applications Partnership
MAPCP Multi-payer Advanced Primary Care Practice
MAV Measure application validity [process]
MCP Monthly capitation payment
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MFP Multi-Factor Productivity
MIPPA Medicare Improvements for Patients and Providers Act (Pub. L. 110–275)
MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003)
MP Malpractice
MPPR Multiple procedure payment reduction
MRA Magnetic resonance angiography
MRI Magnetic resonance imaging
MSA Metropolitan Statistical Areas
MSPB Medicare Spending per Beneficiary
MU Meaningful use
NCD National coverage determination
NCQDIS National Coalition of Quality Diagnostic Imaging Services
NP Nurse practitioner
NPI National Provider Identifier
NPP Nonphysician practitioner
NQS National Quality Strategy
OACT CMS's Office of the Actuary
OBRA '89 Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239)
OBRA '90 Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508)
OES Occupational Employment Statistics
OMB Office of Management and Budget
OPPS Outpatient prospective payment system
OT Occupational therapy
PA Physician assistant
PAMA Protecting Access to Medicare Act of 2014 (Pub. L. 113–93)
PC Professional component
PCIP Primary Care Incentive Payment
PE Practice expense
PE/HR Practice expense per hour
PEAC Practice Expense Advisory Committee
PECOS Provider Enrollment, Chain, and Ownership System
PFS Physician Fee Schedule
PLI Professional Liability Insurance
PMA Premarket approval
PQRS Physician Quality Reporting System
PPIS Physician Practice Expense Information Survey
PT Physical therapy
PY Performance year
QCDR Qualified clinical data registry
QRUR Quality and Resources Use Report
RBRVS Resource-based relative value scale
RFA Regulatory Flexibility Act
RHC Rural health clinic
RIA Regulatory impact analysis
RUC American Medical Association/ Specialty Society Relative (Value) Update Committee
RUCA Rural Urban Commuting Area
RVU Relative value unit
SBA Small Business Administration
SGR Sustainable growth rate
SIM State Innovation Model
SLP Speech-language pathology
SMS Socioeconomic Monitoring System
SNF Skilled nursing facility
TAP Technical Advisory Panel
TC Technical component
TIN Tax identification number
UAF Update adjustment factor
UPIN Unique Physician Identification Number
USPSTF United States Preventive Services Task Force
VBP Value-based purchasing
VM Value-Based Payment Modifier

Addenda Available Only Through the Internet on the CMS Web Site

The PFS Addenda along with other supporting documents and tables referenced in this final rule with comment period are available through the Internet on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2016 PFS Final Rule with Comment Period, refer to item CMS–1631–FC. Readers who experience any problems accessing any of the Addenda or other documents referenced in this rule and posted on the CMS Web site identified above should contact Donta Henson at (410) 786–1947.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2015 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This major final rule with comment period revises payment polices under the Medicare Physician Fee Schedule (PFS) and makes other policy changes related to Medicare Part B payment. These changes are applicable to services furnished in CY 2016.

2. Summary of the Major Provisions

The Social Security Act (the Act) requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The Act requires that RVUs be established for three categories of resources: Work, practice expense (PE); and malpractice (MP) expense; and, that we establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major final rule with comment period, we establish RVUs for CY 2016 for the PFS, and other Medicare Part B payment policies, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. In addition, this final rule with comment period includes discussions and proposals regarding:

- Potentially Misvalued PFS Codes.
- Telehealth Services.
- Advance Care Planning.
- Establishing Values for New, Revised, and Misvalued Codes.
- Target for Relative Value Adjustments for Misvalued Services.
- Phase-in of Significant RVU Reductions.
- ''Incident to'' policy.
- Portable X-ray Transportation Fee.
- Updating the Ambulance Fee Schedule regulations.
- Changes in Geographic Area Delineations for Ambulance Payment.
- Chronic Care Management Services for RHCs and FQHCs.
- HCPCS Coding for RHCs.
- Payment to Grandfathered Tribal FQHCs that were Provider-Based Clinics on or before April 7, 2000.
- Payment for Biosimilars under Medicare Part B.
- Physician Compare Web site.
- Physician Quality Reporting System.
- Medicare Shared Savings Program.
- Electronic Health Record (EHR) Incentive Program.

Pages Intentionally Omitted

(Pages Not Relevant to Stark Law Redacted)

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process that must be followed to access the reports and would note that it is important to protect the information contained in the reports. These security measures are necessary to protect the data contained in the reports and ensure that only authorized users are able to access them. We have made strides to simplify the outreach around how to access the reports and would direct readers to the step-by-step instructions at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Obtain-2013-QRUR.html*. We also acknowledge that the QRUR reports could be perceived as complex. They contain a significant amount of valuable data to help physicians and other eligible professionals understand and improve the quality and efficiency of care they provide. We have added a performance dashboard to provide a visual snapshot and summary of performance to the beginning of the reports. We encourage all physician groups and solo practitioners to access their report and also encourage QRUR users to submit feedback to the PV helpdesk at 1–888–734–6433 (select option 3) or at *pvhelpdesk@cms.hhs.gov.* We have continued to engage our stakeholders and seek input on how best to refine the reports. We disagree that CMS does not provide adequate outreach about the VM. We conduct National Provider Calls in conjunction with each QRUR release, and we provide education and outreach documents that are accessible on our Web site related the VM, how to access the QRURs, and how to interpret the QRURs. We will continue to engage the stakeholder community to determine how best to educate about value-based payment programs.

b. Episode Costs and the Supplemental QRURs

Section 1848(n)(9)(A) of the Act requires CMS to develop an episode grouper and include episode-based costs in the QRURs. An episode of care consists of medical and/or procedural services that address a specific medical condition or procedure that are delivered to a patient within a defined time period and are captured by claims data. An episode grouper organizes administrative claims data into episodes.

In summer 2014, we distributed the Supplemental QRUR: Episodes of Care based on 2012 data to groups with 100 or more EPs. The 2012 Supplemental QRUR provided information on 20 episode subtypes and 6 clinical episode-based measures. In fall 2015, we provided the 2014 Supplemental QRURs to all groups and solo practitioners nationwide who billed for Medicare-covered services under a single TIN in 2014 and for whom we were able to calculate at least one episode measure. The supplemental QRURs are provided in addition to the Annual and Mid-Year QRURs. They provide information on performance on episode-based cost measures that are not included in the VM, to help groups and solo practitioners understand the cost of care they provide to beneficiaries and work toward the provision of more efficient care. The 2014 Supplemental QRURs included 26 major episode measures and 38 sub types of episodes and were made available to over 300,000 groups and solo practitioners. We will continue to seek stakeholder input as we develop the episode framework.

Lastly, we direct readers to the Physician Compare policies in this rule (section III.H. of this final rule with comment period), which did not finalize the proposal to add a green check mark to the profile page of the Physician Compare Web site for physicians and other eligible professionals receiving an upward adjustment under the VM starting in CY 2018. More information is available about Physician Compare on the CMS Web site at *http://www.medicare.gov/physiciancompare/search.html*.

N. Physician Self-Referral Updates

1. Background

a. Statutory and Regulatory History

Section 1877 of the Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. The statute establishes a number of specific exceptions, and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. Section 13624 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) (OBRA 1993), entitled ''Application of Medicare Rules Limiting Certain Physician Referrals,'' added a new paragraph (s) to section 1903 of the Act, to extend aspects of the physician self-referral prohibitions to Medicaid. For additional information about section 1903(s) of the Act, see 66 FR 857 through 858.

Several more recent statutory changes have also affected the physician self-referral law. Section 6001 of the Affordable Care Act amended section 1877 of the Act to impose additional requirements for physician-owned hospitals to qualify for the rural provider and hospital ownership exceptions. Section 6409 of the Affordable Care Act required the Secretary, in cooperation with the Inspector General of the Department of Health and Human Services, to establish a Medicare self-referral disclosure protocol (SRDP) that sets forth a process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral law.

This rulemaking follows a history of rulemakings related to the physician self-referral law. The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law. After the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all DHS) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule), and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was published in the **Federal Register** on January 4, 2001 (66 FR 856) as a final rule with comment period. The second final rulemaking (Phase II) was published in the **Federal Register** on March 26, 2004 (69 FR 16054) as an interim final rule with comment period. Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published on April 6, 2004 (69 FR 17933). The third final rulemaking (Phase III) was published in the **Federal Register** on September 5, 2007 (72 FR 51012) as a final rule.

In addition to Phase I, Phase II, and Phase III, we issued final regulations on August 19, 2008 in the ''Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates'' final rule with comment period (72 FR 48434) (the FY 2009 IPPS final rule). That rulemaking made various revisions to the physician self-referral regulations, including: (1) revisions to the ''stand in the shoes'' provisions; (2) establishment of provisions regarding the period of

disallowance and temporary noncompliance with signature requirements; (3) prohibitions on per-unit of service (''per-click'') and percentage-based compensation formulas for determining the rental charges for office space and equipment lease arrangements; and (4) expansion of the definition of ''entity.'' We are aware of the recent D.C. Circuit decision in *Council for Urological Interests v. Burwell,* 790 F.3d 212 (D.C. Cir. 2015), which addressed the prohibition on per-click equipment lease payments found in § 411.357(b)(4)(ii)(B). In accordance with that decision, the regulation has been remanded to the Secretary for further consideration. Accordingly, we are considering our options as to how to comply with the court's decision.

After passage of the Affordable Care Act, we issued final regulations on November 29, 2010 in the CY 2011 PFS final rule with comment period (75 FR 73170) that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception. We also issued final regulations on November 24, 2010 in the CY 2011 OPPS final rule with comment period (75 FR 71800), on November 30, 2011 in the CY 2012 OPPS final rule with comment period (76 FR 74122), and on November 10, 2014 in the CY 2015 OPPS final rule with comment period (79 FR 66770) that established or revised certain regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act.

b. Purpose of this Final Rule with Comment Period

This rule updates the physician self-referral regulations to accommodate delivery and payment system reform, to reduce burden, and to facilitate compliance. We have learned from stakeholder inquiries, review of relevant literature, and self-disclosures submitted to the SRDP that additional clarification of certain provisions of the physician self-referral law would be helpful. In addition to clarifying the regulations, we are also interested in expanding access to needed health care services. In keeping with those goals, the final rule with comment period expands the regulations to establish two new exceptions and clarifies certain regulatory terminology and requirements.

2. Recruitment and Retention (§ 411.357(e) and § 411.357(t))

In the proposed rule, we proposed to establish new policies and revise certain existing policies regarding recruitment assistance and retention payments. Specifically, we proposed a new exception for assistance to physicians to employ nonphysician practitioners (NPPs). In addition, we proposed to clarify for federally qualified health centers (FQHCs) and rural health clinics (RHCs) how to determine the geographic areas that they serve for the purposes of the exception at § 411.357(e) and to change the language at § 411.357(e)(1)(iii) to ensure the consistency we intend for the ''volume or value'' standard found throughout the statute and our regulations. We also proposed to lengthen the required record retention period at § 411.357(e)(4)(iv) from 5 years to 6 years to ensure consistency with the proposed exception at § 411.357(x) and other CMS record retention policies. For the exception for retention payments to physicians in underserved areas, we proposed to clarify how parties should calculate the maximum amount for permissible retention payments. Those proposals are described in detail below.

a. Assistance To Compensate a Nonphysician Practitioner

(1) Background

Section 1877(e)(5) of the Act sets forth an exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital to be a member of the hospital's medical staff, subject to certain requirements. This exception is codified at § 411.357(e). In Phase III, we declined to expand § 411.357(e) to cover the recruitment of NPPs into a hospital's service area, including into an existing group practice (72 FR 51049).

Significant changes in our health care delivery and payment systems, as well as alarming trends in the primary care workforce shortage projections, have occurred since the publication of Phase III. The demand for primary care is increasing, especially in rural and underserved areas, because the Affordable Care Act expanded health care coverage to the previously uninsured, and because the population is growing and aging. The supply of physicians is projected to not keep pace with the increasing demand for primary care (see 80 FR 41910). We have identified similar trends with respect to mental health care services. NPPs, the fastest growing segment of the primary care workforce, may help to mitigate these shortages. In addition, new and evolving care delivery models, which feature an increased role for NPPs (often as care coordination facilitators or in team-based care) have been shown to improve patient outcomes while reducing costs, both of which are important Department goals as we move further toward quality- and value-based purchasing of health care services in the Medicare program and the health care system as a whole.

(2) New Exception

In light of the changes in the health care delivery and payment systems since we last considered the issue of NPP recruitment assistance to physicians, using the authority granted to the Secretary in section 1877(b)(4) of the Act, we proposed a limited exception for hospitals, FQHCs, and RHCs that wish to provide remuneration to a physician to assist with the employment of an NPP.

The proposed exception at § 411.357(x) would permit remuneration from a hospital, FQHC, or RHC to a physician to assist the physician in employing an NPP in the geographic area served by the hospital, FQHC, or RHC providing the remuneration. (See 80 FR 41910 through 41911 for an explanation of how the proposed exception would apply to remuneration from a hospital, FQHC, or RHC to a group practice or other type of physician practice, both of which qualify as a ''physician organization,'' as defined at § 411.351.) The exception as proposed would have applied only where the NPP is a bona fide employee of the physician receiving the remuneration from the hospital (or of the physician's practice) and the purpose of the employment is to provide primary care services to patients of the physician practice. However, we solicited comments regarding whether we should also permit remuneration to physicians to assist in attracting NPPs to their medical practices in an independent contractor capacity, and, if so, what requirements we should include for such arrangements (for example, a requirement that the arrangement between the physician and the NPP have a minimum term, such as 1 year).

Because our goal in proposing the exception at § 411.357(x) was to promote the expansion of access to primary care services—which we consider to include general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology patient care services—we proposed to define ''nonphysician practitioner,'' for the purposes of this exception, to include only physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified nurse midwives (CNMs). We solicited comments regarding

whether there is a compelling need to expand the scope of the proposed exception to additional types of NPPs who furnish primary care services.

We also proposed at § 411.357(x)(1)(vi) a requirement that the NPP provide only primary care services to patients of the physician's practice. We solicited comments regarding whether we should consider other, more, or fewer types of services to be ''primary care services'' for the purposes of proposed § 411.357(x), whether there is a compelling need to expand the scope of the proposed exception to NPPs who provide services that are not considered ''primary care services'' and, if so, safeguards that could be included in a final exception to ensure no risk of program or patient abuse. We proposed two alternatives for establishing the minimum amount of primary care services furnished to patients of the physician's practice by the NPP: (1) At least 90 percent of the patient care services furnished by the NPP must be primary care services; or (2) substantially all of the patient care services furnished by the NPP must be primary care services. We proposed to define ''substantially all'' patient care services consistent with our regulations. (See § 411.352(d) and § 411.356(c)(1).) We solicited comments regarding which of these alternatives is most appropriate and the nature of the documentation necessary to measure the NPP's services.

Because we do not intend to permit remuneration to physicians through ongoing or permanent subsidies of their NPP's compensation and other practice costs, we proposed a cap on the amount of remuneration from the hospital to the physician and a requirement that the hospital may not provide assistance for a period longer than the first 2 consecutive years of the NPP's employment by the physician. Under § 411.357(x)(1)(iii) as proposed, the amount of remuneration from the hospital, FQHC, or RHC would have been capped at the lower of: (1) 50 percent of the actual salary, signing bonus, and benefits paid by the physician to the NPP; or (2) an amount calculated by subtracting the receipts attributable to services furnished by the NPP from the actual salary, signing bonus, and benefits paid to the NPP by the physician. We proposed to interpret ''benefits'' to include only health insurance, paid leave, and other routine non-cash benefits offered to similarly situated employees of the physician's practice. Because the proposed exception would protect only remuneration to reimburse a physician for amounts actually paid to the NPP, the hospital, FQHC, or RHC providing the remuneration could not increase it to account for any tax implications to the physician. We solicited comments regarding the cap on the amount of remuneration in the proposed exception, including whether the offset of receipts attributable to services furnished by the NPP should include all receipts for all services furnished by the NPP, regardless of payor and regardless of whether the services were primary care services. We also solicited comments regarding whether we should structure the exception with additional or different safeguards to ensure that the remuneration from the hospital, FQHC, or RHC directly benefits the NPP and whether it is necessary to address the issue of the tax implications that could result from the use of the exception to provide remuneration to a physician to assist in the employment an NPP. We also solicited comments specifically addressing the time limitations set forth in our proposal.

The proposed exception at § 411.357(x) closely tracked the structure and requirements of the exception for physician recruitment at § 411.357(e). Similar to the exception at § 411.357(e), the proposed exception for assistance to employ NPPs would include requirements that reference hospitals, but would apply in the same manner to FQHCs and RHCs that wish to provide assistance to physicians to employ NPPs.

We proposed requirements to safeguard against program or patient abuse similar to the requirements found in most of our exceptions in § 411.357. Specifically, we proposed that an arrangement covered by the exception must be set out in writing and signed by the hospital providing the remuneration, the physician receiving the remuneration, and the NPP. In addition, the arrangement may not be conditioned on the physician's or the NPP's referral of patients to the hospital providing the remuneration. Further, the proposed exception would require that the remuneration from the hospital is not determined (directly or indirectly) in a manner that takes into account the volume or value of any actual or anticipated referrals by the physician or the NPP (or any other physician or NPP in the physician's practice) or other business generated between the parties. Because the definition of ''referral'' at § 411.351 relates to the request, ordering of, or certifying or recertifying the need for DHS by a physician, for the purposes of the requirements of the new exception, we proposed at § 411.357(x)(3) a definition of the term ''referral'' as it relates to NPPs that is modeled closely on the definition of a physician's ''referral'' at § 411.351. We also proposed that the arrangement may not violate the Federal anti-kickback statute or any Federal or State law or regulation governing billing or claims submission. Finally, we proposed that records of the actual amount of remuneration provided to the physician (and to the NPP) be maintained for a period of at least 6 years and be made available to the Secretary upon request. We solicited comment regarding whether these ''general'' safeguards are sufficient to protect against program or patient abuse resulting from arrangements to assist with NPP employment, or if additional safeguards are necessary.

We also proposed requirements for the compensation arrangement between the physician receiving remuneration and the NPP that the remuneration assists the physician to recruit. Specifically, we proposed that the aggregate salary, signing bonus, and benefits paid by the physician to the NPP must be consistent with fair market value. In addition, we proposed a requirement that the physician may not impose practice restrictions on the NPP that unreasonably restrict the NPP's ability to provide patient care services in the geographic area served by the hospital, FQHC, or RHC, and stated that we would interpret this provision in the same way that we interpret the requirement at § 411.357(e)(4)(vi) for physician recruitment arrangements.

We proposed to include requirements to prevent gaming by ''rotating'' or ''cycling'' NPPs through multiple physician practices located in the geographic area served by the hospital, FQHC, or RHC, an abuse that would effectively shift the long-term costs of employing NPPs to the hospital, FQHC, or RHC. We noted our concern that parties may misuse the exception to shift to a hospital, FQHC, or RHC the costs of an NPP who is currently employed by a physician but provides patient care services in a medical office of the physician that is located outside of the geographic area served by the hospital, FQHC, or RHC. To address these concerns, we proposed that the hospital, FQHC, or RHC may not provide assistance to a physician to employ an NPP if: (1) the NPP has practiced in the geographic area served by the hospital, FQHC, or RHC within the 3 years prior to becoming employed by the physician (or the physician organization in whose shoes the physician stands); or (2) the NPP was employed or otherwise engaged by a physician (or a physician organization in whose shoes the physician stands) with a medical office in the geographic

area served by the hospital, FQHC, or RHC within the 3 years prior to becoming employed by the physician (or the physician organization in whose shoes the physician stands), even if the NPP did not provide patient care services in that office. For consistency and to ease administrative burden, we proposed to define ''geographic area served by the hospital'' to have the same meaning assigned to this term in the exception at § 411.357(e) for physician recruitment, and to define the term ''geographic area served'' by an FQHC or RHC to have the same meaning assigned to this term in proposed § 411.357(e)(6)(ii).

Finally, we solicited comments regarding whether additional safeguards are necessary to protect against program or patient abuse that might result from arrangements that would be covered by proposed § 411.357(x), including comments addressing whether we should limit the number of times a hospital, FQHC, or RHC may assist the same physician with the employment of NPPs and, if so, during what time period that limitation should apply. We sought comments on whether we should limit the use of the exception to no more than once every 3 years for a particular physician or no more than three times in the aggregate (regardless of time period) for a particular physician. We sought comments as to whether this type of limitation potentially undermines the goal of increased access to primary care in the event the NPP(s) employed by the physician receiving the assistance from the hospital, FQHC, or RHC left such employment after only a short period of time or moved from the geographic area served by the hospital, FQHC, or RHC. We were also interested in comments addressing whether the exception should include a requirement that there be a documented, objective need for additional primary care services in the geographic area served by the hospital, FQHC, or RHC. We also solicited comments specifically from FQHCs and RHCs regarding whether this exception would be useful to such entities and any barriers to its use that they perceive.

With several modifications, described below in response to the comments we received, we are finalizing an exception at § 411.357(x) for remuneration provided by a hospital, FQHC, or RHC to a physician to assist the physician with compensating an NPP to provide primary care services or mental health care services to patients of the physician's practice. The following is a summary of the comments we received.

Comment: Most commenters supported our proposal to permit remuneration from hospitals, FQHCs, and RHCs to assist physicians in employing NPPs, variously noting that this will increase access to quality healthcare nationwide at a time when healthcare workforce shortages are projected to increase, particularly in underserved and rural areas, and in light of a steadily rising tide of insured patients; be of great benefit to institutional providers of services, physicians, and NPPs; and benefit patients who would otherwise need to travel distances to obtain needed health care services.

Response: We agree with the commenters that the new exception codified at § 411.357(x) will both promote beneficiary access to care and remove barriers that could frustrate health care delivery and payment system reform efforts. We believe that the exception, as finalized, includes appropriate safeguards to insure against program or patient abuse, yet is sufficiently flexible to achieve the outcomes described by the commenters. As described elsewhere in this section, we are expanding the scope of the exception to include remuneration from a hospital, FQHC, or RHC to a physician to assist the physician in employing or contracting with an NPP. Therefore, we refer to new § 411.357(x) as an exception for assistance to compensate an NPP. However, because the public comments addressed the proposal to establish an exception for assistance to ''employ'' an NPP, the comment summaries below reflect the use of that terminology. This does not affect final § 411.357(x), which is an exception for assistance to compensate an NPP.

Comment: One commenter stated that we could achieve our policy of permitting a hospital to provide assistance to a physician to employ an NPP simply by permitting NPPs to be included in the existing exception for physician recruitment at § 411.357(e).

Response: We disagree with the commenter. The exception for physician recruitment is statutory and covers only remuneration from a hospital to a physician to induce the physician to relocate his or her medical practice to the geographic area served by the hospital to become a member of the hospital's medical staff. The Secretary's authority in section 1877(e)(5)(C) of the Act permits her to impose on the arrangement between the hospital and the recruited physician other requirements that she determines necessary to protect against program or patient abuse. This authority does not extend to an expansion of the exception to include remuneration to a physician to employ, contract with, or otherwise recruit an NPP.

We are utilizing the authority in section 1877(b)(4) of the Act to establish the exception for assistance from a hospital, FQHC, or RHC to a physician to compensate an NPP. Because the exception for physician recruitment in section 1877(e)(5) of the Act and § 411.357(e) of our regulations only permits remuneration to a physician to induce *the physician* to relocate his or her medical practice and join the medical staff of the recruiting hospital, we believe that a standalone exception addressing recruitment of an NPP is more appropriate.

Comment: Several commenters, although supportive of CMS' ''efforts to think about creative solutions to the severe primary care shortage,'' opposed the proposed exception for NPPs. The commenters voiced concerns that the proposed exception will be used by hospitals to recruit nonphysician providers away from FQHCs, thereby exacerbating the primary care workforce shortage and worsening access issues for vulnerable safety-net populations.

Response: After carefully considering all of the comments, we are persuaded that the availability of the exception for assistance to compensate NPPs will improve access to care by bringing more qualified healthcare providers to areas where they are needed. Although we understand the commenters' concerns, we are finalizing the exception at § 411.357(x) with the modifications described elsewhere in this section.

Comment: Several commenters, using nearly identical language, described our proposed exception for payments to assist a physician in employing an NPP as protecting ''both direct compensation arrangements between the hospital and an individual physician and 'indirect' compensation arrangements between the hospital and a physician 'standing in the shoes' of a physician organization to which the hospital provided remuneration.''

Response: As we explained in the proposed rule (80 FR 41910–11), the exception at § 411.357(x) is available to protect a direct compensation arrangement between a hospital, FQHC, or RHC and a physician, including a compensation arrangement deemed to be a direct compensation arrangement because the physician stands in the shoes of his or her physician organization under § 411.354(c)(1). We do not repeat this analysis here. The exception at § 411.357(x) is not available for a compensation arrangement that qualifies as an ''indirect compensation arrangement'' under § 411.354(c)(2). Parties wishing to except an indirect

compensation arrangement from the law's referral and billing prohibitions must utilize the exception at § 411.357(p).

Comment: One commenter urged CMS to expand the scope of the exception to permit remuneration to advanced practice registered nurses and PAs to employ other advanced practice registered nurses and PAs. Another commenter requested that we expand the exception to permit ''the same incentives'' to a NP practice so that all eligible providers have equal opportunity to provide access to high quality, cost-effective Medicare services. A third commenter suggested that we permit the remuneration to flow ''directly to'' the NPP who is joining a physician practice or ''through'' the physician practice that he or she joins, similar to the exception for physician recruitment at § 411.357(e).

Response: In Phase III, we explained that recruitment payments made by a hospital directly to an NPP would not implicate the physician self-referral law, unless the NPP serves as a conduit for physician referrals or is an immediate family member of a referring physician (72 FR 51049). This is because section 1877 of the Act is implicated only by the existence a financial relationship between a physician (or his or her immediate family member) and an entity to which the physician makes a referral for DHS payable by Medicare. Provided that the NPP is neither a conduit for physician referrals nor an immediate family member of a referring physician, the compensation arrangements described by the first two commenters would not implicate section 1877 of the Act and no exception to the law's referral and billing prohibitions would be necessary. As to the third comment, provided that all of the remuneration from the hospital, FQHC, or RHC remained with the NPP (that is, the physician practice retained none of the remuneration as overhead or other expenses), the arrangement described by the commenter should not implicate the physician self-referral law. We caution, however, that an arrangement involving remuneration to a potential referral source may implicate other laws, including the Federal anti-kickback statute (section 1128B(b) of the Act).

Comment: Three commenters urged CMS to expand the scope of the exception to cover the employment of mental health care providers to address the acute need for mental health care services. Another commenter similarly suggested that we include clinical social workers and clinical psychologists within the scope of the exception.

Response: As described elsewhere in this section, we are finalizing the exception at § 411.357(x) to permit remuneration to a physician who compensates an NPP to provide either primary care services or mental health care services to patients of the physician's practice. Accordingly, we are expanding the definition of ''nonphysician practitioner'' for the purposes of § 411.357(x) to include clinical social workers and clinical psychologists, as well as PAs, NPs, CNSs, and CNMs.

Comment: We received numerous comments regarding the definition of ''nonphysician practitioner'' for the purposes of the new exception at § 411.357(x), which was proposed as including PAs, NPs, CNSs, and CNMs. Several commenters expressed support for the proposed definition of ''nonphysician practitioner,'' and many others requested that we include additional types of NPPs within the scope of the exception. Among the NPPs that commenters suggested we include in the definition of ''nonphysician practitioner'' are physical therapists, CRNAs, registered dieticians, and nutritional professionals. As noted elsewhere, commenters that urged us to permit NPPs to furnish mental health services in addition to primary care services requested the corresponding inclusion of clinical social workers and clinical psychologists in the definition of ''nonphysician practitioner.'' In contrast, one commenter expressed concern regarding any expansion of the exception that would permit assistance to physicians to employ other nonphysicians, such as physical therapists.

In support of its recommended expansion of the definition to include registered dieticians and nutritional professionals, the commenter asserted that these professionals are an important part of the collaborative care system. With respect to expanding the definition of ''nonphysician practitioner'' to include CRNAs, a commenter noted that CRNAs may be licensed in their jurisdictions to furnish evaluation and management (E/M) services, as well as other services that would fit the proposed definition of primary care services, and that, because of this, elsewhere in the proposed rule CMS proposed to add CRNAs to the list of practitioners under section 1834(m)(4)(E) of the Act who may provide Medicare telehealth services. The commenter asserted that CMS should follow the same policy for CRNAs under the proposed exception at § 411.357(x). According to the commenter, CMS has proposed a range of safeguards which, when applied to NPPs, including CRNAs, should alleviate any concerns regarding risk of fraud and abuse. The commenters that supported the inclusion of physical therapists in the definition of ''nonphysician practitioner'' for the purposes of the new exception claimed that a substantial number of primary care practice patients have musculoskeletal complaints.

Response: Except with respect to clinical social workers and clinical psychologists, we decline to expand the definition of ''nonphysician practitioner'' as requested by the commenters. We continue to believe that PAs, NPs, CNSs, and CNMs are the types of NPPs who practice in the areas of general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology, which we consider to be primary care services. As discussed elsewhere in this section, we are finalizing the exception at § 411.357(x) to permit remuneration to a physician who compensates an NPP to provide mental health care services to patients of the physician's practice. Therefore, we are finalizing the exception to define NPP for the purposes of § 411.357(x) as a PA (as defined in section 1861(aa)(5) of the Act), a NP or CNS (as defined in section 1861(aa)(5) of the Act), a certified nurse-midwife (as defined in section 1861(gg) of the Act), a clinical social worker (as defined in section 1861(hh) of the Act), or a clinical psychologist (as defined in § 410.71(d)). The reasoning for this determination is set forth below.

Because we are not persuaded that registered dieticians or nutritional professionals provide the types of services we consider to be primary care services or mental health care services for the purposes of the exception, we do not believe that including registered dieticians or nutritional professionals in the definition of NPP would further the goals of increasing access to primary care services and mental health care services. Moreover, the commenters did not demonstrate a compelling need to include such practitioners in the definition of NPP for the purposes of the exception.

With respect to CRNAs, the commenter is correct that we proposed to revise the regulation at § 410.78(b)(2) to include a CRNA, as described under § 410.69, to the list of distant site practitioners who may furnish Medicare telehealth services (80 FR 41784). Under section 1834(m)(1) of the Act, Medicare makes payment for telehealth services furnished by physicians and practitioners. Section 1834(m)(4)(E) of the Act specifies that, *for the purposes*

of furnishing Medicare telehealth services, the term ''practitioner'' has the meaning given that term in section 1842(b)(18)(C) of the Act, which includes a CRNA as defined in section 1861(bb)(2) of the Act. We initially omitted CRNAs from the list of distant site practitioners for telehealth services in the regulation because we did not believe these practitioners would furnish any of the services on the list of Medicare telehealth services, but now recognize that, in some States, CRNAs are licensed to furnish certain services on the telehealth list, including E/M services. Although we are finalizing our proposal to add CRNAs to the list of distant site practitioners for telehealth services in this final rule, we do not believe that it is necessary or appropriate to include CRNAs in the definition of NPP for the purposes of the exception to the physician self-referral law at § 411.357(x).

Not all E/M services are primary care services. The commenter did not provide sufficient information for us to determine whether the ''other services'' which it claims CRNAs are licensed to furnish in certain States would qualify as general family practice, general internal medicine, pediatrics, geriatrics, or obstetrics and gynecology services. Moreover, although some CRNAs may be licensed to furnish some E/M services, we are not convinced that CRNAs generally furnish primary care services to the extent that the exception mandates. We are similarly not convinced that CRNAs would furnish mental health care services under the expanded exception finalized here. Therefore, we see no compelling need to include CRNAs in the definition of ''nonphysician practitioner'' for the purposes of the exception at § 411.357(x).

We do not believe that physical therapists furnish primary care services or mental health care services to patients. The commenters suggested only that physical therapists may serve the needs of patients of a primary care practice, not that they furnish primary care services themselves. We do not find this a compelling reason to expand the scope of the exception to include physical therapists in the definition of ''nonphysician practitioner.''

Comment: One commenter urged that we allow the employment of any NPP that would qualify as a primary care provider under the definition at § 425.20 and § 425.404, which pertain to accountable care organizations (ACOs) in the Shared Savings Program.

Response: Sections 425.20 and 425.404 relate to (1) definitions of a ''primary care physician'' (not an NPP) and ''primary care services'' (not providers) and (2) special assignment conditions for ACOs that include FQHCs and RHCs, respectively. The definition of ''primary care services'' at § 425.20 includes a set of services identified by certain CPT, HCPCS and revenue center codes. We believe that the commenter is suggesting that we include in our definition of NPP for the purposes of new § 411.357(x) any practitioner that furnishes services denoted by the codes that make up ''primary care services'' for the purposes of the Shared Savings Program. We decline to do so because we see no reason to condition compliance with the physician self-referral law on requirements of the Shared Savings Program. However, we note that the primary care ''specialty designations'' of internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine that qualify a physician as a ''primary care physician'' for performance year 2016 under § 425.20 align identically with the services we consider to be primary care services for the purposes of § 411.357(x).

Comment: Two commenters urged CMS to identify PAs, NPs, CNSs, and CNMs by their properly earned credentials. The commenters stated that the use of the term ''nonphysician practitioners'' diminishes the value of these professions by identifying them in the negative.

Response: Our use of the term ''nonphysician practitioner'' is not intended to diminish the value of PAs, NPs, CNSs, certified nurse-midwives, or any other professional who provides services to Medicare beneficiaries. In the interest of clarity and to simplify compliance with the exception, we are retaining the term ''nonphysician practitioner'' to encompass the PAs, NPs, CNSs, CNMs, clinical social workers, and clinical psychologists that are covered by the exception.

Comment: Numerous commenters urged CMS to include independent contractors within the scope of the exception for NPP employment. One of the commenters noted that, especially in rural areas, primary care providers are usually recruited from urban areas as part-time independent contractors, as it can be difficult to attract such individuals as full-time members of the community. Commenters variously maintained that expanding the scope of the exception to independent contractor NPPs would promote flexibility, remove a barrier to attracting needed practitioners to underserved areas, and help insure increased availability of primary care services. Most commenters emphasized that the fact of an independent contractor relationship does not create or pose any greater potential for fraud and abuse than a standard employment relationship. One commenter noted that Medicare does not limit reassignment only to situations in which the physician organization has employed the NPP, and suggested that we should extend the scope of the exception to any arrangement that is lawful and will permit the physician organization to obtain payment for the services furnished by the NPP.

Response: We agree with the commenters that expanding the exception to permit a hospital, FQHC, or RHC to provide assistance to a physician to employ, contract with, or otherwise engage an NPP under a compensation arrangement to furnish primary care services or mental health care services to patients of the physician's practice would support our underlying goal of increasing access to needed care. However, we do not believe that a contractual relationship between a physician (or a physician organization in whose shoes the physician stands) and an NPP would necessarily result in the same nexus or level of accountability as an employment relationship between the parties. In order to safeguard against program or patient abuse that may arise in the absence of the close nexus between employer and employee, we are requiring that, where the NPP is an independent contractor, the contractual relationship for which assistance is provided by a hospital, FQHC, or RHC is *directly* between the physician (or a physician organization in whose shoes the physician stands under § 411.354(c)) and the NPP. Accordingly, the exception finalized at § 411.357(x) would permit both (1) a compensation arrangement between a physician and an NPP for employment and (2) a compensation arrangement directly between a physician and an NPP for contracted services. As noted previously, we refer to new § 411.357(x) as an exception for assistance to compensate an NPP. An arrangement between a physician and a staffing company that has the direct contractual or employment arrangement with the NPP that provides services to patients of the physician's practice would not be permitted under the new exception.

Comment: One commenter requested that we expand the exception to permit assistance to recruit an NPP to become an owner of a physician practice. According to this commenter, given the increasing numbers of NPPs, primary care practices are ''resorting to bringing in NPPs as owners'' of the practices. The commenter also requested that, if we

expand the exception to cover ownership interests within its scope, we establish a different cap on remuneration where the NPP joins the practice as an owner. The commenter did not specify what the ''ownership'' cap should be.

Response: We decline to adopt the commenter's suggestion. We are unclear whether the commenter is requesting that we establish an exception that permits a hospital, FQHC, or RHC to provide remuneration directly to an NPP to purchase an ownership interest in a physician practice, or whether the commenter is requesting that we expand the scope of § 411.357(x) to permit a hospital, FQHC, or RHC to reimburse a physician for amounts loaned to an NPP that purchases an ownership or investment interest in the physician's practice. As to the first alternative, as discussed above, a direct compensation arrangement between a DHS entity and an NPP does not implicate the physician self-referral law unless the NPP serves as a conduit for physician referrals or is an immediate family member of a referring physician. However, such an arrangement may implicate other laws, including the Federal anti-kickback statute (section 1128B(b) of the Act). As to the second alternative, we are not persuaded that facilitating ownership in a physician practice poses no risk of program or patient abuse.

Comment: Two commenters also urged us to expand the types of services listed as primary care services for the purposes of the exception to include mental health care services. In support of this request, one of the commenters stressed the well-documented, pressing need for mental health care in the United States and decreasing access to mental health care. A third commenter noted the compelling need for access to mental health care services, referencing a study indicating that up to 70 percent of primary care visits stem from psychosocial issues; that is, although patients may present with physical health complaints, underlying mental health or substance abuse frequently triggers these visits. The commenter stated that this problem is exacerbated by the fact that many communities have a critical shortage of providers to whom patients with mental health needs can be referred. The commenter cited in support of its recommendations, Collins, C., Hewson, D., Munger, R., Wade, T. (2010), ''Evolving Models of Behavioral Health Integration in Primary Care (Milbank Memorial Fund),'' August 29, 2015, available at *http://www.milbank.org/uploads/documents/10430EvolvingCare/EvolvingCare.pdf*.

Response: We agree with the commenters that there is a severe lack of access to mental health care services, and that the exception should be expanded to permit financial assistance for the compensation of NPPs who furnish mental health care services. We are persuaded by the study cited by the commenter, as well several other studies and surveys showing a high demand for mental health care services and a substantial shortage of providers.

The demand for mental health services is considerable; one in every five adults will suffer from a mental illness or substance abuse disorder in a given year. In 2013, national surveyors found that 43.8 million adults in the United States (18.5 percent of the national population) had a mental illness during the year. (Substance Abuse and Mental Health Administration, *Results from the 2013 National Survey on Drug Use and Health*). Additionally, surveys indicate there are 12.3 million adults in the United States who have a substance abuse disorder without a concurrent mental illness. (*Substance Abuse and Mental Health Administration, Results from the 2014 National Survey on Drug Use and Health*).

A large portion of those suffering from mental illness are not receiving treatment. Of the adults suffering from a mental illness in 2013, only 19.6 million (44.7 percent) received mental health services. (*2013 National Survey*). One of the most significant barriers to care was a lack of mental health care professionals. In fact, 25.5 percent of those who were unable to receive services did not know where to go for help. (*2013 National Survey*). This is because, in many areas, there are few or no mental health care professionals available. Seventy-seven percent of counties in the United States have a severe shortage of mental health workers, and 55 percent of counties have no practicing psychiatrists, psychologists, or social workers. (Substance Abuse and Mental Health Services Administration, *Report to Congress on the Nation's Substance Abuse and Mental Health Workforce Issues*). In 2012, HRSA reported that there were 3,669 mental health care professional shortage areas that collectively contained 91 million people. (*Report to Congress*). This equates to a shortage of 1,846 psychiatrists and 5,931 NPPs. (*Report to Congress*). HRSA projects that by 2020, 16,624 child and adolescent psychologists will be needed, but the expected supply is 8,312 (*Report to Congress*), and that between 2012 and 2025, overall demand will grow by 10 percent while supply will decline by 900 psychologists. (Health Resources and Service Administration, *Health Workforce Projections,* Psychologists).

We agree with the commenters that there is a compelling need for more mental health care professionals. We believe further that permitting hospitals, FQHCs, and RHCs to provide assistance to a physician to compensate NPPs to provide mental health care services to patients of the physician's practice may improve access to such critically needed services. In turn, we anticipate that increased access will promote treatment, improve outcomes, and may reduce the societal costs of mental illness. We are expanding the scope of the exception at § 411.357(x) to permit an NPP for whom a physician receives assistance from a hospital, FQHC, or RHC to furnish mental health care services to patients of the physician's practice.

Comment: Some commenters urged CMS to broaden the exception to include arrangements under which the NPP furnishes any type of care because NPPs contribute to addressing specialty workforce shortages, particularly in underserved and rural areas, remove barriers to needed care, such as ongoing management of chronic conditions by specialists, and address important needs of beneficiaries, including increased access to care. One of these commenters suggested that, provided there is a demonstrated shortage of specialty providers and where additional availability of NPPs may help address the specialty care shortage concerns, payments made to a physician to employ an NPP to furnish specialty care services should be permissible. A different commenter urged us to expand the exception to all specialties because all specialties are feeling increased demand for services created by the Affordable Care Act.

Response: In the proposed rule, we solicited comments regarding whether there is a compelling need to expand the scope of the exception to NPPs who provide services that are not considered primary care services and, if so, safeguards that could be included to ensure no risk of program or patient abuse (80 FR 41911). Other than the studies discussed in a separate comment and response regarding mental health care services, none of the commenters that advocated for an expansion of the scope of the exception to include services that are not considered primary care services provided documentation or other evidence of the compelling need for such an expansion. We do not believe that an increase in demand for specialty services necessarily correlates

to a barrier to access to those specialty services. Although we appreciate the views of these commenters, without support for a compelling need to expand the exception to NPPs who furnish services that are not considered primary care services or mental health care services, we are not inclined to adopt the revisions requested by the commenters. The exception at § 411.357(x), as finalized here, is limited to NPPs who furnish primary care services or mental health care services.

Comment: Several commenters urged us to expand the scope of the exception to permit a hospital, FQHC, or RHC to provide remuneration to a physician to employ NPPs who practice in certain other specialties, including those who provide neurology, urology, cardiology, surgery, and orthopedic services. One commenter stated that there is an acute need for NPPs who provide neurology and urology services in many community hospitals and, further, that it is not unusual for a surgical practice or an anesthesia practice to have the same ''compelling need'' for a hospital's assistance as does a primary care practice. Some commenters suggested that we permit the NPP to practice in *any* specialty. One commenter recommended that CMS ease the requirement on the services furnished by the NPP to include those non-primary care services for which the local jurisdiction licenses NPPs. A different commenter urged CMS to extend the scope of the proposed exception to remuneration provided to physicians who employ NPPs who provide cancer care, noting that such NPPs often provide enhanced primary care and care coordination services to many of their patients. Yet another commenter requested an equal playing field for specialty and subspecialty physician organizations, stating that this would be a more straightforward way for CMS to encourage access to NPPs and the services that they provide as part of care teams.

Response: For the reasons described in the response to the previous comment, we decline to expand the scope of the exception to permit NPPs to furnish services other than primary care services or mental health care services to patients of the practice of the physician receiving the assistance from a hospital, FQHC, or RHC. Moreover, in our view, a physician practice's perceived need for financial assistance does not equate to or necessarily demonstrate a need for health care services in a geographic area. We note that nothing in § 411.357(x) prohibits a hospital, FQHC, or RHC from providing remuneration to a specialty physician who compensates an NPP to furnish primary care services or mental health care services to patients of the physician's practice. We remind readers that the purpose of the exception as finalized is to remove barriers to care that may frustrate certain goals of health care delivery system reform and to promote beneficiary access to primary care services and mental health care services, not to promote access to the services of particular type of care provider (for example, an NPP).

Comment: One commenter expressed concerns with expanding the exception to permit the employment of NPPs who provide services other than primary care services, specifically raising concerns regarding physical therapy furnished by therapists employed by a physician or physician organization.

Response: We are expanding § 411.357(x) only to the extent that the exception permits the a hospital, FQHC, or RHC to provide assistance to a physician to compensate an NPP who furnishes primary care services or mental health care services to patients of the physician's practice. As finalized, § 411.357(x) would not protect assistance to a physician who compensates an NPP to furnish physical therapy services to patients of the physician's practice. As described above, none of the commenters that advocated for an expansion of the scope of the exception to include services that are not considered primary care services provided documentation or other evidence of the compelling need for such an expansion. Without support for a compelling need to expand the exception to NPPs who furnish services that are not considered primary care services or mental health care services, including physical therapy services, we are not inclined to adopt the revisions requested by the commenters.

Comment: Two commenters urged CMS to expand the exception to hospitals that provide remuneration to physicians providing specialty care who employ NPPs. One of these commenters suggested specifically that we expand the exception to permit the employment of NPPs who furnish only primary care services, but furnish such services to the patients of a specialty physician practice. The other commenter suggested that CMS should not use the physician self-referral regulations to support one particular specialty over another, and that an expansion poses no risk of program or patient abuse. Another commenter went so far as to state that it is an abuse of CMS's authority to extend the scope of the exception to only certain physician specialties.

Response: The exception is available to any physician who compensates an NPP to furnish primary care services or mental health services to patients of the physician's practice. The physician's specialty, even if it is not primary care or mental health care, would not prohibit a hospital, FQHC, or RHC from providing assistance to the physician. However, any assistance to the physician must be for the purpose of compensating an NPP to furnish primary care services or mental health care services.

Comment: One commenter sought confirmation that the exception would permit hospitals, FQHCs, and RHCs to provide remuneration to physicians who practice in hospital-based emergency departments. The commenter noted that such physicians provide enhanced primary care and care coordination services to many of their patients, particularly those who present to the emergency department without a primary care provider or those who have limited access to community-based primary care providers. The commenter read our proposal to be limited to assistance to individual physicians.

Response: We understand the commenter to be questioning the availability of the exception for hospitals, FQHCs, and RHCs that wish to provide assistance to private physician practices that specialize in emergency medicine and furnish patient care services in hospital emergency departments. As such, we reiterate that the physician's specialty, even if it is emergency medicine, would not prohibit a hospital, FQHC, or RHC from providing assistance to the physician. However, any assistance to the physician must be for the purpose of compensating an NPP to furnish primary care services or mental health care services, and the arrangement must satisfy all of the requirements of the exception at § 411.357(x).

Comment: One commenter urged us to interpret ''primary care services'' as broadly as possible because, as health care delivery shifts to patient-centered models of care, a greater diversity of services will be necessary to meet the needs of patients in the primary care setting. Other commenters urged us to broaden the definition of ''primary care services'' to include services furnished by allergists, immunologists, and rheumatologists.

Response: After careful consideration of these comments and the comments urging us to permit assistance to a physician to compensate an NPP who furnishes any type of services to patients of the physician's practice, we decline to consider any types of services

other than those in our proposal to be ''primary care services.'' General or family practice, general internal medicine, pediatrics, and obstetrics and gynecology are the four primary care specialties counted by the Health Resources and Services Administration (HRSA) when determining primary care health professional shortage areas (HPSAs). Further, geriatrics is considered an acceptable primary care specialty under the Primary Care Loan program administered by HRSA. We note that nothing in this rule or the exception at § 411.357(x) precludes a qualified professional, including an NPP, from furnishing general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology services—which we consider ''primary care services'' for the purposes of § 411.357(x)—regardless of the individual's specialty training or designation.

Comment: One commenter suggested that the term ''only primary care services'' at proposed § 411.357(x)(1)(vi)(B) could generate uncertainty and necessitate additional rulemaking. Another commenter understood ''only primary care services'' to mean that at least 75 percent of the services furnished by the NPP must be primary care services and found this requirement to be reasonable. Other commenters explicitly asked that we adopt a ''substantially all'' test for the primary care services furnished by the employed NPP, stating that this standard is most appropriate and consistent with other CMS regulations. Moreover, according to these commenters, a standard requiring that the NPP provide ''only'' primary care services could hamper the impact of the exception. We received no comments in support of a different standard for the minimum amount of primary care services that an NPP must furnish under the exception.

Response: Proposed § 411.357(x)(1)(vi)(B) set forth a minimum amount of primary care services that must be furnished by the NPP for whose employment a physician receives assistance from a hospital, FQHC, or RHC, and stated that the NPP must provide ''only'' primary care services to patients of the physician practice. In our discussion of this requirement, we proposed two alternatives for establishing the minimum amount of primary care services furnished to patients of the physician's practice by the NPP: (1) At least 90 percent of the patient care services furnished by the NPP must be primary care services; or (2) substantially all of the patient care services furnished by the NPP must be primary care services (80 FR 41911). We stated that we would define ''substantially all'' patient care services consistent with our regulations at § 411.352(d) and § 411.356(c)(1); that is, at least 75 percent of the NPP's services to patients of the physician's practice must be primary care services.

We agree with the commenters that a ''substantially all'' standard is the appropriate standard for the minimum amount of primary care services or mental health care services that an NPP must furnish to patients of the physician's practice. Therefore, we are finalizing § 411.57(x)(1)(vi) to require that substantially all of the patient care services furnished by the NPP must be primary care services or mental health care services. We expect that physician organizations that qualify as ''group practices'' are familiar with this standard, as are rural providers. As we have throughout the physician self-referral regulations, we are defining ''substantially all'' patient care services to mean at least 75 percent of the NPP's services to patients of the physician's practice. To ensure consistency in the interpretation of identical terms used in our regulations, we are requiring that ''patient care services'' be measured by one of the following: (1) The total time the NPP spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries); or (2) any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented. See § 411.352(d)(1). For clarity, we are including this requirement in § 411.357(x) as finalized in this final rule.

Comment: Two commenters urged us to adopt only the bright-line test of 50 percent of the actual salary, signing bonus, and benefits paid to the NPP as the limit on the amount of remuneration that a hospital, FQHC, or RHC may provide to a physician to employ an NPP. One of these commenters suggested that the remuneration methodology should be as simple and straightforward as possible, and that the final rule should avoid complicating the exception and exposing hospitals to noncompliance due to incomplete or inaccurate documentation related to receipts for the NPP's services to patients of the physician's practice. Another commenter urged us to permit hospitals to utilize either method of determining the maximum amount of permissible assistance set forth at § 411.357(x)(1)(iii), without regard to which results in the lower amount of remuneration from the hospital, FQHC, or RHC to the physician. The commenter stated that the ''payments less receipts'' methodology (with payments equal to the salary, signing bonus, and benefits paid to the NPP) is speculative at the outset of the compensation arrangement and cannot be determined with certainty at that time to be lower than 50 percent of the actual salary, signing bonus, and benefits paid to the NPP by the physician or physician organization. The commenter also raised the complicating issue of nonphysician services billed incident to a physician's service rather than under the NPI assigned to the NPP. Moreover, having a ''lower of'' standard effectively requires parties to use both methodologies to determine which results in the lower amount of remuneration, even if only one is desired. To avoid ''after-the-fact'' violations of the physician self-referral law, the commenter suggested that hospitals, FQHCs, and RHCs should be given the choice of selecting either of these two methodologies for determining the amount of assistance they will provide to the physician or physician organization.

Response: We agree with the commenters that recommended establishing a clear, objective standard for determining the maximum amount of assistance that a hospital, FQHC, or RHC may provide to a physician would best serve the interests of hospitals, FQHCs, and RHCs that provide assistance to a physician to compensate an NPP. Such a standard would serve to facilitate compliance with the physician self-referral law, which is a primary purpose of certain of these updates to our regulations. Upon further consideration of the ''receipts minus salary, signing bonus, and benefits'' methodology, we are abandoning this option in favor of a bright-line approach that permits a hospital, FQHC, or RHC to provide assistance to a physician in an amount that does not exceed 50 percent of the actual aggregate compensation, signing bonus, and benefits paid to the NPP who joins the physician's practice. We interpret ''benefits'' to include only health insurance, paid leave, and other routine non-cash benefits offered to similarly situated employees of the physician's practice. As we stated in the proposed rule, we recognize that compensation arrangements may change over time, for example, moving from full-time status to part-time status or changing a compensation methodology from hourly

payments to a pre-determined flat, monthly salary. Because of the fair market value requirement and because we are finalizing a limit on the amount that the hospital may provide to the physician, we do not believe that it is necessary to require that the NPP's salary, signing bonus, and benefits be set in advance.

We recognize the challenges posed by a standard under which a hospital's, FQHC's, or RHC's compliance with the law depends on precise determinations of which services are ''attributable'' to an NPP, adequate record keeping of the physician, and the cooperation of the physician in sharing information regarding the receipts for services furnished by the NPP's services. Compliance challenges would be exacerbated where the NPP furnishes services that are incident to a physician's service and billed under the name (or NPI) of the physician. The third commenter's recommended approach of an ''either/or'' standard, rather than a ''lower of'' standard, while providing flexibility to hospitals, FQHCs, and RHCs, does not alleviate the significant compliance challenges posed by the ''receipts minus salary, signing bonus, and benefits'' standard, and we are not adopting it. We note that our goal in establishing the exception at § 411.357(x) is to expand access to critically needed primary care services and mental health care services. The exception is not intended to provide a physician with the means to increase profit from the services of an NPP in his or her practice at the expense of a hospital, FQHC, or RHC. We intend to monitor the use and impact of the exception for potential program or patient abuse.

Comment: One commenter requested that we increase the limit on the amount of salary, signing bonus and benefits for which a hospital, FQHC, or RHC may provide assistance. The commenter stated that 60 percent would be a more appropriate cap, as that percentage is more closely aligned with added overhead associated with adding an NPP to a physician practice. The commenter provided no data to support this statement. Another commenter recommended that we permit remuneration to a physician to cover the cost of the NPP's relocation. This commenter suggested that a hospital, FQHC, or RHC should be permitted to cover such costs if the NPP was located outside the geographic area served by the hospital and moves at least 25 miles to join the physician practice, as measured from the physician practice's primary place of business (or, if multiple locations, the location where the NPP will primarily practice). The commenter did not specify whether the previous location of the NPP refers to his or her practice location or whether remuneration to cover relocation costs should be subject to the overall cap on remuneration provided under the exception.

Response: Nothing in the exception at § 411.357(x) prohibits a hospital, FQHC, or RHC from providing assistance to a physician that includes an amount associated with the relocation costs of the NPP joining the physician's practice, provided that: (1) The amount is included when calculating the aggregate compensation from the physician to the NPP; (2) the assistance from the hospital, FQHC, or RHC does not exceed the cap established at § 411.357(x)(1)(iii)(A); and (3) the compensation to the NPP—including any amount associated with the relocation costs—does not exceed fair market value for the patient care services furnished by the NPP to patients of the physician's practice. In other words, the hospital, FQHC, or RHC may provide remuneration to the physician to cover relocation costs of the nonphysician provider if the relocation costs are included in the calculation of the actual aggregate compensation, signing bonus, and benefits paid by the physician to the NPP, and all other requirements of the exception are satisfied.

Comment: One commenter recommended that we replace the cap on remuneration in proposed § 411.357(x)(1)(iii)(A) with the analogous safeguards in the exception for physician recruitment, namely a limitation on remuneration not to exceed the actual additional incremental costs attributed to the NPP. The commenter claimed that doing so would serve the same goal of limiting any windfall to the physician while having the advantage of administrative simplicity. Another commenter stated that it failed to see any rationale for limiting assistance to only a portion of the additional incremental costs attributable to the NPP, such as 50 percent of the actual salary, signing bonus, and benefits as set forth in proposed § 411.357(x)(1)(iii)(A), and suggested that assistance should be limited to ''no more than'' the actual additional incremental costs attributable to the employed NPP (that is, 100 percent of the actual incremental costs attributable to the NPP). The commenter stated in support that hospitals have experience in using this methodology, but recognized that it could be difficult to determine amounts under an income guarantee if the NPP's services were billed incident to a physician's service.

Response: We decline to adopt a standard that would potentially permit a hospital, FQHC, or RHC to cover 100 percent of the costs attributable to adding an NPP to a physician's practice and thus result in a windfall to the physician. We stated in the proposed rule and continue to believe that hospitals, FQHCs, or RHCs should not bear the full costs of employing (or otherwise compensating) NPPs who work in private physician practices (80 FR 41912). We are establishing the exception at § 411.357(x) using the Secretary's authority in section 1877(b)(4) of the Act, which allows exceptions only for those financial relationships that do not pose a risk of program or patient abuse. Permitting a physician to shift unlimited overhead costs to the hospital, FQHC, or RHC to which he or she refers may pose a risk of program or patient abuse. Moreover, the methodology advocated by the commenters would not further our goal of facilitating compliance and reducing complexity in our regulations.

Comment: One commenter requested that we increase the permissible period for assistance from 2 years to 3 years, noting that it may require more than 2 years for an NPP's practice to develop and for the physician organization to break even on the NPP's employment. The commenter gave the example of a CNM whose services are often not paid for until the baby is delivered, resulting in a lengthy period until his or her practice develops and for the physician organization to realize the revenue for the CNM's services. Another commenter recommended that we expand the permissible period for assistance to at least 3 years, which, in the commenter's view, will help achieve the policy goals of reducing workforce shortages and increasing access to quality care. The commenter stated that adding an additional year to the permissible period of assistance poses no risk of program or patient abuse.

Response: The purpose of the exception at § 411.357(x) is not to permit a hospital, FQHC, or RHC to subsidize a physician until the physician ''breaks even'' or earns a profit on the NPP's employment or contract. Rather, the exception is intended to promote beneficiary access to care and support the goals of health care delivery and payment system reform. As we stated in the proposed rule, we do not intend to permit remuneration to physicians through ongoing or permanent subsidies of their NPP employment (or contracting) and other practice costs (80 FR 41911). As

discussed elsewhere in this section, we are finalizing a 3-year limitation on the frequency of a hospital's, FQHC's, or RHC's use of the exception for a particular physician. In light of this, we believe that the 2-year limit on assistance to employ or contract with an NPP is necessary to prevent the program or patient abuse that may result from ongoing or permanent subsidies of a physician's NPP employment (or contracting) and other practice costs. A 3-year limit on assistance effectively would permit permanent subsidies of physician practices. As we noted in the proposed rule, ongoing or permanent subsidies could serve as a reward for past referrals or an inducement to continue making referrals to the hospital, FQHC, or RHC providing the assistance (80 FR 41912). We disagree with the commenter that stated that adding an additional year to the permissible period of assistance would not pose a risk of program or patient abuse.

Comment: One commenter supported the safeguards we proposed for the new exception, noting that they are appropriate to prevent abuse. The commenter endorsed a limit on the number of times a hospital, FQHC or RHC may assist the same physician with the employment of a nonphysician, noting that once every 3 years is reasonable and consistent with other physician self-referral regulations, but requested that CMS include a waiver of the frequency limit in the event the NPP remains employed by the physician or his or her physician organization for less than 1 year. Another commenter requested that, if we impose a limitation on the frequency of the use of the exception, we include an exception for situations where an NPP leaves his or her employment or otherwise ceases to meet the requirements of the exception. The commenter did not suggest an appropriate time limitation for the NPP's departure from the physician practice. In contrast, two commenters submitted that the general safeguards proposed for the exception are sufficient and that additional safeguards would unnecessarily restrict the usefulness or availability of the exception. One of these commenters stated that physicians will not hire NPPs unnecessarily if doing so will result in a financial loss to the practice. The other of these commenters suggested that a limitation on the frequency or aggregate use of the exception for a particular referring physician is inconsistent with the exception for recruitment of a physician. Another commenter stated that a frequency limitation could potentially undermine the goal of increased access to primary care and also considered it unnecessary to limit the number of times a hospital, FQHC, or RHC may assist the same physician.

Response: We understand the commenters' concerns that a frequency limitation could serve to undermine the goal of increased access to primary care services and mental health care services, but we are not convinced that omitting this safeguard would pose no risk of program or patient abuse. As discussed in response to other comments in this final rule, we believe that ongoing or permanent subsidies of a physician's NPP and other practice costs, which could occur in the absence of a limitation on the number of times a hospital, FQHC, or RHC may assist the same physician, may serve as an inducement to continue making referrals to the hospital, FQHC, or RHC and pose a risk of program or patient abuse. Therefore, we are finalizing a requirement in the new exception that limits the use of the exception for a particular physician to once every 3 years. However, we agree that the goal of increased access to primary care services and mental health care services could be undermined if this limitation prevented a physician from replacing an NPP who left the physician's practice after only a short time. To address this, we are making an exception to the frequency limitation finalized at § 411.357(x)(8) to permit a hospital, FQHC, or RHC to provide assistance to a physician more than once every 3 years in the event that an NPP for whom the physician received assistance (the original NPP) did not remain with the physician's practice for 1 year or more. The 3-year period would begin on the date the hospital, FQHC, or RHC initially provided remuneration to the physician (to compensate the original NPP). Under final § 411.357(x)(8), the hospital, FQHC, or RHC may provide assistance to the physician to compensate a second (or subsequent) NPP, provided that: (1) The aggregate remuneration from the hospital, FQHC, or RHC does not exceed 50 percent of the actual aggregate compensation, signing bonus, and benefits paid to the replacement NPP; and (2) the assistance is limited to the consecutive 2-year period that begins on the date the original NPP commenced employment or a contractual arrangement with the physician (or physician organization in whose shoes the physician stands under § 411.354(c)).

Comment: One commenter opposed an aggregate limitation on the number of times any individual physician could receive assistance. The commenter gave the example of a physician with a long-term career in a single geographic service area and noted that an absolute limit on the use of the exception vis-à-vis this physician could result in failure to meet CMS's goal of facilitating a meaningful increase in access to primary care.

Response: We are not finalizing an aggregate limit on the number of times a hospital, FQHC, or RHC may provide assistance to the same physician to compensate an NPP to furnish primary care services or mental health services to patients of the physician's practice.

Comment: One commenter referred to the limitation on the availability of the exception to situations where the NPP was not employed or otherwise engaged to provide patient care services in the geographic area served by the hospital, FQHC, or RHC for at least 3 years prior to the commencement of the compensation arrangement between the hospital, FQHC, or RHC and the physician as the ''disqualification'' period. The commenter expressed its belief that a 3-year disqualification period is too restrictive and urged CMS to reduce the time period for ''disqualification'' to 1 year. For the same reason, the commenter urged CMS to remove the limitation on employing an NPP who has been employed or otherwise engaged by a physician practice that maintains a medical practice site within the geographic area served by the hospital, FQHC, or RHC, even if the NPP has not provided patient care services at that practice site (or sites). The commenter stated that both of these provisions restrict the mobility of NPPs and will decrease the effectiveness of the exception.

Response: The underlying purpose of the exception is to increase access to primary care services and mental health care services while removing barriers that could frustrate the goals of health care delivery and payment system reform. Although we do not wish to restrict the mobility of NPPs, we are not convinced that we should remove from the exception important requirements that guard against program or patient abuse. We believe that prohibiting assistance from a hospital, FQHC, or RHC to a physician to compensate an NPP who already furnishes patient care services in the geographic area served by the hospital, FQHC, or RHC (or furnishes patient care services to patients of a physician practice that has a medical office site located in the geographic area served by the hospital, FQHC, or RHC) is necessary to guard against shifting the long-term costs of employing and contracting with NPPs

from private physician practices to hospitals, FQHCs, and RHCs.

However, we agree that a 3-year ''disqualification'' period could undermine the important goals of the exception and are finalizing § 411.357(x)(1)(v) to include a 1-year limitation on the NPP's prior practice in the geographic area served by the hospital, FQHC, or RHC. As finalized, the exception would not be available unless the NPP, within 1 year of being compensated by the physician (or the physician organization in whose shoes the physician stands under § 411.354(c)): (1) Has not practiced in the geographic area served by the hospital, FQHC, or RHC providing the assistance; and (2) has not been employed or otherwise engaged to provide patient care services by a physician or physician organization that has a medical practice in the geographic area served by the hospital, FQHC, or RHC providing the assistance, regardless of whether the NPP furnished services at the medical practice site located in the geographic area served by the hospital, FQHC, or RHC. We believe that a 1-year ''disqualification'' period (to use the commenter's terminology) will serve adequately to prevent gaming by rotating or cycling NPPs through multiple physician practices located in the geographic area served by the hospital, FQHC, or RHC. Similarly, retaining the requirement that the NPP may not have been employed or otherwise engaged to provide patient care services by a physician or physician organization that has a medical practice in the geographic area served by the hospital, FQHC, or RHC providing the assistance for at least 1 year prior to the remuneration to the physician, regardless of whether the NPP furnished services at the medical practice site located in the geographic area served by the hospital, FQHC, or RHC, will serve to prevent physicians from shifting the cost of currently employed NPPs to hospitals, FQHCs, and RHCs. In addition, these limitations may serve to protect against potentially competitive practices, such as a physician luring an NPP from another physician practice using hospital funding.

Comment: Two commenters requested that we include relief in the exception at § 411.357(x) similar to that at § 411.357(e)(3). According to one of these commenters, such an exception to the ''geographic'' requirement would allow a physician or physician practice to employ an NPP who was: (1) Immediately prior to the employment, in training or in practice for less than 1 year; or (2) employed on a full-time basis by a Federal or State entity for at least 2 years immediately prior to the employment. The commenter stated that such a provision would expand the pool from which NPPs could be recruited and open up employment opportunities for NPPs who are either transitioning to private practice or beginning their careers without creating a risk of program or patient abuse. The other commenter also requested that, to recognize that unique circumstances could exist that support the availability of assistance in special cases, we provide in the exception for a waiver of the ''geographic'' requirement and the ''temporal'' requirement (that is, the 3-year ''disqualification'' period) if the Secretary determines in an advisory opinion that the area has a demonstrated need for the NPP.

Response: We decline to adopt the commenters' recommendations. We believe the exception as finalized is sufficiently flexible to achieve its purpose. Although it may benefit NPPs in the way the first commenter suggested, the purpose of the exception at § 411.357(x) is not to facilitate opportunities for NPPs, but rather to increase access to primary care services and mental health care services.

Comment: One commenter urged us not to limit the exception to rural or underserved areas, because providers other than those in rural areas are experiencing shortages. We received no comments in support of limiting the use of the exception to hospitals, FQHCs, and RHCs located in rural or underserved areas.

Response: We did not propose to limit the availability of the exception to hospitals, FQHCs, and RHCs that provide assistance to physicians who compensate NPPs to furnish services only in rural or underserved areas. We are not finalizing such a limitation.

Comment: One commenter suggested that CMS make clear that the definition of ''referral'' in proposed § 411.357(x) applies only to the exception for hospital assistance to a physician to employ an NPP, and not to the physician self-referral regulations in their entirety.

Response: As we explained in the proposed rule, the definition of ''referral'' at § 411.351 relates to the request, ordering of, or certifying or recertifying the need for DHS by a physician (80 FR 41912). This term is used throughout our regulations and is applicable when used in reference to the referrals of a *physician*. Our regulations currently do not include a term that references the request, ordering of, or certifying or recertifying the need for DHS by an NPP. For this reason, solely for the purposes of the requirements of the new exception, we proposed to define the term ''referral,'' *as it relates to NPPs,* as a request by an NPP that includes the provision of any DHS for which payment may be made under Medicare, the establishment of any plan of care by an NPP that includes the provision of such DHS, or the certifying or recertifying of the need for such DHS, but not including any DHS personally performed or provided by the NPP. We are finalizing this definition at § 411.357(x)(4).

Summary of the provisions in the exception for assistance to compensate an NPP, as finalized at § 411.357(x)

After careful consideration of the comments regarding the exception for assistance from a hospital, FQHC, or RHC to a physician to compensate an NPP, we are finalizing our proposed exception at § 411.357(x) with the following modifications: (1) We are including in the definition of ''nonphysician practitioner,'' for the purposes of the exception at § 411.357(x) clinical social workers and clinical psychologists; (2) we are expanding the type of services that may be furnished by the NPP to patients of the physician's practice to include mental health care services; (3) we are including a requirement that the NPP furnish substantially all primary care services or mental health services (rather than ''only'' such services) to patients of the physician's practice; (4) we are not limiting the type of compensation arrangement between the physician (or physician organization in whose shoes the physician stands) and the NPP, but we are requiring that the contractual relationship for which assistance is provided by a hospital, FQHC, or RHC is directly between the physician (or a physician organization in whose shoes the physician stands under § 411.354(c)) and the NPP; (5) we are establishing a bright-line approach to the amount of permissible remuneration from the hospital, FQHC, or RHC to the physician, limiting it to 50 percent of the actual aggregate compensation, signing bonus, and benefits paid to the NPP; (6) we are finalizing a limit on the frequency with which a hospital, FQHC, or RHC may provide assistance to the same physician and setting the limitation at no more than once every 3 years, with an exception if the NPP does not remain with the physician's practice for at least 1 year; and (7) we are shortening from 3 years to 1 year the period of time that the NPP must not have practiced in the geographic area served by the hospital, FQHC, or RHC providing the assistance.

b. Geographic Area Served by Federally Qualified Health Centers and Rural Health Clinics

Section 1877(e)(5) of the Act sets forth an exception for remuneration provided by a hospital to an individual physician to induce the physician to relocate his or her medical practice to the geographic area served by the hospital to become a member of the hospital's medical staff. This exception was codified in our regulations at § 411.357(e) in the 1995 final rule. In Phase II and Phase III, we expanded the exception to FQHCs and RHCs, respectively, and revised the definitions of ''geographic area served by a hospital.'' As we explained at 80 FR 41913, the definition of ''geographic area served by a hospital'' adopted in Phase III does not provide guidance as to the geographic area into which an FQHC or RHC may recruit a physician, a concept critical for compliance with the exception's requirements. Therefore, we proposed to revise § 411.357(e)(6) to add a new definition of the geographic area served by an FQHC or RHC.

We proposed two alternative approaches for this policy, which aligns closely with the special optional rule for rural hospitals at § 411.357(e)(2)(iii) in recognition that rural hospitals, FQHCs, and RHCs often serve patients who are dispersed in wider geographic areas and may need to recruit physicians into more remote areas to achieve their goals of providing needed services to the communities that they serve. The first proposed approach closely mirrors our current definition of a rural hospital's geographic service area. It would define the geographic area served by an FQHC or RHC as the area composed of the lowest number of *contiguous* zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis. Under our first proposal, if the FQHC or RHC draws fewer than 90 percent of its patients from all of the contiguous zip codes from which it draws patients, the geographic area served by the FQHC or RHC could include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of its patients reside, and continuing to add noncontiguous zip codes in decreasing order of percentage of patients. The geographic area served by the FQHC or RHC could include one or more zip codes from which it draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area from which it draws at least 90 percent of its patients.

In the alternative, we proposed to define the geographic area served by an FQHC or RHC as the area composed of the lowest number of *contiguous or noncontiguous* zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis. This would be determined by beginning with the zip code in which the highest percentage of the FQHC's or RHC's patients reside, and continuing to add zip codes in decreasing order of percentage of patients. We solicited comments on each of these alternatives, including whether patient encounters is the appropriate measure for determining the geographic area served by an FQHC or RHC. Finally, we solicited comments specifically from FQHCs and RHCs regarding whether the exception at § 411.357(e) for physician recruitment is useful to such entities and any barriers to its use that they perceive.

We are finalizing our proposal to define, for the purposes of the exception at § 411.357(e), the geographic area served by an FQHC or RHC as the lowest number of *contiguous or noncontiguous* zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis. The following is summary of the comments we received.

Comment: Several commenters recommended that CMS use the definition for geographic area served by an FQHC or RHC that does not use contiguity as a factor. These commenters noted that the prior lack of clarity regarding the area into which a physician recruited by an FQHC or RHC must move his or her medical practice may have deterred such entities from making recruitment payments to attract physicians to underserved areas. Another commenter noted concurrence with our proposed approach to defining the geographic area served by an FQHC or RHC, but requested that we allow the FQHC or RHC to include one or more zip codes from which the entity draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area from which it draws at least 90 percent of its patients. According to the commenter, this would allow an FQHC or RHC to take into account potential patients. The commenter also suggested that we determine service areas based on patients rather than encounters, but gave no reason why this measure would be more appropriate than encounters. A different commenter agreed that patient encounters are the appropriate measure for determining the geographic area served by an FQHC or RHC.

Response: We are finalizing our alternative proposal to define the ''geographic area served'' by an FQHC or RHC as the area composed of the lowest number of contiguous or noncontiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis. As stated in the proposed rule, we see no potential for program or patient abuse in selecting noncontiguous zip codes to identify 90 percent of the patient base as long as there are patients in those areas (80 FR 41913). Also, under this final rule, the FQHC or RHC is permitted to include one or more zip codes from which the FQHC or RHC draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area from which the FQHC or RHC draws at least 90 percent of its patients. Hospitals that provide recruitment assistance to physicians are provided this flexibility under § 411.357(e)(2)(i). As described at § 411.357(e)(6), the exception applies to remuneration provided by an FQHC or RHC in the same manner as it applies to remuneration provided by a hospital, provided that the arrangement does not violate the Federal anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission. We see no risk of program or patient abuse in extending the ability to include ''hole'' zip codes (as we described them in Phase III (72 FR 51050)) to FQHCs and RHCs when determining the geographic areas that they serve. We are not persuaded that ''patients'' is a more appropriate measure than ''encounters'' for determining service areas, and are not adopting the change recommended by the commenter who suggested that we determine the geographic area served by an FQHC or RHC based on patients of the FQHC or RHC.

Comment: In response to our solicitation of comments regarding whether the exception at § 411.357(e) for physician recruitment is useful to FQHCs and RHCs, several commenters noted that, in their experience, the existing exception is not widely known or used. The commenters encouraged CMS to better publicize the exception to the rural health community so that it may take advantage of this recruitment tool. Another commenter stated that the exception is of limited utility to FQHCs because, as safety net providers, FQHCs struggle to pay market salaries to attract clinicians, and incentive payments are often financially infeasible for FQHCs.

Response: We appreciate the input of the commenters and will consider ways to provide better outreach to FQHCs and

RHCs regarding the physician self-referral law and its exceptions.

After careful consideration of the comments, we are finalizing our proposal to define the geographic area served by an FQHC or RHC, for the purposes of the exception at § 411.357(e), as the lowest number of contiguous or noncontiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis. We are also permitting FQHCs and RHCs to include one or more zip codes from which they draw no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area from which the FQHC or RHC draws at least 90 percent of its patients, determined on an encounter basis.

c. Conforming Terminology: ''Takes Into Account''

Several exceptions for compensation arrangements in section 1877(e) of the Act contain provisions pertaining to the volume or value of a physician's referrals. In each case, the statutory language consistently states that compensation cannot be determined in a manner that ''takes into account'' the volume or value of a physician's referrals. (See sections 1877(e)(1)(A)(iv), (e)(1)(B)(iv), (e)(2)(B)(ii), (e)(3)(A)(v), (e)(3)(B)(i), (e)(5)(B), (e)(6)(A), and (e)(7)(A)(v).) As we explained in the proposed rule (80 FR 41914), our longstanding policy is to interpret the volume or value standard in all provisions under section 1877(e) of the Act uniformly.

Despite our uniform interpretation of the volume or value standard, the phrase ''takes into account'' is not used consistently in the exceptions for compensation arrangements in § 411.357. In particular, the regulatory exception for the recruitment of physicians at § 411.357(e) has two provisions relating to the volume or value standard, and the provisions use different terms. Current § 411.357(e)(1)(iii) excepts payments to a recruited physician if the hospital does not determine the amount of compensation (directly or indirectly) ''based on'' the volume or value of referrals. Where the recruited physician joins a physician practice, § 411.357(e)(4)(v) provides that the amount of remuneration may not be determined in a manner that ''takes into account'' (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital. Like the physician recruitment exception, the following exceptions do not use the phrase ''takes into account'' in reference to the volume or value standard: The exception for medical staff incidental benefits at § 411.357(m); the exception for obstetrical malpractice insurance subsidies at § 411.357(r); and the exception for professional courtesy at § 411.357(s). The exception for obstetrical malpractice insurance premiums at § 411.357(r) provides that the amount of payment cannot be ''based on'' the volume or value of actual or anticipated referrals. The exceptions at § 411.357(m) and § 411.357(s) require that medical staff incidental benefits and professional courtesies, respectively, are offered to physicians ''without regard to'' the volume or value of referrals.

We are concerned that the use of different phrases pertaining to the volume or value of referrals (''takes into account,'' ''based on,'' and ''without regard to'') may cause some to conclude incorrectly that there are different volume or value standards in the compensation exceptions. See 80 FR 41914. To clarify the regulations, we proposed to modify § 411.357(e)(1)(iii) to conform to the exact language in section 1877(e)(5)(B) of the Act. Specifically, we proposed to amend § 411.357(e) to require that the compensation provided to a recruited physician may not take into account (directly or indirectly) the volume or value of the recruited physician's referrals to the hospital, FQHC, or RHC providing the recruitment remuneration. We also proposed to amend § 411.357(r) to require that the amount of payment under the arrangement may not take into account the volume or value of any actual or anticipated referrals. Lastly, we proposed to revise the language of § 411.357(m) and (s) to provide that the offer of medical staff incidental benefits or professional courtesy, respectively, may not take into account the volume or value of a physician's referrals. Taken together, these revisions would make the use of the phrase ''takes into account'' consistent throughout the compensation exceptions in § 411.357. The consistent terminology would reflect our longstanding policy that the volume or value standard in the various compensation exceptions should be interpreted uniformly.

The following is a summary of the comments we received.

Comment: We received several comments supporting our proposal to consistently and uniformly use the phrase ''takes into account'' in reference to the volume or value standard in the exceptions for compensation arrangements in § 411.357. One commenter asked CMS to distinguish between compensation that ''varies with'' the volume or referrals and compensation that ''takes into account'' the volume or value of referrals. Another commenter asked CMS to include in the regulations at § 411.351 a definition of the phrase ''takes into account.''

Response: We are finalizing our proposal to make the use of the phrase ''takes into account'' consistent and uniform throughout the compensation arrangement exceptions in § 411.357. We did not propose to define the term ''takes into account,'' and we decline to do so at this time. Nevertheless, we are considering the commenter's proposed definition of ''takes into account'' and related discussion as part of our solicitation of comments on the perceived need for clarification regarding permissible physician compensation. Likewise, we decline to discuss the meaning of the phrase ''takes into account'' in relation to the phrase ''varies with,'' but we will consider the commenter's discussion of the issue as part of our solicitation of comments on permissible physician compensation.

As a result of the comments, we are finalizing the proposed changes to the regulations at § 411.357(e), (m), (r), and (s). The revision of the regulatory language reflects our policy that the volume or value standard is uniform and consistent in the exceptions for compensation arrangements in § 411.357.

d. Retention Payments in Underserved Areas

Our regulation at § 411.357(t) permits certain retention payments made to a physician with a practice located in an underserved area. This exception was first established in Phase II, and covered only retention payments made to a physician who has a *bona fide* firm, written recruitment offer that would require the physician to move his or her medical practice at least 25 miles and outside of the geographic area served by the hospital or FQHC making the retention payment (69 FR 16142). In Phase III, we modified the exception to permit a hospital, FQHC, or RHC to retain a physician who does not have a *bona fide* written offer of recruitment or employment if the physician certifies in writing that he or she has a *bona fide* opportunity for future employment that meets the requirements at § 411.357(t)(2) (72 FR 51066).

In Phase III, we explained that a retention payment based on a physician

certification may ''not exceed the lower of the following: (1) An amount equal to 25 percent of the physician's current *annual* income (*averaged over the previous 24 months*) using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician'' (72 FR 51066). We intended the regulations to mirror the preamble language precisely. However, the regulations at § 411.357(t)(2)(iv) state that such retention payments may not exceed the lower of: (1) An amount equal to 25 percent of the physician's current income (measured over no more than a 24-month period), using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician. Thus, the current regulation text appears to permit entities to make retention payments that consider only part of the prior 24-month period instead of the entire period as we intended.

The policy stated in the Phase III preamble is correct and remains our policy at this time. Therefore, to avoid confusion due to conflicting regulation text, we proposed to modify our regulations at § 411.357(t)(2)(iv)(A) to reflect the regulatory intent we articulated in Phase III. The following is a summary of the comments we received.

Comment: We received one comment supporting our proposed regulatory change to § 411.357(t). However, the commenter also stated that the current exception is too narrow, and urged CMS to expand the exception to permit retention payments as long as the hospital has a good faith belief that the physician is considering relocating his or her practice.

Response: We appreciate the commenter's support, and we are finalizing the proposed revision of § 411.357(t). We are not making any other changes to the exception at this time.

After reviewing the comments, we are finalizing our proposal to modify our regulations at § 411.357(t)(2)(iv)(A). The revised regulatory text clearly states our intention, as formulated in Phase III, that entities contemplating retention payments must consider the entire 24-month period prior to the payment.

3. Reducing Burden and Improving Clarity Regarding the Writing, Term, and Holdover Provisions in Certain Exceptions and Other Regulations

The SRDP enables providers and suppliers to disclose actual or potential violations of the physician self-referral law to CMS and authorizes the Secretary to reduce the amount potentially due and owing for disclosed violations. Since the SRDP was established, we have received numerous submissions to the SRDP disclosing actual or potential violations relating to the writing requirement of various compensation exceptions (for example, failure to set an arrangement out in writing, failure to obtain the signatures of the parties in a timely fashion, or failure to renew an arrangement that expired on its own terms after at least 1 year). This final rule with comment period clarifies the writing requirement of various compensation exceptions by making the terminology in the compensation exceptions more consistent and by providing policy guidance on the writing and 1-year minimum term requirements in many exceptions. In addition, to reduce regulatory burden, we proposed to except certain holdover arrangements, provided that certain safeguards are met.

a. The Writing Requirement in Certain Compensation Exceptions and Other Regulatory Provisions

The exceptions for the rental of office space and the rental of equipment (section 1877(e)(1) of the Act; § 411.357(a) and (b)) require that a lease be set out in writing. Several other compensation exceptions have a similar writing requirement: The exception at § 411.357(d) for personal service arrangements; the exception at § 411.357(e) for physician recruitment; the exception at § 411.357(h) for certain group practice arrangements with a hospital; the exception at § 411.357(l) for fair market value compensation; the exception at § 411.357(p) for indirect compensation arrangements; the exception at § 411.357(r) for obstetrical malpractice insurance subsidies; the exception at § 411.357(t) for retention payments in underserved areas; the exception at § 411.357(v) for electronic prescribing items and services; and the exception at § 411.357(w) for electronic health records items and services. Through our experience administering the SRDP, we have learned that there is uncertainty in the provider community regarding the writing requirement of the leasing and other compensation exceptions. In particular, we have been asked whether an arrangement must be reduced to a single ''formal'' written contract (that is, a single document that includes all material aspects of the arrangement) to satisfy the writing requirement of the applicable exception.

The original exception for the rental of office space required ''a written *agreement*, signed by the parties, for the rental or lease of the space . . . .'' (Omnibus Budget Reconciliation Act of 1989, Pub. L. 101–386, section 6204(e)(1)). In OBRA 1993, the Congress clarified the exception for the rental of office space (H. Rept. 103–213 at 812). Section 13562(e)(1) of OBRA 1993 (codified at section 1877(e)(1) of the Act) provides exceptions for the rental of office space and equipment if ''the *lease* is set out in writing . . . .'' OBRA 1993 also excepted personal service arrangements if ''the *arrangement* is set out in writing . . . .'' (OBRA 1993 section 13562(e)(3), codified at section 1877(e)(3) of the Act). The current regulatory exceptions for the rental of office space and the rental of equipment require at § 411.357(a)(1) and (b)(1), respectively, that an ''agreement'' be set out in writing. In contrast, the regulatory exception for personal service arrangements requires at § 411.357(d)(1)(i) that the ''arrangement'' be set out in writing.

Despite the different terminology in the statutory and regulatory exceptions, we believe that the writing requirement for the leasing exceptions and the personal service arrangements exception is the same. Specifically, we interpret the term ''lease'' in sections 1877(e)(1)(A) and (B) of the Act to refer to the lease *arrangement*. Notably, in the statutory scheme of section 1877 of the Act, the exceptions for the rental of office space, the rental of equipment, and personal service arrangements are classified as ''Exceptions Relating to Other Compensation Arrangements.'' The lease arrangement is the underlying financial relationship between the parties (that is, payments for the use of office space or equipment for a period of time). To satisfy the writing requirement, the facts and circumstances of the lease arrangement must be sufficiently documented to permit the government to verify compliance with the applicable exception. (For a similar discussion regarding arrangements among components of an academic medical center, see Phase II (69 FR 16110).)

In most instances, a single written document memorializing the key facts of an arrangement provides the surest and most straightforward means of establishing compliance with the applicable exception. However, there is no requirement under the physician

self-referral law that an arrangement be documented in a single formal contract. Depending on the facts and circumstances of the arrangement and the available documentation, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing.

Through the SRDP, we have learned that some stakeholders interpret the term ''agreement,'' as it is used at § 411.357(a)(1) and (b)(1), to mean that a single written contract is necessary to satisfy the writing requirement of the applicable exception. To clarify the exceptions for the rental of office space and the rental of equipment, we proposed to substitute the term ''lease arrangement'' for the term ''agreement'' at § 411.357(a)(1) and (b)(1). We believe that this revision underscores the fact that the writing requirement at § 411.357(a)(1) and (b)(1) for the rental of office space and the rental of equipment, respectively, is identical to the writing requirement at § 411.357(d)(1)(i) for personal service arrangements. Broadly speaking, we believe that there is no substantive difference among the writing requirements of the various compensation exceptions that require a writing. To emphasize the uniformity of the writing requirement in the compensation exceptions, we proposed to remove the term ''agreement'' from the exception for physician recruitment at § 411.357(e)(4)(i), the exception for fair market value compensation at § 411.357(l)(1), the special rule on compensation that is set in advance at § 411.354(d)(1), and the special rule on physician referrals to a particular provider, practitioner, or supplier at § 411.354(d)(4)(i).

In light of our proposal to clarify the writing requirement at § 411.354(d)(1), (d)(4)(i), (a)(1), (b)(1), (e)(4)(i), and (1)(1) by removing the term ''agreement,'' we proposed to make conforming changes where possible to other provisions in the compensation exceptions and the special rules on compensation. Specifically, we proposed to replace the term ''agreement'' with the term ''lease arrangement'' in § 411.357(a)(2), (a)(4), (a)(5), (a)(6), (b)(3), (b)(4), and (b)(5). We proposed to replace the term ''agreement'' with the term ''arrangement'' in § 411.357(c)(3) (the exception for *bona fide* employment relationships) and § 411.357(f)(2) (exception for isolated transactions). Likewise, we proposed to remove the phrase ''set forth in an agreement'' from the introductory language to the exception for fair market value compensation at § 411.357(l). Finally, we are also concerned that the words ''contract'' and ''contracted for,'' like the word ''agreement,'' may suggest that a formal contract or other specific kind of writing is required to satisfy the applicable exception. To address this issue, we proposed to revise § 411.354(d)(4) by replacing the word ''contract'' as it relates to personal service arrangements with the word ''arrangement,'' and we proposed similar changes to § 411.357(e)(1)(iv) and (r)(2)(v), both of which refer back to § 411.354(d)(4). We proposed to replace the phrase ''contracted for'' at § 411.357(d)(1)(iii) with the phrase ''covered by the arrangement.'' In the exception at § 411.357(p)(2) for indirect compensation arrangements, we proposed to replace the phrase ''written contract'' with the word ''writing.''

Certain compensation exceptions use the phrase ''written agreement'': The exception at § 411.357(h) for certain group practice arrangements with a hospital; the exception at § 411.357(v) for electronic prescribing items and services; and the exception at § 411.357(w) for electronic health records items and services. Although these exceptions use the term ''written agreement,'' we did not propose any revisions. The exception at § 411.357(h) is rarely used, because it only protects arrangements that began before, and continued without interruption since, December 19, 1989. The exceptions at § 411.357(v) and (w) are aligned with the Federal anti-kickback statute safe harbors at § 1001.952(x) and (y) that protect the provision of these items and services. To avoid creating apparent inconsistencies between the physician self-referral law exceptions and the corresponding anti-kickback statute safe harbors, we are not modifying § 411.357(v) or (w). However, we believe that the principles elucidated above regarding the writing requirement of the other compensation exceptions to the physician self-referral law also apply to § 411.357(v) and (w).

We are finalizing the proposed changes to clarify that parties need not reduce the key terms of an arrangement to a single formal contract to satisfy the writing requirement of the compensation exceptions at § 411.357 that require a writing. The following is a summary of the comments we received.

Comment: All the commenters addressing this issue supported our statement in the preamble that a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of various compensation exceptions. Two commenters complained that the writing and signature requirements, when interpreted narrowly, elevate form over substance. Several commenters requested that CMS confirm that our statement regarding a collection of documents is a clarification of existing policy, and that parties need not self-disclose arrangements where the writing requirement was satisfied by multiple documents (and all other requirements of the applicable exception were satisfied), even if the conduct occurred prior to the finalization of this rule.

Response: CMS' existing policy is that a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the exceptions for compensation arrangements that require a writing. Our proposal to substitute the word ''arrangement'' for ''agreement'' throughout the exceptions for compensation arrangements was intended to clarify and confirm this existing policy regarding the writing requirement. Parties considering submitting self-disclosures to the SRDP for conduct that predates the proposed rule may rely on guidance provided in the proposed rule to determine whether the party complied with the writing requirement of an applicable exception. To determine compliance with the writing requirement, the relevant inquiry is whether the available contemporaneous documents (that is, documents that are contemporaneous with the arrangement) would permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made.

Comment: Some commenters stated that State law contract principles should determine what constitutes an arrangement ''set out in writing'' for the purposes of the physician self-referral law. The commenters stated that health care providers and suppliers typically rely on State law principles to determine the validity and enforceability of written agreements, and that it would reduce the burden on providers and suppliers to use the same principles to determine compliance with the physician self-referral law.

Response: We decline to adopt the commenters' recommendation that State contract law principles should determine what constitutes an arrangement that is ''set out in writing'' for the purposes of the physician self-referral law. We are concerned that

reliance on State contract law would result in different standards for compliance for different States and territories. In addition, the requirements for a contract to be valid and enforceable under State law may differ substantively from the requirements of the physician self-referral law. For example, in certain instances, a short term service contract may be valid and enforceable under State law even if the agreement is not reduced to writing. In contrast, if the parties sought to protect the arrangement under the exception for fair market value compensation at § 411.357(l), the arrangement would have to be set out in writing to satisfy the requirements of the exception. Similarly, a contract for the provision of items may be enforceable under State law even if the price for the items is not in writing. In contrast, if the parties sought to protect the arrangement under the exception for fair market value compensation at § 411.357(l), the price of the items would have to be in writing to satisfy the requirements of the exception. Finally, we believe that it may be possible in some instances that writings documenting an arrangement may satisfy the writing requirement of the physician self-referral law, yet not form an enforceable contract under State law. In this context, we are concerned that reliance on State law contract principles may unduly narrow the scope of permissible arrangements under the physician self-referral law.

Although State law contract principles do not definitively determine compliance with the writing requirement of the physician self-referral law, the physician self-referral law does not negate or preempt State contract law. (See 72 FR 51049). Nothing prevents a party from drawing on State law contract principles, as well as other bodies of relevant law, to inform the analysis of whether an arrangement is set out in writing. The important point is this: What determines compliance with the writing requirement of the physician self-referral law is not whether the writings form a valid and enforceable contract under State law, but rather whether the contemporaneous writings would permit a reasonable person to verify that the arrangement complied with an applicable exception at the time a referral is made. For this reason, a written contract that is enforceable under State law may not satisfy the writing requirement if the actual arrangement differed in material respects from the terms and conditions of the written contract.

Comment: Two commenters pointed out that the preamble discussion of the writing requirement did not address the corresponding signature requirement in various compensation arrangement exceptions. The commenters noted that the ''collection of documents'' that may satisfy the writing requirement would still have to be signed by the parties for the arrangement to comply with the applicable exception. The commenter indicated that it is not clear to the commenter what is required to satisfy the signature requirement when parties are relying on a collection of documents to satisfy the writing requirement. Two commenters requested confirmation that a party's signature need only be included on one of the documents in the collection. Another commenter suggested that we draw on State law principles to clarify what constitutes a signed writing for the purposes of the physician self-referral law.

Response: As explained elsewhere in this section, we do not believe that State law principles determine compliance with the physician self-referral law, including compliance with the signature requirement. Regarding the signature requirement as it relates to a collection of documents, we note that the proposed rule clarified that a single written contract is not necessary to satisfy the writing requirement of an applicable exception. We substituted the word ''arrangement'' for ''agreement'' in the compensation exceptions to underscore the fact that it is the arrangement (that is, the underlying financial relationship between the parties) that must be set out in writing; there is no requirement that this writing take the form a formal contract between the parties. Likewise, under the proposed rule—which is a clarification of our existing policy—it is the arrangement that must be signed by the parties to satisfy the exception. (See, for example, the proposed language for § 411.357(a)(1) (''The lease arrangement . . . is signed by the parties . . . .'')). For the same reason that parties do not need a *single* formal written contract to comply with the writing requirement, parties also do not need to sign a *single* formal written contract to comply with the signature requirement of an applicable exception. Nor do we expect every document in a collection of documents to bear the signature of one or both parties. To satisfy the signature requirement, a signature is required on a contemporaneous writing documenting the arrangement. The contemporaneous signed writing, when considered in the context of the collection of documents and the underlying arrangement, must clearly relate to the other documents in the collection and the arrangement that the party is seeking to protect.

Comment: Some commenters asked for concrete examples of the kinds of documents (other than formal written agreements) that may satisfy the writing requirement of various compensation exceptions. In addition, one commenter specifically requested that CMS recognize that electronic documents, such as email communications, may be used to satisfy the writing requirement.

Response: Because compliance with the writing requirement is fact-specific, we decline to give an example of a collection of documents that would, taken as a whole, satisfy the writing requirement. However, we are providing some examples of individual documents that a party might consider as part of a collection of documents when determining whether a compensation arrangement complied with the writing requirement of an applicable exception: Board meeting minutes or other documents authorizing payments for specified services; written communication between the parties, including hard copy and electronic communication; fee schedules for specified services; check requests or invoices identifying items or services provided, relevant dates, and/or rate of compensation; time sheets documenting services performed; call coverage schedules or similar documents providing dates of services to be provided; accounts payable or receivable records documenting the date and rate of payment and the reason for payment; and checks issued for items, services, or rent. This list of examples is not exhaustive, and we emphasize that, depending on the facts and circumstances, a party could have documents of each type listed and nevertheless not satisfy the writing requirement of an applicable exception. Among other things, the documents must clearly relate to one another and evidence one and the same arrangement between the parties.

Comment: One commenter stated that parties should be permitted a 60- or 90-day grace period for satisfying the writing requirement of various compensation exceptions. The commenter stated that such a grace period is needed for last minute arrangements between physicians and DHS entities.

Response: We decline to adopt the commenter's suggestion. A grace period for the writing requirement would not incent parties to document the terms and conditions of the arrangement promptly. For this reason, we believe that a grace period for the writing requirement poses a risk of program or

patient abuse. For example, to the extent that the rate of compensation is not documented before a physician provides services to a DHS entity, the entity could adjust the rate of compensation during the proposed grace period in a manner that takes into account the volume or value of the physician's referrals. In this context, we note that the special rule at § 411.353(g)(1) for temporary noncompliance applies only to noncompliance with the signature requirement of an applicable exception. All other elements of an applicable exception, including the applicable writing requirement, must be satisfied once a compensation arrangement between the parties is established (that is, as soon as items, services, or compensation under the arrangement passes between the parties) and the physician makes referrals to the DHS entity.

We remind parties that DHS entities have the burden of proof to establish that services were not furnished as a result of prohibited referrals, and that all requirements of an exception must be met at the time a referral is made. (See § 411.353(c)(2)(i) and 73 FR 48703.) If an arrangement with a physician fails to comply with the writing requirement of an applicable exception when the arrangement commences, then the entity is not permitted to bill for DHS furnished as a result of the physician's referrals unless and until the arrangement is sufficiently documented over the course of the arrangement (and all other requirements of the applicable exception are met). Contemporaneous documents evidencing the course of conduct between the parties cannot be relied upon to protect referrals that predate the documents. Likewise, parties cannot meet the set in advance requirement from the inception of an arrangement if the only documents stating the compensation term of an arrangement were generated after the arrangement began; however, depending on the facts and circumstances, if parties create contemporaneous documents during the course of the arrangement, and the documents set the compensation out in writing, then parties may be able to satisfy the set in advance requirement for referrals made *after* the contemporaneous documents are created. We reiterate that the surest and most straightforward means of complying with the writing requirement of the physician self-referral law is to reduce the key facts of an arrangement to a single signed writing before either party provides items, services, space, or compensation to the other party under the arrangement.

After careful consideration of the comments, we are finalizing our proposal to substitute the word ''arrangement'' for ''agreement'' in various provisions of § 411.354 and § 411.357 identified in the proposed rule. The revision of the regulatory language reflects our existing policy that a single formal contract is not required to satisfy the writing requirement of those compensation exceptions at § 411.357 that require a writing.

b. Term Requirements in Certain Compensation Arrangements Exceptions

The exceptions at § 411.357(a), (b), and (d) for the rental of office space, the rental of equipment, and personal service arrangements, respectively, require that the compensation arrangement between an entity furnishing DHS and a referring physician has a term of at least 1 year. Parties submitting self-disclosures to the SRDP have asked whether the term of the arrangement must be in writing to satisfy the requirements of the relevant exceptions. We proposed to revise § 411.357(a)(2), (b)(3), and (d)(1)(iv) to clarify the documentation requirements related to the term of lease arrangements for the rental of office space, lease arrangements for the rental of equipment, and personal service arrangements.

The statutory exceptions for the rental of office space and the rental of equipment in sections 1877(e)(1)(A)(iii) and (B)(iii) of the Act, respectively, require that the lease arrangement provides for a term of rental or lease for at least 1 year. The statutory exception for personal service arrangements in section 1877(e)(3)(A)(iv) of the Act requires that the term of the arrangement is at least 1 year. Although our regulations at § 411.357(d)(1)(iv) (the exception for personal service arrangements) use language similar to the statutory exception for personal service arrangements, our current regulations at § 411.357(a)(2) and (b)(3) (the exceptions for the rental of office space and equipment, respectively) use the term ''agreement'' in addressing the minimum term requirement. As explained elsewhere in this section, we interpreted ''lease'' in section 1877(e)(1) of the Act to refer to the lease arrangement between the parties, and we also believe that the writing requirement of sections 1877(e)(1)(A) and (B) of the Act is identical to the requirement in section 1877(e)(3) of the Act.

We believe that some stakeholders have interpreted the term ''agreement'' at § 411.357(a)(2) and (b)(3) to mean that a formal written contract or other document with an explicit provision identifying the term of the arrangement is necessary to satisfy the 1-year term requirement of the exceptions. As we noted in the 1998 proposed rule, the 1-year term requirement is satisfied ''as long as the arrangement clearly establishes a business relationship that will last for at least 1 year'' (63 FR 1713). An arrangement that lasts as a matter of fact for at least 1 year satisfies this requirement. Parties must have contemporaneous writings establishing that the arrangement lasted for at least 1 year, or be able to demonstrate that the arrangement was terminated during the first year and that the parties did not enter into a new arrangement for the same space, equipment, or services during the first year, as required by § 411.357(a)(2), (b)(3), and (d)(1)(iv), as applicable. As is the case with the writing requirement in these and other exceptions, depending on the facts and circumstances of the arrangement and the available documentation, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, can establish that the arrangement in fact lasted for the required period of time. A formal contract or other document with an explicit ''term'' provision is generally not necessary to satisfy this element of the exception. To clarify that a written contract with a formalized ''term'' provision is not necessary to satisfy the regulations at § 411.357(a)(2) and (b)(3), we proposed to remove the word ''agreement'' and to revise the first sentence of these provisions to mirror the 1-year term requirement in the personal service arrangements exception at § 411.357(d)(1)(iv).

We are finalizing revised regulatory language that clearly reflects the policy stated in the proposed rule, namely that an arrangement need only last at least 1 year as a matter of fact to satisfy the 1-year term requirement at § 411.357(a)(2), (b)(3), and (d)(1)(iv). The following is a summary of the comments we received.

Comment: All those that commented on this issue (38, 50, 68, 73, 80) supported our statement in the preamble that arrangements that last for at least 1 year satisfy the 1-year term requirement. One commenter requested that CMS confirm that the statement in the preamble regarding the 1-year requirement is a clarification of existing law. Another commenter (38) recommended that CMS further revise the regulatory language at § 411.357(a)(2), (b)(3), and (d)(1)(iv), to make it more clear that arrangements need only last as a matter of fact for at

least 1 year satisfy the 1-year requirement.

Response: To clarify that the length of an arrangement need not be stated explicitly in a formal contract, we proposed to revise the 1-year term provisions at § 411.357(a)(2), (b)(3), and (d)(1)(iv), by substituting the word ''arrangement'' for the word ''agreement.'' In the preamble, we explained that an arrangement that lasts as a matter of fact for at least 1 year would satisfy this requirement. We agree with the commenter that the proposed regulatory language does not unambiguously express our intent, as it was stated in the preamble. Specifically, we believe the word ''term'' in the phrase ''the term of the lease arrangement is at least 1 year'' is ambiguous. ''Term'' could mean either the duration of the arrangement as a matter of fact or the formal term provision of the arrangement as prescribed by contract. To clarify in the regulatory text that arrangements that last for at least 1 year as a matter of fact satisfy the requirement, we are further modifying § 411.357(a)(2), (b)(3), and (d)(1)(iv). We are removing the word ''term'' and simply stating that the duration of the arrangement must be at least 1 year. Finally, we are taking this opportunity to clarify that our statement in the preamble regarding compliance with the 1-year term requirement represents CMS' existing policy.

Comment: One commenter generally supported our proposal, but suggested that CMS rely on State law contract principles to determine compliance with the 1-year term requirement of the physician self-referral law.

Response: As stated elsewhere in this section, we do not believe that State law principles are appropriate for determining compliance with the physician self-referral law, including the 1-year requirement.

Upon review and consideration of the comments regarding the 1-year term requirement, we are finalizing revised regulatory language for the exceptions at § 411.357(a)(2), (b)(3), and (d)(1)(iv). The revised language at § 411.357(a)(2) provides that the duration of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter a new lease arrangement for the same space during the first year of the original lease arrangement. We are finalizing similar language for § 411.357(b)(3) and (d)(iv). The revised regulatory text clearly states our current policy that an arrangement need only last 1 year to satisfy the 1-year term requirement of the exceptions for the rental of office space, the rental of equipment, and personal service arrangements.

c. Holdover Arrangements

The exceptions at § 411.357(a), (b), and (d) currently permit a ''holdover'' arrangement for up to 6 months if an arrangement of at least 1 year expires, the arrangement satisfies the requirements of the exception when it expires, and the arrangement continues on the same terms and conditions after its stated expiration. We proposed to amend the holdover provisions at § 411.357(a)(7), (b)(6), and (d)(1)(vii) to permit indefinite holdovers, provided that certain additional safeguards are met. In the alternative, we proposed to extend the holdover to a definite period that is greater than 6 months (for example, 1 year, 2 years, or 3 years), provided that additional safeguards are met. Finally, we proposed to revise the exception for fair market value compensation at § 411.357(l)(2) to permit renewals of arrangements of any length of time, including arrangements for 1 year or greater.

The holdover provisions in § 411.357(a), (b), and (d) developed over the course of our rulemaking in *Response*: to inquiries regarding the expiration, termination, and renewal of arrangements. See 80 FR 41916 through 41917 for a discussion of the development of the holdover provisions.

Through our administration of the SRDP, we have reviewed numerous rental and personal service arrangements that failed to satisfy the requirements of an applicable exception solely because the arrangement expired by its terms and the parties continued the arrangement on the same (compliant) terms and conditions after the 6-month holdover period ended. In our experience, an arrangement that continues beyond the 6-month period does not pose a risk of program or patient abuse, provided that the arrangement continues to satisfy the specific requirements of the applicable exception, including the requirements related to fair market value, compensation that does not take into account the volume or value of referrals or other business generated between the parties, and reasonableness of the arrangement. We reconsidered our previous position and proposed to eliminate the time limitations on holdovers with safeguards to address two potential sources of program or patient abuse: frequent renegotiation of short term arrangements that take into account a physician's referrals and compensation or rental changes that become inconsistent with fair market value over time.

To prevent frequent renegotiation of short term arrangements, the holdover must continue on the same terms and conditions as the original arrangement. If the parties change the original terms and conditions of the arrangement during the holdover, we would consider this a new arrangement. The new arrangement would be subject to the 1-year term requirement at § 411.357(a)(2), (b)(3), or (d)(1)(iv) (or it must satisfy the requirements of the exception for fair market value compensation at § 411.357(l), if applicable). We believe that these safeguards, which are already incorporated into the current exceptions, prevent frequent renegotiations of short-term arrangements.

To ensure that compensation is consistent with or does not exceed fair market value, as applicable, the proposed holdover provisions require that the holdover arrangement satisfy all the elements of the applicable exception when the arrangement expires and on an ongoing basis during the holdover. Thus, if office space rental payments are fair market value when the lease arrangement expires, but the rental amount falls below fair market value at some point during the holdover, the lease arrangement would fail to satisfy the requirements of the applicable exception at § 411.357(a) as soon as the fair market value requirement is no longer satisfied, and DHS referrals by the physicians to the entity that is party to the arrangement would no longer be permissible. In addition, the entity could not bill the Medicare program for DHS furnished as a result of a referral made by the physician after the rental charges were no longer consistent with fair market value. The requirement that the arrangement is set out in writing continues to apply during the holdover. To satisfy this requirement, the parties must have documentary evidence that the arrangement in fact continued on the same terms and conditions. Depending on the facts and circumstances of the arrangement and the available documentation, the expired written agreement and a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement for the holdover.

As noted above, we proposed to revise the holdover provisions at § 411.357(a)(7), (b)(6), and (d)(1)(vii) to permit indefinite holdovers under certain conditions. Specifically, the arrangement must comply with the applicable exception when it expires by its own terms; the holdover must be on the same terms and conditions as the

immediately preceding arrangement; and the holdover must continue to satisfy the requirements of the applicable exception. In the alternative, we proposed to extend the holdover for a definite period (for example, a 1-, 2-, or 3-year holdover period) or for a period of time equivalent to the term of the immediately preceding arrangement (for example, a 2-year lease arrangement would be considered renewed for a new 2-year period). We stated in the proposed rule our belief that, if the holdover is extended for a definite period beyond 6 months, the safeguards outlined above for indefinite holdovers are necessary to prevent program or patient abuse. We sought comments on what additional safeguards, if any, are necessary to ensure that holdovers lasting longer than 6 months do not pose a risk of program or patient abuse.

In addition to our proposals to extend the holdover provisions at § 411.357(a)(7), (b)(6), and (d)(1)(vii), we proposed to amend the exception at § 411.357(l) for fair market value compensation arrangements. Section 411.357(l)(2) currently allows arrangements for less than 1 year to be renewed any number of times, provided that the terms of the arrangement and the compensation for the same items or services do not change. Currently, the renewed arrangement must continue to satisfy all the requirements of the exception, including the requirement that the compensation is consistent with fair market value. We proposed to amend § 411.357(l)(2) to permit arrangements of any timeframe, including arrangements for more than 1 year, to be renewed any number of times. We believe that the proposal does not pose a risk of patient or program abuse, because the arrangement must be renewed on the same terms and conditions. In addition, as is the case currently, the renewed arrangement must satisfy all the requirements of the exception at the time the physician makes a referral for DHS and the entity bills Medicare for the DHS. We solicited comments as to whether the proposed revision of § 411.357(l)(2) would be necessary if we revise § 411.357(d)(1)(vii) to permit indefinite holdovers.

We are finalizing the proposed indefinite holdover provisions for the exceptions at § 411.357(a)(7), (b)(6), and (d)(1)(vii). We are also finalizing our proposal to remove the phrase ''made for less than 1 year'' at § 411.357(l)(2). The following is a summary of the comments we received.

Comment: The majority of commenters supported our proposal to permit indefinite holdovers of arrangements that continue on the same terms and conditions as an expired arrangement, provided all elements of the applicable exception continue to be satisfied during the holdover. No commenter suggested that additional safeguards would be necessary, and no commenter favored holdover provisions with potentially shorter durations, such as 1, 2, or 3 years. One commenter stated that additional safeguards for holdovers arrangements are not necessary, because, according to the commenter, an arrangement that continues after the expiration of a term in a contract, but is contemporaneously documented during the ''holdover'' period, may satisfy the writing requirement of an exception even if there is no special regulatory provision relating to holdovers.

Response: We appreciate the commenters' support, and we are finalizing the proposed indefinite holdover provisions. We agree with the commenter that, even without a holdover provision, an arrangement that continued after a contract expired on its own terms could potentially satisfy the writing requirement of an applicable exception, provided that the parties had sufficient contemporaneous documentation of the arrangement. Nevertheless, we believe that the proposed holdover provision will facilitate compliance without posing a risk of program or patient abuse. If a written contract with an explicit term provision expires on its own terms, but the parties nevertheless continue the arrangement past the expiration, the expired written contract by its own terms does not apply to the continued arrangement. For this reason, without a holdover provision, an expired written contract, on its own, could not satisfy the writing requirement of an applicable exception. Without additional supporting documentation, there may be gaps in compliance, as it may take some time after the expiration of the written contract to generate sufficient documents evidencing the course of conduct between the parties after the contract expired. In contrast, with a holdover provision, parties can rely in part on the expired written contract to satisfy the writing requirement for the holdover period. We note, however, that parties relying on the holdover provisions must still have contemporaneous documents establishing that the holdover continued on the same terms and conditions as the immediately preceding arrangement. That is, a party must be able to establish that it satisfied the requirements for the holdover provisions at § 411.357(a)(7), (b)(6), or (d)(1)(vii) for referrals made during the holdover period.

Comment: One commenter objected to our statement in the proposed rule that, if rental amounts fall below fair market value during a holdover, the lease arrangement would no longer satisfy the fair market value requirement of the exception at § 411.357(a). According to the commenter, our statement implies that an arrangement that falls out of fair market value during its term loses protection under the exception. The commenter suggested that we retract the statement in the final rule. Another commenter supported our proposal to require holdover arrangements to continue to satisfy the applicable fair market value requirement during the holdover, but requested that CMS confirm that fair market value is determined at the commencement of the arrangement, taking into account the length of the term.

Response: The statement cited by the commenter regarding rental amounts falling below fair market value referred only to the application of the relevant fair market value requirement during a holdover. We believe that ongoing compliance with the fair market value requirement during the holdover is necessary to prevent program or patient abuse. Regarding the fair market value requirement during the original term, we expect parties to make a determination of fair market value at the time the financial relationship is created. (See 73 FR 48739.) The exception at § 411.357(a)(4) requires rental charges to be consistent with fair market value ''over the term of the arrangement,'' but we note that fair market value is expressed as a range of values. We caution that rental payments may cease to be consistent with fair market value in long-term arrangements.

Comment: One commenter stated that it may be difficult for an arrangement to satisfy the fair market value requirement during a holdover that lasts for more than 1 year. The commenter requested guidance on how the fair market value requirement should be analyzed in a multiple year holdover.

Response: As noted elsewhere in this section, the requirement that an arrangement continue to meet the fair market value requirement throughout the holdover is necessary to prevent program or patient abuse. Parties relying on a holdover provision bear the risk of fluctuations in the relevant market that may cause an arrangement to no longer satisfy the applicable fair market value requirement. In most instances, fair market value is expressed as a range, and minor fluctuations in market value may not cause an arrangement to

become noncompliant. (See 73 FR 48739.) However, as soon as a holdover arrangement ceases to meet all the requirements of an applicable exception, including the fair market value requirement, referrals for DHS by the physician to the entity that is a party to the arrangement are no longer permissible. It is up to the parties to determine the best way to analyze fair market value during a holdover. The best means of ensuring ongoing compliance is to enter into a new agreement in a timely manner after a previous contract expires, and to reassess fair market value to the extent that is necessary at the time of the renewal.

Comment: One commenter requested that CMS permit changes to the terms and conditions of an arrangement during a holdover, provided that the changes do not impact compliance with the elements of an applicable exception.

Response: Under the revised regulations, an indefinite holdover lease arrangement or personal service arrangement is permitted if the arrangement continues on the same terms and conditions as the immediately preceding arrangement. As stated in the proposed rule, the holdover arrangement must continue on the same terms and conditions because frequent renegotiation of short term arrangements poses a risk of program or patient abuse. (See 80 FR 41917). If parties were permitted to amend the terms and conditions of an arrangement in the course of the holdover, then parties would be able to frequently renegotiate the terms of the arrangement during the holdover in a manner that could take into account the volume or value of referrals. Thus, parties are not permitted to amend the terms and conditions of an arrangement during a holdover, because such changes pose a risk of program or patient abuse.

Comment: One commenter stated that many leases provide that the rental amount will increase if the tenant holds over after the lease expires on its own terms. The commenter requested guidance on how the fair market value requirement would apply to increased rental amounts during the holdover period.

Response: In Phase III, we stated that lessors can charge a holdover premium, ''provided that the amount of the premium was set in advance in the lease agreement (or in any subsequent renewal) at the time of its execution and the rental rate (including the premium) remains consistent with fair market value and does not take into account the volume or value of referrals or other business generated between the parties.'' (See 72 FR 51045). The same principles apply to the indefinite holdover provisions that we are finalizing. The rental amount with the holdover premium must satisfy the fair market value requirement when the original agreement expires and throughout the holdover.

We caution that, depending on the facts and circumstances, the failure to apply a holdover premium that is legally required by the original arrangement may constitute a change in the terms and conditions of the original arrangement. In such circumstances, the ''holdover'' arrangement will not meet the requirement at § 411.357(a)(7)(ii) that the arrangement continue on the same terms and conditions as the immediately preceding arrangement. In addition, the failure to charge a holdover premium may constitute the forgiveness of a debt, thus creating a secondary financial relationship between the parties that must satisfy the requirement of an applicable exception.

Comment: One commenter supported the proposal to allow parties to renew arrangements of any duration, including arrangements of 1 year or more, under the exception for fair market value compensation at § 411.357(l). Several other commenters requested that an indefinite holdover provision, similar to the proposal for lease arrangements and personal service arrangements, be applied to the exception for fair market value compensation. The commenters stated that the exception for fair market value compensation is similar in many respects to the exceptions for lease arrangements and personal service arrangements, and therefore, the commenters saw no reason to include an indefinite holdover provision in the latter exceptions while not including such a provision in the exception for fair market value compensation.

Response: We believe that permitting parties to renew arrangements of any length under the exception for fair market value compensation, provided that the terms of the arrangement and the compensation for the same items or services do not change, affords parties sufficient flexibility without posing a risk of program or patient abuse. For this reason, we do not believe that a separate holdover provision is necessary for the exception for fair market value compensation. We note that nothing in the exception requires parties to renew the arrangement in writing. However, the parties must have written documentation establishing that the renewed arrangement was on the same terms and conditions as the original arrangement.

Comment: One commenter stated that the exception at § 411.357(l) as it is currently worded does not prohibit the renewal of arrangements with a term of more than 1 year. The commenter stated that our proposed revision was unnecessary and requested clarification in the final rule that the exception has always permitted the renewal of arrangements of more than 1 year.

Response: The exception as it is currently written permits arrangement for less than 1 year to be renewed any number of times if the terms of the arrangement and compensation for the same items or services do not change. There is no requirement that the arrangement of less than 1 year be renewed in writing. The arrangement can be renewed by course of conduct, and the writing requirement for the renewal period would be satisfied (assuming that it was satisfied for the initial term) if the parties had documents establishing that the arrangement continued on the same terms and conditions. Under our proposed rule, arrangements for 1 year or longer could also be renewed by course of conduct, provided that the parties have documentation establishing that the terms of the arrangement and the compensation for the same items or services do not change during the renewal.

It is true that the exception as currently written does not expressly prohibit parties from renewing arrangements of 1 year or longer. Nonetheless, given the purpose of the exception when it was first established, we believe the better reading of the exception does not rely on reading missing words into the text and, therefore, we are not retracting our statement from the proposed rule.

Comment: One commenter stated that the exception for fair market value compensation currently requires that the term of the arrangement must be specified in writing. The commenter requested that CMS create a ''safe harbor'' timeframe of 6 months for arrangements that do not specify the timeframe in writing.

Response: We decline to create a ''safe harbor'' timeframe for the exception for fair market value compensation. We note, however, that the timeframe can be specified in a collection of documents setting out the arrangement in writing.

After reviewing the comments, we are finalizing the proposed indefinite holdover provisions for the exceptions at § 411.357(a)(7), (b)(6), and (d)(1)(vii). We are also finalizing our proposal to remove the phrase ''made for less than 1 year'' at § 411.357(l)(2). We believe

that lease arrangements and personal service arrangements that continue on the same terms and conditions and satisfy the requirements for the new holdover provisions (including ongoing compliance with all the requirements of an applicable exception) do not pose a risk of program and patient abuse. We also believe that allowing renewals of an arrangement of any timeframe under the exception for fair market value compensation at § 411.357(l), provided the arrangement is renewed on the same terms and conditions, affords DHS entities additional flexibility in their arrangements and facilitates compliance, without posing a risk of program or patient abuse; we remind stakeholders that the renewed arrangement must satisfy all the requirements of the exception at the time a referral for DHS is made.

The indefinite holdover provisions will be available to parties on the effective date of this final rule. Parties who are in a valid holdover arrangement under the current 6-month holdover provisions on the effective date of this final rule may make use of the indefinite holdover provisions that we are finalizing, provided that all the requirements of the new holdover provisions are met. On the other hand, if an arrangement does not qualify for the 6-month holdover under the current regulations at § 411.357(a)(7), (b)(6), or (d)(1)(vii) on the effective date of this rule (for example, if the holdover has lasted for more than 6 months as of the effective date of the rule), then the parties cannot make use of the indefinite holdover provisions.

4. Definitions

In the proposed rule, we proposed to revise several definitions in our regulations to improve clarity and ensure proper application of our policies. We describe below the specific proposals. We are now finalizing the revised definitions as proposed, without additional modification.

a. Remuneration (§ 411.351)

A compensation arrangement between a physician (or an immediate family member of such physician) and a DHS entity implicates the referral and billing prohibitions of the physician self-referral law. Section 1877(h)(1)(A) of the Act defines the term ''compensation arrangement'' as any arrangement involving any ''remuneration'' between a physician (or an immediate family member of such physician) and an entity. However, section 1877(h)(1)(C) of the Act identifies certain types of remuneration which, if provided, would not create a compensation arrangement subject to the referral and billing prohibitions of the physician self-referral law. Under section 1877(h)(1)(C)(ii) of the Act, the provision of the following items, devices, or supplies does not create a compensation arrangement between the parties: Items, devices, or supplies that are ''used solely'' to collect, transport, process, or store specimens for the entity providing the items, devices, or supplies, or to order or communicate the results of tests or procedures for such entity. Furthermore, under our regulations at § 411.351, the provision of such items, devices, or supplies is not considered to be remuneration. As explained at 80 FR 41918, we proposed to revise the definition of ''remuneration'' at § 411.351 to make it clear that the provision of an item, device, or supply that is used for one or more of the six purposes listed in the statute, and no other purpose, does not constitute remuneration.

We received two comments in support of our proposed revision of the definition of ''remuneration.'' We are finalizing the revisions to § 411.351 as proposed.

Although we did not propose regulatory revisions, we noted in the proposed rule that we are concerned about potential confusion regarding whether remuneration is conferred by a hospital to a physician when both facility and professional services are provided to patients in a hospital-based department. Following commentary by the Third Circuit Court of Appeals in its decision in *United States ex rel. Kosenske v. Carlisle HMA*, 554 F.3d 88 (3d Cir. 2009), we received several written inquiries asking whether certain so-called ''split bill'' arrangements between physicians and DHS entities involve remuneration between the parties that gives rise to a compensation arrangement for the purposes of the physician self-referral law. We are taking the opportunity afforded by this rulemaking to address this issue.

In a ''split bill'' arrangement, a physician makes use of a DHS entity's resources (for example, examination rooms, nursing personnel, and supplies) to treat the DHS entity's patients. The DHS entity bills the appropriate payor for the resources and services it provides (including the examination room and other facility services, nursing and other personnel, and supplies) and the physician bills the payor for his or her professional fees only. We do not believe that such an arrangement involves remuneration between the parties, because the physician and the DHS entity do not provide items, services, or other benefits to one another. Rather, the physician provides services to the patient and bills the payor for his or her services, and the DHS entity provides its resources and services to the patient and bills the payor for the resources and services. There is no remuneration between the parties for the purposes of section 1877 of the Act.

In contrast, if a physician or a DHS entity bills a non-Medicare payor (that is, a commercial payor or self-pay patient) globally for both the physician's services and the hospital's resources and services, a benefit is conferred on the party receiving payment. Specifically, the party that bills globally receives payment for items or services provided by the other party. Such a global billing arrangement involves remuneration between the parties that implicates the physician self-referral law.

The following is a summary of the comments we received.

Comment: The overwhelming majority of those that commented on the issue of split billing and remuneration agreed that a physician's use of hospital resources when treating hospital patients does not constitute remuneration between the parties for the purposes of the physician self-referral law, if the hospital bills the appropriate payor for the resources and services it provides and the physician bills the payor for his or her services. One commenter asked CMS to confirm that our statement is a clarification of existing law. Several other commenters requested that we codify our position in regulatory text. Two commenters requested that we confirm our interpretation by amending the definition of ''remuneration'' at § 411.351.

Response: Our discussions in the preamble to the proposed rule and in this final rule regarding remuneration and split bill arrangements is a statement of CMS' existing policy. We did not propose any regulatory revisions in the proposed rule because we did not think it necessary, and therefore, we cannot make revisions to the regulatory text at this time.

Comment: One commenter asked whether a hospital's promise to grant a physician organization exclusive use of the hospital's space constituted remuneration for the purposes of the physician self-referral law, if the hospital bills the appropriate payor for the space it provides and the physician bills the payor for his or her services. According to the commenter, in Kosenske the hospital promised a physician group exclusive use of the hospital's space.

Response: Our clarification regarding split bill arrangements and remuneration applied only to the use of a hospital's space, items, and equipment. We are not addressing exclusive use of space in this final rule with comment period.

Following our review of the comments, we are confirming our existing policy that a physician's use of a hospital's resources (for example, examination rooms, nursing personnel, and supplies) when treating hospital patients does not constitute remuneration under the physician self-referral law, when the hospital bills the appropriate payor for the resources and services it provides (including the examination room and other facility services, nursing and other personnel, and supplies) and the physician bills the payor for his or her professional fees only. We emphasize that this statement reflects our interpretation of the term ''remuneration'' and policy on the issue.

b. Compensation Arrangements—''Stand in the Shoes'' (§ 411.354(c))

Phase III included provisions under which all physicians would be treated as ''standing in the shoes'' of their physician organizations for the purposes of applying the rules regarding direct and indirect compensation arrangements at § 411.354(c) (72 FR 51026 through 51030). (Since Phase II, we have considered a referring physician and the professional corporation of which he or she is the sole owner to be the same for the purposes of the physician self-referral regulations (69 FR 16131).) The FY 2009 IPPS final rule amended § 411.354(c) to: (1) Treat a physician with an ownership or investment interest in a physician organization as standing in the shoes of that physician organization; and (2) permit parties to treat a physician who does not have an ownership or investment interest in a physician organization as standing in the shoes of that physician organization. An exception to the mandatory treatment of physicians with ownership or investment interests as standing in the shoes of their physician organizations was made for physicians with ''titular'' ownership or investment interests only (73 FR 48691 through 48700). A ''physician organization'' is defined at § 411.351 as a physician, a physician practice, or a group practice that complies with the requirements of § 411.352. Therefore, as of October 1, 2008, for the purposes of determining whether a direct or indirect compensation arrangement exists between a physician and an entity to which the physician makes referrals for the furnishing of DHS, if the physician has an ownership or investment interest in the physician organization that is not merely titular, the physician stands in the shoes of the physician organization. The physician is considered to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization in whose shoes he or she stands.

In Phase III, we established the rule at § 411.354(c)(3)(i), which provides that a physician who stands in the shoes of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. The regulation also states that, when applying the exceptions in § 411.355 and § 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the relevant referrals and other business generated ''between the parties'' are referrals and other business generated between the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians). Our intent for this provision was to make clear that, under the Phase III ''stand in the shoes'' policy (which considered all physicians in a physician organization to stand in the shoes of the physician organization), each physician in the physician organization was considered a ''party'' to an arrangement between the physician organization and a DHS entity.

Following the FY 2009 IPPS final rule changes limiting the ''stand in the shoes'' rules only to physicians with ownership or investment interests in their physician organizations (other than those with merely a titular ownership or investment interests) and physicians who voluntarily stand in the shoes of their physician organizations, stakeholders inquired whether the change in the ''stand in the shoes'' policy meant that, when applying the exceptions in § 411.355 and § 411.357, for the purposes of determining whether compensation takes into account the volume or value of referrals or other business generated between the ''parties,'' the only ''parties'' to consider are the physicians with ownership or investment interests in their physician organizations. This was not our intent in revising the ''stand in the shoes'' rules in the FY 2009 IPPS final rule.

To address the issue raised by the stakeholders, we proposed to revise § 411.354(c)(3)(i) so that it is consistent with our work in the FY 2009 IPPS final rule. Our intent there was, and currently remains, that only physicians who stand in the shoes of their physician organization are considered parties to an arrangement for the purposes of the signature requirements of the exceptions. For such purposes, we do not consider employees and independent contractors to be parties to a physician organization's arrangements unless they voluntarily stand in the shoes of the physician organization as permitted under § 411.354(c)(1)(iii) or (c)(2)(iv)(B). Guidance regarding physicians who stand in the shoes of their physician organizations may be found on our Web site at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/FAQs.html.* Specifically, consistent with our response in Frequently Asked Question #12318, for the purposes of satisfying the requirements of an exception to the physician self-referral prohibition, we consider a physician who is standing in the shoes of his or physician organization to have satisfied the signature requirement of an applicable exception when the authorized signatory of the physician organization has signed the writing evidencing the arrangement.

For purposes other than satisfying the signature requirements of the exceptions, we remain concerned about the referrals of *all* physicians who are part of a physician organization that has a compensation arrangement with a DHS entity when we analyze whether the compensation between the DHS entity and the physician organization takes into account the volume or value of referrals or other business generated between the parties. If we did not consider the referrals of all the physicians in the physician organization, and instead only considered the referrals of those physicians who stand in the shoes of the physician organization, DHS entities would be permitted to establish compensation methodologies that take into account the volume or value referrals or other business generated by non-owner physicians in a physician organization when entering into a compensation arrangement with the physician organization. Therefore, we proposed to amend § 411.354(c)(3)(i) to clarify that, for all purposes other than the signature requirements, all physicians in a physician organization are considered parties to the compensation arrangement between the physician organization and the DHS entity.

The following is a summary of the comments we received.

Comment: One commenter disliked the proposed revisions to the ''stand in the shoes'' regulations at § 411.354(c)(3)(i), stating that, prior to

the revision, a physician who did not stand in the shoes of his or her physician organization was not a ''party'' to any compensation arrangement between the physician organization and a DHS entity. The commenter recognized that such a physician's referrals had to be considered when determining the compliance of the compensation arrangement with the volume or value standard in various exceptions, but did not agree that the identifier ''party'' should be applied to a physician who does not stand in the shoes of his or her physician organization. Another commenter was concerned that this revision would create direct compensation arrangements between a DHS entity and the physician employees of a physician organization who do not stand in the shoes of the physician organization under the current regulations.

Response: We disagree that the revised regulation at § 411.354(c)(3)(i) will have the effect of transforming physicians who do not stand in the shoes of their physician organizations into ''parties'' to a compensation arrangement between a DHS entity and the physician organization. In many exceptions, the volume or value standard (described in detail elsewhere in this section) is expressed by prohibiting compensation that is determined in a manner that takes into account the volume or value of referrals or other business generated ''between the parties.'' Most exceptions also include a requirement that the writing evidencing the arrangement be signed by the ''parties.'' In interpreting the physician self-referral exceptions, we attach the same meaning to a term or phrase wherever it is used, unless otherwise specified explicitly in the regulation text. To do otherwise would introduce confusion into the regulations, as a single term or phrase could have different meanings in different exceptions, or even in the same exception if the term or phrase is used more than once. Therefore, if a physician is considered a ''party'' for the purposes of the volume or value standard, he or she would be considered a ''party'' for the purposes of the signature requirement.

As the commenter correctly recognized, the referrals of all physicians in a physician organization—regardless of whether the physicians stand in the shoes of the physician organization—must be considered when determining compliance with the volume or value standard in the exceptions at § 411.355 and § 411.357. Thus, the physicians who do not stand in the shoes of the physician organization would nonetheless be considered ''parties'' for the purposes of analyzing compliance with the volume or value standard. Given our uniform interpretation of terms and phrases used in the physician self-referral regulations, under our current regulations, even physicians who do not stand in the shoes of their physician organizations may be required to meet the signature requirements for ''parties.'' We do not believe there is a need to include these physicians as ''parties'' that must sign the writing evidencing the arrangement between a DHS entity and a physician organization. The revision to § 411.354(c)(3)(i) is merely intended to alleviate the burden on physician organizations related to the signature requirements in many of the exceptions at § 411.355 and § 411.357 that would otherwise require the signatures of physicians who do not stand in the shoes of their physician organizations. It does not affect the regulations at § 411.354(c)(1)(ii) or (c)(2)(iv), which identify physicians who are deemed to stand in the shoes of their physician organizations and have the same compensation arrangements as their physician organizations. Moreover, we note that our determination of which physicians are ''parties'' for the purposes of applying the exceptions at § 411.355 and § 411.357 should not affect which physicians and entities are considered parties to a contract under State or any other law.

Comment: One commenter requested additional clarification regarding our statements in the proposed rule regarding the ''stand in the shoes'' provisions at § 411.354(c)(3)(i). Specifically, the commenter was concerned that the language in the proposed rule could be construed as conflating what it understands to be two separate analyses: (1) The analysis of a direct compensation arrangement between a DHS entity (and the resulting ''deemed'' direct compensation arrangements between the DHS entity and the physicians who stand in the shoes of the physician organization); and (2) the potential existence of an indirect compensation arrangement between the DHS entity and non-owner physicians of the physician organization (employees, independent contractors, and titular owners). As to the second analysis, the commenter recognized that the question of whether aggregate compensation to a non-owner physician (that is, one who does not stand in the shoes of the physician organization) varies with or takes into account the volume or value of referrals or other business generated for the DHS entity must be considered for the purposes of identifying any indirect compensation arrangements, but questioned why ''downstream compensation'' to non-owner physicians would factor into analyzing the direct compensation arrangement between the DHS entity and the physician organization (and the ''deemed'' direct compensation arrangements between the DHS entity and the physicians who stand in the shoes of the physician organization).

Response: Current § 411.354(c)(3)(i) states that a physician who stands in the shoes of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. Further, when applying the exceptions at § 411.355 and § 411.357 to arrangements where a physician stands in the shoes of his or her physician organization, § 411.354(c)(3)(i) states that the relevant referrals and other business generated ''between the parties'' are referrals and other business generated between the DHS entity and the physician organization, including all members, employees, and independent contractor physicians. In the first analysis noted by the commenter, the parties must consider whether the compensation under the arrangement between the DHS entity and the physician organization takes into account the volume or value of referrals or other business generated by any physician in the physician organization, regardless of whether the physician stands in the shoes of the physician organization. Because a physician who stands in the shoes of his or her physician organization has the same compensation arrangements as the physician organization, the result of this analysis would be the same for any ''deemed'' direct compensation arrangement between the DHS entity and a physician who stands in the shoes of the physician organization. Where no direct or ''deemed'' direct compensation arrangement exists between a physician and a DHS entity, parties should consider whether an indirect compensation arrangement exists under § 411.354(c)(2). Nothing in revised § 411.354(c)(3)(i) impacts the analysis regarding whether an indirect compensation arrangement exists between a physician and a DHS entity.

We are uncertain what ''downstream compensation'' the commenter believes is factored into the analysis of the direct compensation between a DHS entity and the physician organization with which it has a compensation arrangement. As noted earlier, compensation between a

DHS entity and a physician organization may not be determined in a manner that takes into account the volume or value of *referrals and other business generated* by any physician in the physician organization, including physicians who do not stand in the shoes of the physician organization. The *compensation from the physician organization to its employed or contracted physicians* is relevant to whether an indirect compensation arrangement exists between the DHS entity and a physician.

Comment: One commenter opposed the proposed revisions to the ''stand in the shoes'' rules at § 411.354(c)(3)(i), stating that the effect of considering all referrals from a physician organization when determining whether the compensation under a particular compensation arrangement takes into account the volume or value of referrals between the parties would be to convert presently lawful transactions into a violation of the physician self-referral law.

Response: The ''stand in the shoes'' regulations, including § 411.357(c)(3)(i) specifically, were established in Phase III and became effective on December 4, 2007 (72 FR 51028). Our Phase III policy considered all physicians in a physician organization to stand in the shoes of the physician organization, and § 411.354(c)(3)(i) originally stated that for the purposes of applying the exceptions in § 411.355 and § 411.357 to arrangements [in which a physician stands in the shoes of his or her physician organization], the 'parties' to the arrangements are considered to be the entity furnishing DHS and the physician organization (including all members, employees, or independent contractor physicians). Both the policy and § 411.354(c)(3)(i) were amended in the FY 2009 IPPS final rule and became effective on October 1, 2008. The regulation currently states that when applying the exceptions in § 411.355 and § 411.357 of this part to arrangements in which a physician stands in the shoes of his or her physician organization, the relevant referrals and other business generated 'between the parties' are referrals and other business generated between the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians). Thus, at all times, the regulation at § 411.354(c)(3)(i) has required parties to consider the referrals of all physicians in a physician organization—regardless of whether they stand in the shoes of the physician organization—when analyzing whether the compensation under a particular compensation arrangement takes into account the volume or value of referrals or other business generated ''between the parties.'' We do not believe that, under any iteration of § 411.354(c)(3)(i) or the regulation finalized in this final rule, an arrangement between a DHS entity and a physician organization could comply with the volume or value standard in an applicable exception if the compensation under the arrangement is determined in a manner that takes into account the volume or value of referrals or other business generated by the physicians who do not stand in the shoes of the physician organization.

As a result of the comments, we are finalizing our proposed revisions to the ''stand in the shoes'' regulations at § 411.354(c)(3)(i).

c. Locum Tenens Physician (§ 411.351)

The term ''*locum tenens* physician'' was first defined for the purposes of the physician self-referral law in Phase I (66 FR 954). The definition of ''*locum tenens* physician'' adopted in Phase I used the phrase ''stand in the shoes.'' (See 80 FR 41919 through 41920.) As described in this section, in subsequent rulemaking we established certain rules regarding when a physician ''stands in the shoes'' of his or her physician organization. The ''stand in the shoes'' provisions are specific to compensation arrangements and described in our regulations at § 411.354(c).

We proposed to revise the definition of *locum tenens* physician to remove the reference to ''stand in the shoes.'' We believe that the definition of a *locum tenens* physician is clear without the phrase ''stands in the shoes.'' We also believe that it is clear that the ''stand in the shoes'' provisions at § 411.354(c) are specific to compensation arrangements and are separate and distinct from the definition of a *locum tenens* physician. However, to eliminate unnecessary verbiage and to avoid any potential ambiguity, we proposed to revise the definition of *locum tenens* physician at § 411.351 by removing the phrase ''stands in the shoes.''

We received no comments opposing our proposal to revise the definition of *locum tenens* at § 411.351 by removing the phrase ''stands in the shoes,'' and we are finalizing the revisions to § 411.351 as proposed.

5. Exception for Ownership of Publicly Traded Securities

Section 1877(c)(1) of the Act sets forth an exception for ownership in certain publicly traded securities and mutual funds. The exception applies to several categories of securities, including securities that are traded under the automated interdealer quotation system operated by the National Association of Securities Dealers (NASD). This exception is codified in our regulations at § 411.356(a), which closely mirrors section 1877(c) of the Act.

Through a question posed to us by a stakeholder, it has come to our attention that the NASD no longer exists and that it is no longer possible to purchase a publicly traded security traded under the automated interdealer quotation system it formerly operated. In response, we researched whether we could modernize the exception for ownership of publicly traded securities by including currently existing systems that are equivalent to the NASD's now-obsolete automated interdealer quotation system. (See 80 FR 41920 for a summary of our research).

We proposed to use our authority in section 1877(b)(4) of the Act to revise the regulations at § 411.356(a)(1) to include securities listed for trading on an electronic stock market or OTC quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent. Trades made through a physical exchange (such as the NYSE or the American Stock Exchange) are standardized and publicly transparent. To protect against risk of program or patient abuse, we believe that trades on the electronic stock markets and OTC quotation systems that are eligible for this exception must also be standardized and publicly transparent. Accordingly, we did not propose to include any electronic stock markets or OTC quotation systems that trade unlisted stocks or that involve decentralized dealer networks. We also believe it is appropriate to limit the proposed exception to those electronic stock markets or OTC quotation systems that publish quotations on a daily basis, as physical exchanges must publish on that basis. We solicited comments regarding whether fewer, different, or additional restrictions on electronic stock markets or OTC quotation systems are necessary to effectuate the Congress' intent and to protect against patient or program abuse.

We received no comments on our proposal to update the provision at § 411.356(a)(1) to except ownership or investment interest in securities listed for trading on an electronic stock market or over-the-counter quotation system, provided that quotations are published on a daily basis and trades are standardized and publicly transparent. We are finalizing the revisions to § 411.356(a) as proposed.

6. New Exception for Timeshare Arrangements

a. Statutory and Regulatory Background

Section 1877(e)(1)(A) of the Act sets forth an exception for the rental of office space. Under this exception, lease arrangements must satisfy six specific criteria, one of which is that the office space rented or leased is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any other person or entity related to the lessor). The exception also permits payments by the lessee for the use of space consisting of common areas (which do not afford exclusive use to the lessee) if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. The 1995 final rule (60 FR 41959) incorporated the provisions of section 1877(e)(1)(A) of the Act into our regulations at § 411.357(a).

Section 1877(e)(8) of the Act sets forth an exception for: (1) Payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services; and (2) payments made by a physician to an entity as compensation for items or services other than clinical laboratory services if the items or services are furnished at fair market value (the ''payments by a physician exception''). The 1995 final rule (60 FR 41929) incorporated the provisions of section 1877(e)(8) of the Act into our regulations at § 411.357(i). In the 1998 proposed rule (63 FR 1703), we proposed to interpret ''other items or services'' to mean any kind of items or services that a physician might purchase, but not including clinical laboratory services or those specifically excepted under another provision in §§ 411.355 through 411.357. In that proposal, we stated that we did not believe that the Congress meant for the payments by a physician exception to cover a rental arrangement as a service that a physician might purchase, because it had already included in the statute specific exceptions, with specific standards for such arrangements, in section 1877(e)(1) of the Act. In Phase II (69 FR 16099), we responded to commenters that disagreed with our position that the exception for payments by a physician is not available for arrangements involving items and services addressed by another exception, stating that our position is consistent with the overall statutory scheme and purpose and is necessary to prevent the exception from negating the statute (69 FR 16099). We made no changes to the exception in Phase II to accommodate the commenters' concerns.

In the 1998 proposed rule (63 FR 1699), we proposed an exception for compensation arrangements that are based upon fair market value and meet certain other criteria. We finalized the exception at § 411.357(l) in Phase I, noting that, although it only covered services provided by a physician (or an immediate family member of a physician) to an entity furnishing DHS, it was available for some arrangements that are covered by other exceptions (66 FR 917 through 919). Although commenters requested that we expand the exception to cover the transfer, lease or license of real property, intangible property, property rights, or a covenant not to compete (69 FR 16111), we made no substantive changes to the exception for fair market value compensation in Phase II. In Phase III, we expanded the exception at § 411.357(l) for fair market value compensation to include arrangements involving compensation from a physician to an entity furnishing DHS. We reiterated that the exception for fair market value compensation does not protect office space lease arrangements; rather, arrangements for the rental of office space must satisfy the requirements of the exception at § 411.357(a) (72 FR 51059 through 51060).

In Phase III, a commenter suggested that ''timeshare'' leasing arrangements would be addressed more appropriately in the exception for fair market value compensation at § 411.357(l) or the exception for payments by a physician at § 411.357(i), instead of the exception for the rental of office space at § 411.357(a) (72 FR 51044). The commenter described a timeshare lease arrangement under which a physician or group practice pays the lessor for the right to use office space exclusively on a turnkey basis, including support personnel, waiting areas, furnishings, and equipment, during a schedule of time intervals for a fair market value rate per interval of time or in the aggregate, and urged us to clarify that such timeshare arrangements may qualify under § 411.357(i) or (l), the exceptions for payments by a physician and fair market value compensation, respectively. We note that the commenter specifically described lease arrangements where the lessee had exclusive, but only periodic, use of the premises, equipment, and personnel. In response, we declined to permit office space lease arrangements to be eligible for the fair market value exception at § 411.357(l), and stated that we were not persuaded that § 411.357(i) should protect office space leases (72 FR 51044 through 51045).

b. Timeshare Arrangements

Through our administration of the SRDP, as well as stakeholder inquiries, we have been made aware of arrangements for the use of another person or entity's premises, equipment, personnel, items, supplies, or services by physicians who, for various legitimate reasons, do not require or are not interested in a traditional office space lease arrangement. For example, in a rural or underserved area, there may be a need in the community for certain specialty services but that need is not great enough to support the full-time services of a physician specialist. Under ''timeshare'' arrangements, a hospital or local physician practice may ask a specialist from a neighboring community to provide services in space owned by the hospital or practice on a limited or as-needed basis. Most often, under such an arrangement, the specialist does not establish an additional medical practice office by renting office space and equipment, hiring personnel, and purchasing services and supplies necessary for the operation of a medical practice. Rather, it is common for a hospital or local physician practice to make available to the visiting independent physician on a ''timeshare'' basis the space, equipment and services necessary to treat patients. Under the ''timeshare'' arrangement, the hospital or physician practice may provide the physician with a medical office suite that is fully furnished and operational. The physician does not need to make any improvements to the space or to bring any medical or office supplies to begin seeing patients. ''Timeshare'' arrangements also may be attractive to a relocating physician whose prior medical practice office lease has not expired or to a new physician establishing his or her medical practice.

In general, a license—or permission—to use the property of another person differs from a lease in that ownership and control of the property remains with the licensor. That is, a lease transfers dominion and control of the property from the lessor to the lessee, giving the lessee an exclusive ''right against the world'' (including a right against the lessor) with respect to the leased property, but a license is a mere privilege to act on another's property and does not confer a possessory interest in the property. A license may be granted in writing or orally, and ordinarily does not convey an exclusive right. For a license to convey the right

to exclusive use, it must be specified in the writing that documents the license. As with a license, a ''timeshare'' arrangement, as we use the term in this final rule, does not transfer dominion and control over the premises, equipment, personnel, items, supplies, and services of their owner, but rather confers a privilege to use (during specified periods of time) the premises, equipment, personnel, items, supplies, and services that are the subject of the arrangement.

c. New Exception

Under our current regulations, an arrangement that includes the use of office space, as timeshare arrangements commonly do, must be analyzed under the exception for the rental of office space. The exceptions for payments by a physician and fair market value compensation arrangements are unavailable under our current regulations because of the inclusion of office space in the bundle of items and services in a typical timeshare arrangement.

We believe that timeshare arrangements that permit the use of office space, equipment, personnel, items, supplies, or services can be structured in a way that does not pose a risk of program or patient abuse. To address such arrangements, which we believe are often necessary to ensure adequate access to needed health care services (especially in rural and underserved areas), we proposed a new exception at § 411.357(y) that would have applied to timeshare arrangements that meet certain criteria, including that: (1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement; (2) the arrangement is between a hospital or physician organization (licensor) and a physician (licensee) for the use of the licensor's premises, equipment, personnel, items, supplies, or services; (3) the licensed premises, equipment, personnel, items, supplies, and services are used predominantly to furnish E/M services to patients of the licensee; (4) the equipment covered by the arrangement, if any: (i) Is located in the office suite where the physician performs E/M services, (ii) is used only to furnish DHS that is incidental to the physician's E/M services and furnished at the time of such E/M services, and (iii) is not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests); (5) the arrangement is not conditioned on the licensee's referral of patients to the licensor; (6) the compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; (7) the arrangement would be commercially reasonable even if no referrals were made between the parties; and (8) the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission.

The proposed exception at § 411.357(y) would have applied only to timeshare arrangements where the licensor is a hospital or physician organization; it would not protect arrangements where the licensor is another type of DHS entity. We solicited comments regarding whether the scope of the exception is sufficiently broad to improve beneficiary access to care (especially in rural or underserved areas), whether there is a compelling need to allow DHS entities other than hospitals and physician organizations to enter into timeshare arrangements with referring physicians, and whether the exception should apply if the licensor is a physician who is a source of DHS referrals to the licensee. We also solicited comments on whether the exception should be limited to arrangements in rural and underserved areas.

We proposed to protect only those timeshare arrangements under which the physician uses the licensed premises, equipment, personnel, items, supplies, and services predominantly for the E/M of patients. The proposed exception at § 411.357(y) would not protect the license of office space used by the physician solely or primarily to furnish DHS to patients. We solicited comments regarding whether ''predominant use'' is an appropriate measure of the use of the licensed premises and, if so, how we might define this standard, or whether we should include a different measure, such as one that would require that ''substantially all'' of the services furnished to patients on the licensed premises are not DHS. We also proposed to limit the type and location of the equipment that may be licensed to only that which is used to furnish DHS that is incidental to the patient's E/M visit and furnished contemporaneously with that visit. We noted that such a requirement would not affect the manner in which the DHS is billed (for example, ''incident to'' a physician's service or directly by an NPP). Because we believe that DHS that is ''incidental to'' the patient's E/M includes a limited universe of diagnostic tests and other procedures (such as x-rays, rapid strep tests, and urine dipstick tests to diagnose pregnancy) that assist the physician in his or her diagnosis and treatment of the patient, we proposed to exclude from the protection of the exception the license of advanced imaging equipment, radiation therapy equipment, and clinical and pathology laboratory equipment (other than that which is used to furnish CLIA-waived laboratory tests). Finally, we proposed to require that the equipment be located on the licensed premises; that is, in the office suite. We solicited comments on these requirements and limitations. Specifically we solicited comments regarding whether the equipment location requirement should be expanded to include equipment located in the same building (as defined at § 411.351) as the licensed office suite or an off-site location, and whether we should prohibit the license of equipment in the absence of a corresponding license of office space.

We also proposed to prohibit certain per unit-of-service and percentage compensation methodologies for determining the license fees under timeshare arrangements. Under the exception as proposed, parties could determine license fees on an hourly, daily, or other time-based basis, but would not be permitted to use a compensation methodology based on, for example, the number of patients seen. Parties also would not be permitted to use a compensation methodology based on the amount of revenue raised, earned, billed, collected, or otherwise attributable to the services provided by the licensee while using the licensor's premises, equipment, personnel, items, supplies or services. We solicited comments on whether these limitations on compensation methodologies for license fees are necessary and whether a timeshare arrangement for the use of a licensor's premises, equipment, personnel, items, supplies, or services would pose a risk of program or patient abuse in the absence of this prohibition on per-click and percentage compensation methodologies for the license fees paid by the licensee to the licensor.

We solicited comments on the proposed new exception for timeshare arrangements and any additional criteria that may be necessary to safeguard against program or patient abuse.

We are finalizing an exception at § 411.357(y) for timeshare arrangements with several modifications to our proposal. Importantly, the exception as

finalized is not available for arrangements that transfer control—that is, a ''right against the world''—over the premises that are the subject of the arrangement. Rather, the exception protects only those arrangements that grant a right or permission to use the premises, equipment, personnel, items, supplies, or services of another person or entity without establishing a possessory leasehold interest (akin to a lease) in the medical office space that constitutes the premises. However, because the public comments addressed the proposal to establish an exception for remuneration provided by a licensee to a licensor under an arrangement for the use of the licensor's premises, equipment, personnel, items, services, or supplies, the comment summaries below reflect the use of ''licensor'' and ''licensee'' terminology. This does not affect final § 411.357(y), which is an exception for ''remuneration provided under an arrangement for the use of premises, equipment, personnel, items, supplies, or services,'' and does not use the terms ''license,'' ''licensee,'' or ''licensor.'' In our responses to the public comments, we refer to the party granting a right or permission to use its premises, equipment, personnel, items, supplies, or services variously as the ''grantor'' or ''party granting permission.''

The following is a summary of the comments we received.

Comment: Citing a variety of reasons, the majority of commenters supported the establishment of an exception for timeshare arrangements. Many commenters stated that the exception for timeshare arrangements will promote important policy goals. One commenter commended CMS for recognizing the need for arrangements that support specialists who would like to provide services in rural areas that cannot maintain a full-time specialist. Another commenter expressed a belief that the exception will help to provide E/M services that may be needed on only a periodic basis to assist a physician in diagnosing or treating his or her patients. A third commenter stated that the exception will facilitate patient convenience and coordination and continuity of care. Two commenters that supported the establishment of the exception described how current arrangements for the limited use of space and equipment must be structured to fit within some combination of the existing exceptions for the rental of office space, rental of equipment, personal service arrangements, and fair market value compensation, which creates scheduling and other operational difficulties. One of these commenters identified certain requirements of these exceptions that reduce flexibility and potentially inhibit patient access, such as the ''exclusive use'' requirement in the exceptions for the rental of office space and the rental of equipment. In the commenters' view, the new exception for timeshare arrangement offers the promise of simplicity and will allow for much greater functionality and creativity in arrangements for patient services. However, one of these commenters proclaimed the proposed exception too narrow.

Response: After careful consideration of the comments we received in response to the proposed exception, and for the reasons discussed in the proposed rule (80 FR 41921–22), we continue to believe that timeshare arrangements may serve to ensure adequate access to needed health care services. We are finalizing the exception for timeshare arrangements at § 411.357(y) with the following modifications: (1) Regardless of which party grants and which party receives permission to use the premises, equipment, personnel, items, supplies, and services of the other party, a timeshare arrangement must be between a physician (or the physician organization in whose shoes the physician stands under § 411.354(c)) and: (i) A hospital or (ii) a physician organization of which the physician is not an owner, employee, or contractor; (2) equipment included under the timeshare arrangement may be in the same building (as defined at § 411.351) as the office suite where E/M services are furnished; and (3) all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, must be used on identical schedules. In addition, the exception as finalized protects only those arrangements that grant a right or permission to use the premises, equipment, personnel, items, supplies, or services of another person or entity without establishing a possessory leasehold interest (akin to a lease) in the medical office space that constitutes the premises. We believe that the other safeguards in the exception finalized here are necessary at this time to protect against program or patient abuse. In order not to inhibit flexibility for parties to arrangements involving office space, equipment, personnel, items, supplies or services, the existing exceptions to the physician self-referral law remain available to parties that wish to structure their arrangements in a way that satisfies all of the requirements of the applicable exception(s).

Comment: One commenter stated that its clients ''successfully and without any type of abuse long utilized 'Time Share Agreements' with a physician organization either as the landlord (licensor) or as a tenant (licensee)'' prior to the publication of Phase III. The commenter described a timeshare arrangement as one under which a physician is ''embedded'' in another party's medical practice with permission to use the space, equipment and personnel of the practice for a fair market payment. The commenter depicted the Phase III commentary as prohibiting such arrangements unless they can be arranged so that the embedded physician has the exclusive use of patient care areas and equipment of the practice into which the physician is embedded. Based on its reading of the Phase III commentary, the commenter welcomed the proposed exception for timeshare arrangements, declaring that the new exception is warranted because the types of arrangements it would cover are different from the lease arrangements described at § 411.357(a) and (b).

Response: The Phase III remarks referenced by this commenter related to an arrangement described to CMS in response to the Phase II rulemaking as including the exclusive—but only periodic—use of office space, personnel, waiting areas, furnishings, and equipment. Based on our prior guidance, we declined to permit office space leases to be eligible for the exceptions for fair market value compensation at § 411.357(l) and payments by a physician at § 411.357(i) (72 FR 51044 through 51045). Our position regarding the availability of the exceptions for fair market value compensation at § 411.357(l) and payments by a physician at § 411.357(i) for arrangements involving the rental of offices space has not changed.

As we described in the proposed rule, we believe that timeshare arrangements may improve access to needed care, especially in rural and underserved areas, by facilitating part-time or periodic access to physicians in communities where the need for the physician is not great enough to support the full-time services of the physician or where physicians, for various legitimate reasons, do not require or are not interested in a traditional office space lease arrangement (80 FR 41921). The new exception at § 411.357(y) is intended to promote access to needed services and provide parties with an option for structuring arrangements in the way that best suits the needs of the parties and the community in which the timeshare arrangement is located.

We note that we do not agree with the commenter's description of a timeshare arrangement as one in which a physician is embedded in another party's medical practice with permission to use the space, equipment, and personnel of the practice for a fair market payment. Although such an arrangement may qualify as a timeshare arrangement under the new exception depending on the facts and circumstances, we do not intend to limit the types of arrangements that may qualify as timeshare arrangements to those in which a physician is located within another physician's practice.

Comment: A commenter expressed concern that the use of the terms ''licensor'' and ''licensee'' could prohibit use of the exception for otherwise qualifying arrangements that, through a quirk of State law or the arrangement, are something other than a ''license'' under State law. Another commenter feared that compliance with the physician self-referral law could turn on considerations such as how an arrangement might be classified under landlord/tenant law or technical ''lease'' versus ''license'' considerations.

Response: Nothing in § 411.357(y) is meant to impact parties' rights and obligations as construed under State law. The exception is intended to address the challenge of satisfying the requirements of an available exception to the physician self-referral law in the case of arrangements that merely permit the use of office space without conveying a possessory leasehold interest in the premises or a ''right against the world'' with respect to the office space that is the subject of the arrangement.

We used the term ''license'' in the proposed exception at § 411.357(y) to describe the type of arrangement that could qualify for the exception. Generally, a license grants permission to do something which, without the license, would not be allowable. *See Barnett v. Lincoln*, 162 Wash. 613, 299 P. 392, 394. It is merely a personal privilege or permissive use of the licensor's premises, equipment, personnel, items, supplies, or services. We contrast this with a ''tenancy'' or ''possessory leasehold interest'' which implies some interest in the office space leased. *See Klein v. City of Portland*, 106 Or. 686, 213 P. 147, 150; Vicker v. Byrne, 155 Wis. 281, 143 N.W. 186, 188. One fundamental way that a license differs from a lease is that ownership and control of the property remains with the licensor.

Upon further reflection and after careful consideration of the issues raised by the commenters, we agree that the use of the term ''license'' without a definition that is specific to the exception at § 411.357(y) could introduce unnecessary confusion into the regulations and potentially exclude non-abusive arrangements that we believe should qualify for the exception. The terminology used by the parties in the documentation that describes and supports the timeshare arrangement should not control whether the parties can satisfy the requirements of the exception. Whether the arrangement is styled as a ''license'' or otherwise is not dispositive when determining compliance with new § 411.357(y). Rather, the facts and circumstances of the arrangement are critical to its compliance with the requirements of the exception. Therefore, we are not finalizing § 411.357(y) to include the terms ''license,'' ''licensor,'' or ''licensee.'' As finalized, § 411.357(y) includes a set of requirements for arrangements that we consider to be ''timeshare'' arrangements that do not violate the physician self-referral law's referral and billing prohibitions.

Parties wishing to avail themselves of the exception at § 411.357(y) need not utilize any particular terminology, provided that the arrangement itself grants one party the permission to use the premises, equipment, personnel, items, supplies, or services of the other party to the arrangement. Moreover, the arrangement may qualify for protection under the final exception even if the grant of permission to use the premises, equipment, personnel, items, supplies, or services provides for exclusive use of the premises, equipment, personnel, items, supplies, or services or has a duration of 1 year of more. However, the timeshare arrangement may not convey a possessory leasehold interest in the office space that is the subject of the arrangement. Where control over office space is conferred on a party such as to give that party a ''right against the world'' (including a right against the owner or sub-lessor of the office space), the arrangement must qualify for the exception for the rental of office space at § 411.357(a) in order not to run afoul of the physician self-referral law.

Again, what is imperative for compliance with the physician self-referral law when relying on the exception at § 411.357(y) is that the timeshare arrangement grant to one party the permission to use the premises, equipment, personnel, items, supplies, or services of the other party without conveying a possessory leasehold interest in the office space that is the subject of the arrangement. Of course, the arrangement must also satisfy the other requirements of the exception for timeshare arrangements as finalized at § 411.357(y) in this final rule. And, regardless of the structure of the arrangement or the terminology used by the parties, we do not intend to protect potentially abusive arrangements such as exclusive-use timeshare arrangements that essentially function as full-time leases for medical practice sites; arrangements in which physicians are selected or given preferred time slots based on their referrals to the party granting permission to use the premises, equipment, personnel, items, supplies, or services; or consecutive short-term arrangements that are modified frequently in ways that take into account a physician's referrals.

Comment: One commenter requested clarification that a medical foundation model physician practice would be a permitted licensee under a timeshare arrangement protected by the new exception.

Response: A medical foundation model physician practice may utilize the new exception at § 411.357(y). Because we are not dictating the roles of the parties to a timeshare arrangement, a medical foundation model physician practice may qualify as the party granting permission to use its premises, equipment, personnel, items, supplies, or services, or as the party to whom the permission is granted.

Comment: Many commenters, although supportive of an exception to protect timeshare arrangements, urged CMS not to limit the application of the exception for timeshare arrangements to rural or underserved areas. One of the commenters noted that non-rural areas and areas not determined to be underserved may nonetheless experience a practical shortage in certain specialties. Two of the commenters indicated that the exception for timeshare arrangements will address a longstanding problem that not all physicians are interested in committing to rent or accepting ownership or control over the premises, equipment, personnel, and supplies of a DHS entity. One of these commenters also stated that, although the exception would add much needed flexibility, especially for areas where there are shortages of physicians (and, in particular, specialists), patients in all areas would benefit from these arrangements. This commenter stated its belief that the risk of program abuse would be minimal given the proposed safeguards, which should adequately address any fraud and abuse concerns.

Response: We agree with the commenters. We did not propose to limit the exception to timeshare

arrangements in rural or underserved areas, and are not including such a limitation in the exception at § 411.357(y) finalized here.

Comment: A commenter took issue with our statement in the preamble to the proposed rule indicating that timeshare arrangements structured as licenses ''cannot satisfy the requirements of [the exception for the rental of office space] because a license generally does not provide for exclusive use of the premises.'' The commenter expressed concern that this statement could call into question many existing arrangements that are styled as licenses yet satisfy the requirements of the exception at § 411.357(a), including the ''exclusive use'' requirement. Another commenter recommended that CMS not finalize the proposed exception for timeshare arrangements, stating that it is not necessary because timeshare leases or ''licenses'' fit within the existing exceptions. Both of the commenters were concerned that the establishment of a new exception could cast doubt whether longstanding arrangements have been in compliance with the physician self-referral law. These commenters and a third commenter recommended that we clarify that license arrangements may satisfy the requirements of the exception for the rental of office space, depending on the facts and circumstances of the arrangement.

Response: The establishment of the new exception for timeshare arrangements at § 411.357(y) is not intended to call into question the compliance of any prior or existing arrangement or type of arrangement involving the use of office space, equipment, personnel, items, supplies, or services. Our questioning in the proposed rule of whether an arrangement (as it relates to office space) can satisfy the requirements of the exception at § 411.357(a) pertained only to those arrangements that involve the use of office space on a non-exclusive basis or for a term of less than 1 year. Although we stated our belief that a license generally does not provide for exclusive use of the premises (80 FR 41921), we did not rule out the possibility that it may.

A financial relationship between a physician (or immediate family member of the physician) and a DHS entity must satisfy the requirements of an applicable exception to the physician self-referral law to avoid the law's billing and referral prohibitions. Where more than one exception is available to protect a financial relationship, we do not dictate which exception the parties must use. The exception for timeshare arrangements finalized at § 411.357(y) establishes another—not a replacement—exception for parties to a timeshare arrangement. If a timeshare arrangement includes the exclusive use of office space but does not convey a possessory leasehold interest in the office space that is the subject of the arrangement, the new exception at § 411.357(y) is available to protect the arrangement (provided that all other requirements of the exception are satisfied). Depending on the facts and circumstances of the arrangement, it may also qualify for the exception at § 411.357(a). In short, the parties to a timeshare arrangement may elect to use any available exception(s) to protect the arrangement. However, where control over office space is conferred on a party such as to give that party a ''right against the world'' (including a right against the owner or sub-lessor of the office space), the arrangement must qualify for the exception for the rental of office space at § 411.357(a) in order not to run afoul of the physician self-referral law.

Comment: A commenter requested that we eliminate the proposed restriction on the hospital (or other DHS entity) being the licensee in a timeshare arrangement. The commenter described a scenario where the purpose of the timeshare arrangement is to embed a hospital-employed physician in an independent physician practice, which the commenter maintained is a convenient practice setting for Medicare beneficiaries. The commenter requested that we modify the exception at § 411.357(y) to accommodate timeshare arrangements in which the physician (or a physician organization) is the licensor and the DHS entity is the licensee. A few commenters believed that the proposed requirement that the licensor be a hospital or a physician organization is overly limiting. Two of these commenters noted that hospitals often employ physicians and may require timeshare arrangements that include space in a physician or physician organization's clinic. These commenters requested that we permit hospitals or other entities that employ physicians to be the licensee and still qualify for the protection of the exception. One of the commenters also requested that we permit physician organizations, rather than physicians, to be the licensee under a protected timeshare arrangement. This commenter stated that it is more common for a physician organization or professional corporation to enter into a timeshare arrangement than an individual physician in his or her personal capacity. Another of the commenters noted that many hospitals have affiliates (such as real estate subsidiaries and management service organizations) that act as the licensor in timeshare arrangements. The commenter recommended that hospital affiliates be included as permissible licensors under the exception.

Response: After consideration of the commenters' suggestions, we believe that it would not pose a risk of program or patient abuse to permit timeshare arrangements under which the hospital or physician organization is the party using the premises, equipment, personnel, items, supplies, or services of a physician (or the physician organization in whose shoes the physician stands under § 411.354(c)), provided that the arrangement satisfies all other requirements of the exception. We do not believe, nor did any commenters suggest, that it is necessary to permit other types of DHS entities, such as independent diagnostic testing facilities or laboratories, to be parties to timeshare arrangements to address the potential barriers to access to care described in the proposed rule. As we stated in the proposed rule, we believe that timeshare arrangements offered by independent diagnostic testing facilities or laboratories may serve to lock in referral streams from a physician licensee as a result of the physician's proximity to the DHS furnished by such entities (80 FR 41922). The exception finalized at § 411.357(y) only covers timeshare arrangements under which the DHS entity that is a party to the arrangement is a hospital or physician organization.

As to the request that we permit a physician organization, rather than a physician in his or her personal capacity, to enter into a timeshare arrangement, we refer readers to the discussion in the proposed rule regarding the analysis of arrangements between DHS entities and physician organizations where physicians may stand in the shoes of the physician organizations (80 FR 41911). There, we explained that, under our regulations at § 411.354(c), remuneration from an entity furnishing DHS to a physician organization would be deemed to be a direct compensation arrangement between each physician who stands in the shoes of the physician organization and the entity furnishing DHS. A ''deemed'' direct compensation arrangement must satisfy the requirements of an applicable exception if the physician makes referrals to the DHS entity and the DHS entity bills the Medicare program for DHS furnished as a result of the physician's referrals. The exception at § 411.357(y) would be

available to protect a direct compensation arrangement between a physician and a hospital or physician organization of which the physician is not an owner, employee, or contractor, as well as ''deemed'' direct compensation arrangements between a physician standing in the shoes of his or physician organization and a hospital or physician organization of which the physician is not an owner, employee, or contractor. Parties would also need to apply the rules regarding indirect compensation arrangements at § 411.354(c) to any chain of financial relationships that runs between the entity furnishing DHS and any physician who does not stand in the shoes of the physician organization to determine whether an indirect compensation arrangement exists. To protect an indirect compensation arrangement that exists as a result of remuneration provided by the entity furnishing DHS, the arrangement must satisfy the requirements of the exception at § 411.357(p) for indirect compensation arrangements.

Timeshare arrangements between physicians and organizations, such as real estate subsidiaries and management service organizations, that are not themselves DHS entities should be analyzed under the rules regarding indirect compensation arrangements at § 411.354(c). To protect an indirect compensation arrangement that exists as a result of a chain of financial relationships that runs hospital or physician organization—affiliate—physician, the arrangement must satisfy the requirements of the exception at § 411.357(p) for indirect compensation arrangements.

Comment: One commenter urged CMS to finalize a bright-line standard that includes a precise percentage for the minimum amount of E/M services furnished under a timeshare arrangement. The commenter noted that, depending on the volume and types of services furnished, ''predominant'' could be more or less than 50 percent. Another commenter recommended that we define ''predominant use'' to require that more than 50 percent of patients receive E/M services in the timeshare office space.

Response: We decline to adopt either commenter's suggestion. We attribute the common meaning to the term ''predominant'' and an attempt to define this standard further could inadvertently narrow the exception or constrain parties to a timeshare arrangement. We are not prescribing how parties determine compliance with § 411.357(y)(3). Parties may determine predominant use through any reasonable, objective, and verifiable means, which, depending on the circumstances, may include assessing the volume of patients seen, the number of patient encounters, the types of CPT codes billed, or the amount of time spent using the timeshare premises, equipment, personnel, items, supplies, and services. Further, we note that this standard is used in the exception at § 411.357(w) for nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) that are necessary and used predominantly to create, maintain, transmit, or receive electronic health records, and we are not aware of any difficulty on the part of physicians and entities involved in such arrangements. We remind readers that the use of office space by the physician *solely* or *primarily* to furnish DHS to patients would not be protected by the new exception at § 411.357(y).

Comment: One commenter objected to limiting the DHS furnished on the equipment covered by the timeshare arrangement to DHS that is incidental to the E/M services furnished by the physician at the time of the patient's visit. This commenter gave the example of a cardiologist ordering a test during a patient visit that is to be performed the following week when the ordering cardiologist is elsewhere and another cardiologist from the same physician practice is on the timeshare premises to supervise the test and read the results.

Response: We do not disagree with the commenter that there may be circumstances where a patient would benefit from receiving DHS but does not need an E/M service at the time of the furnishing of the DHS. However, a timeshare arrangement shifts to the party granted the use of the premises, equipment, personnel, items, supplies, or services only minimal financial risk related to the resources used to furnish DHS, and we cannot be certain that a timeshare arrangement would pose no risk of program or patient abuse without a limitation on the amount or scope of the DHS furnished using the timeshare equipment or in the timeshare premises. As we discussed in the proposed rule, our purpose in establishing the exception at § 411.357(y) is to improve access to care and outcomes for our beneficiaries. It is not to facilitate the ability of physicians to furnish a full array of DHS in supplemental medical practice sites. Therefore, we are retaining in the final exception a requirement that the timeshare equipment is not used to furnish DHS other than DHS that are incidental to the patient's E/M visit and furnished contemporaneously with that visit. In light of our determination to permit hospitals and physician organizations to either grant or receive permission to use premises, equipment, personnel, items, supplies, or services under the exception, we are modifying the regulation text slightly to clarify that the DHS furnished using equipment covered by the arrangement must be both: (1) Incidental to the E/M service furnished by the physician using the equipment; and (2) furnished at the time of the E/M service to which it is incidental. We note that the requirement that the DHS be ''incidental'' to E/M services is unrelated to and does not affect the ''incident to'' billing rules elsewhere in our regulations (80 FR 41922).

Comment: Two commenters opposed the exclusion of certain DHS, such as advanced imaging, radiation therapy, and laboratory equipment, from the scope of the exception. One of these commenters stated that limiting the equipment permissible under the exception would hamper patient access to care and immediate diagnosis. This commenter stated that any DHS furnished under a timeshare arrangement would need to satisfy the requirements of the in-office ancillary services exception and stated that safeguards to address potential risks of program or patient abuse from the use of such equipment are already built into that exception. The other of these commenters offered that, provided that fair market value is paid, a licensee physician should be able to use available advanced imaging, radiation therapy, laboratory, or other equipment.

In contrast, two commenters supported our proposal to limit the scope of the exception for timeshare arrangements to those arrangements that do not include the use of radiation therapy equipment, and another supported our proposal to prohibit the use of advanced imaging equipment. A different commenter urged us to prohibit the furnishing of physical therapy services on the premises protected by the new exception.

Response: We decline to remove from the exception finalized at § 411.357(y) the requirement that the equipment covered by the timeshare arrangement is not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests). As discussed in the preamble to the proposed rule and elsewhere in this section, the purpose of the exception for timeshare arrangements is to improve access to care and outcomes for our

beneficiaries. In the case of radiation therapy equipment, we do not believe that it is necessary to include the use of such equipment under the exception to improve access to care. Radiation therapy equipment generally is not portable. Thus, any radiation therapy equipment that could be included in a timeshare arrangement would already be available to patients in the community. Including it in a timeshare arrangement would merely permit a physician to bill for the services that are already available to his or her patients from the hospital or physician organization granting the physician permission to use the equipment. As to advanced imaging equipment and laboratory equipment, we are not convinced and the commenter provided no proof that excluding such equipment from the scope of a protected timeshare arrangement would hamper access to care or delay a patient's diagnosis.

We also disagree with the first commenter's statement that DHS furnished under a timeshare arrangement would need to satisfy the requirements of the in-office ancillary services exception and, therefore, the safeguards built into that exception are sufficient to address any risk of program and patient abuse. Other exceptions, such as the exceptions for *bona fide* employment at § 411.357(c) and personal service arrangements at § 411.357(d), may be available to protect referrals from the physicians in a group practice to the group. Further, not every physician organization that would bill for services furnished using premises and equipment under a timeshare arrangement will qualify as a ''group practice'' and have access to the in-office ancillary services exception.

We do not believe that it is necessary at this time to prohibit additional types of equipment under a timeshare arrangement, including equipment that is used to furnish physical therapy services. As discussed in the response to a previous comment, we are finalizing the requirement that the equipment covered by a timeshare arrangement is not used to furnish DHS other than those incidental to the patient's E/M visit and furnished contemporaneously with that visit. To be protected under the exception, physical therapy services furnished using timeshare equipment must be incidental to the patient's E/M services and furnished at the time of the evaluation and management service to which they are incidental. We question whether it would be medically necessary for a patient to receive an E/M service at the time of each physical therapy visit. Moreover, we doubt that a physician furnishes an E/M service prior to each physical therapy session, which would be necessary to satisfy the requirement at final § 411.357(y)(4).

Finally, we note that parties may use the existing exceptions for the rental of office space at § 411.357(a) and the rental of equipment at § 411.357(b), which include different safeguards against program and patient abuse, if they wish to include advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests) in their arrangements.

Comment: Several commenters requested that we not require that equipment be located in the office suite where E/M services are furnished, suggesting that such a requirement could limit access to needed care, as an office suite may not adequately accommodate the equipment necessary to furnish DHS. One of these commenters noted that permitting the use of equipment in the ''same building'' where the E/M services are furnished is consistent with the requirements of the in-office ancillary services exception. This commenter suggested that, as an additional safeguard, where there are two licensed locations (for example, an office suite with E/M services and a room in the same building with equipment and DHS), CMS could require that the two locations be included in a single arrangement and used on identical schedules.

Response: We do not wish to impose restrictions that hinder the usefulness of the exception for ensuring access to needed care, but we must include requirements sufficient to guard against program or patient abuse when utilizing the Secretary's authority under section 1877(b)(4) of the Act. We agree that the usefulness of the exception for timeshare arrangements would be enhanced if we do not limit the location of the equipment to the office suite where E/M services are furnished to the patient. Accordingly, we are revising the requirement regarding the location of the equipment covered by the timeshare arrangement to require instead that the equipment is located in the same building as the office suite where the E/M services are furnished to the patient. To offset any potential increased risk of program or patient abuse due to this expansion of the exception, we are adopting the commenter's suggestion to include in the exception a requirement that all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, must be used on identical schedules. A requirement that the use of the premises where E/M services are furnished and the use of the premises where DHS are furnished must be included in a single arrangement would be superfluous because the exception would not protect premises used solely or predominantly for the furnishing of DHS. An arrangement to use premises, equipment, personnel, items, supplies, or services for the furnishing of DHS would satisfy the requirements of the new exception for timeshare arrangements only if the arrangement also includes permission to use the premises, equipment, personnel, items, supplies, or services predominantly for the furnishing of E/M services.

Comment: Three commenters urged us not to limit compensation methodologies or prohibit per-unit of service compensation for timeshare arrangements, stating that, in light of the substantial protections of the other requirements of the exception, a limitation on compensation methodologies is unnecessary and burdensome. Another commenter sought clarification regarding whether the limitation on compensation formulas in the exception would effectively require block lease arrangements. The commenter stated that block lease arrangements are generally not conducive to either the licensor's or the licensee's delivery of services to their respective patients and recommended that we not require block lease arrangements.

Response: We are adopting our proposal to exclude from new § 411.357(y) any timeshare arrangements that incorporate compensation formulas based on: (1) a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the timeshare; or (2) per-unit of service fees, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the timeshare to the party to which the permission is granted. We are using the authority at section 1877(b)(4) of the Act to establish this exception. Because that authority permits only those exceptions that present no risk of program or patient abuse, we are protecting under new § 411.357(y) only those timeshare arrangements that are based on other forms of compensation, such as those using flat-fee or time-based formulas. Timeshare arrangements that are based on percentage compensation or per-unit of service compensation formulas present a risk of program or patient abuse because they may incentivize

overutilization and patient steering. By way of example, we believe that a per-patient compensation formula could incentivize the timeshare grantor to refer patients (potentially for unnecessary consultations or services) to the party using the timeshare because the grantor will receive a payment each time the premises, equipment, personnel, items, supplies, or services are used. Similarly, a compensation formula that uses services as the unit of measure (for example, a per-CPT code compensation formula) could incentivize the timeshare grantor to refer sicker patients or patients with a likely need for DHS to the party using the timeshare, regardless of the preferences or best interests of the patients, because the grantor will receive a payment for each service furnished in the timeshare premises or using the timeshare equipment.

We recognize that many timeshare arrangements include compensation formulas that are set as a pre-determined amount for each hour, half-day or full-day spent using the premises, equipment, personnel, items, supplies, or services that are covered under the arrangement. We do not believe such compensation formulas raise the same risks as formulas that result in a payment to the party that provides the timeshare premises, equipment, personnel, items, supplies, or services each time that party refers a patient to the party using the timeshare. Under time-based compensation formulas, the ''usage'' fee is paid regardless of the number of patients referred by the timeshare grantor or the number of services furnished to such patients (or any other patients). We do not wish to call into question non-abusive timeshare arrangements with time-based compensation terms. Therefore, we are finalizing the requirement at § 411.357(y)(6)(ii) to require that compensation under a timeshare arrangement is not determined using a formula based on per-unit of service fees, and we expressly do not prohibit compensation using a formula that is time-based (for example, per-hour or per-day). We are not prescribing a minimum amount of time per unit for compensation that utilizes a time-based formula and we remind readers that a compensation formula based on per-unit of service ''usage'' fees is prohibited under the exception only to the extent that such fees reflect services furnished to patients referred by the party granting permission to use its premises, equipment, personnel, items, supplies, or services to the party that receives such permission.

Although not addressed by any commenter, we are also aware of the recent DC Circuit decision in *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2014), which addressed the prohibition on per-click leasing arrangements with respect to the rental-equipment exception found in § 411.357(b)(4)(ii)(B). We established this prohibition in the FY 2009 IPPS final rule using our authority under section 1877(e)(1)(B)(vi) of the Act, which requires an equipment lease to meet such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse in order for that lease to qualify for the exception for the rental of equipment. In the same rule, we also discussed certain legislative history contained in a House Conference Report addressing sections 1877(e)(1)(A)(iv) and 1877(e)(1)(B)(iv) of the Act, which establish requirements that rental charges over the term of a lease for office space or rental equipment be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. With respect to those statutory conditions, the language in the House Conference Report stated that—

> The conferees intend that charges for space and equipment leases may be based on . . . time-based rates or rates based on units of service furnished, so long as the amount of time-based or units of service rates does not fluctuate during the contract period. (H.R. Rep. No. 103–213, at 814 (1993).)

We noted in the FY 2009 IPPS final rule that CMS had previously interpreted this legislative history as indicating a view that per-click leases do not run afoul of section 1877(e)(1)(B)(iv), but we then stated that this language could also be interpreted as suggesting the Congress's disapproval of per-click leases. We explained, though, that our prohibition on per-click leasing arrangements was ultimately based on our authority to promulgate ''other requirements'' under section 1877(e)(1)(B)(vi) of the Act, and not on an interpretation of section 1877(e)(1)(B)(iv) of the Act.

In the *Council for the Urological Interests* case, the Court agreed with CMS that it had the authority to prohibit per-click leasing arrangements under section 1877(e)(1)(B)(vi) of the Act. The Court concluded that—

> The text of the statute does not unambiguously preclude the Secretary from using her authority to add a requirement that bans per-click leases. (Council for Urological Interests, 790 F.3d at 219.)

The Court further concluded that the relevant language in the House Conference Report merely interpreted section 1877(e)(1)(B)(iv) of the Act, and thus did not preclude CMS from imposing additional requirements under section 1877(e)(1)(B)(vi) of the Act. See id. at 222 (explaining that the legislative history ''simply indicates that, as written, the rental-charge clause [in section 1877(e)(1)(B)(iv)] does not preclude per-click leases'' and ''[n]othing in the legislative history suggests a limit on [CMS's] authority'' to prohibit per-click leases under section 1877(e)(1)(B)(vi) of the Act).

The Court concluded, however, that CMS's revised interpretation of the House Conference Report was arbitrary and capricious, and it remanded the case to the agency to permit a fuller consideration of the legislative history. As previously noted, we are considering options as to how to comply with the court's ruling.

Nonetheless, our current decision to prohibit per-unit of service compensation formulas under § 411.357(y) is not affected by the Court's decision in *Council for Urological Interests.* As explained, the Court did not hold that the House Conference Report requires us to allow per-click arrangements; to the contrary, the Court upheld our authority to prohibit per-click arrangements where we determine that such a prohibition is necessary to protect against program or patient abuse. (See *Council for Urological Interests*, 790 F.3d at 219–22.) Thus, we possess the authority to exclude timeshare arrangements that use a compensation formula based on per-unit of service fees from the new exception at § 411.357(y), and we employ that authority here to ensure that the new exception will not pose a risk of program or patient abuse, as section 1877(b)(4) of the Act requires.

Comment: One commenter recommended that CMS allow the space that is used on a timeshare basis to be used as a provider-based department when it is not licensed to a physician. The commenter stated that this would allow hospitals to use its property and personnel more efficiently than currently allowed.

Response: The commenter's recommendation is outside the scope of this regulation.

Summary of the exception for timeshare arrangements as finalized at § 411.357(y)

After careful consideration of the comments we received in response to the proposed exception, we are

finalizing the exception for timeshare arrangements at § 411.357(y) with the following modifications: (1) regardless of which party grants and which party receives permission to use the premises, equipment, personnel, items, supplies, and services of the other party, a timeshare arrangement must be between a physician (or the physician organization in whose shoes the physician stands under § 411.354(c)) and: (i) a hospital or (ii) a physician organization of which the physician is not an owner, employee, or contractor; (2) equipment covered by the timeshare arrangement may be in the same building (as defined at § 411.351) as the office suite where E/M services are furnished; and (3) all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, must be used on identical schedules. In addition, the exception as finalized protects only those arrangements that grant a right or permission to use the premises, equipment, personnel, items, supplies, or services of another person or entity without establishing a possessory leasehold interest (akin to a lease) in the medical office space that constitutes the premises.

7. Temporary Noncompliance With Signature Requirements (§ 411.353(g))

Several compensation arrangement exceptions to the physician self-referral law require that an arrangement be signed by the parties. Our current regulations at § 411.353(g) include a special rule for arrangements involving temporary noncompliance with signature requirements. The regulation permits an entity to submit a claim or bill and receive payment for DHS if an arrangement temporarily does not satisfy the applicable exception's signature requirement but otherwise fully complies with the exception. Under the current rule, if the failure to comply with the signature requirement is inadvertent, the parties must obtain the required signature(s) within 90 days. If the failure to comply is not inadvertent, the parties must obtain the required signature(s) within 30 days.

In the FY 2009 IPPS final rule, we stated that we would evaluate our experience with the regulation at § 411.353(g) and propose more or less restrictive modifications at a later date (73 FR 48707). In the proposed rule, we proposed to modify the current regulation to allow parties 90 days to obtain the required signatures, regardless of whether or not the failure to obtain the signature(s) was inadvertent. We recognize that it is not uncommon for parties who are aware of a missing signature to take up to 90 days to obtain all required signatures. We also proposed to revise § 411.353(g) to include reference to the new regulatory exceptions for payments to a physician to employ an NPP and timeshare arrangements that we proposed at new § 411.357(x) and § 411.357(y), respectively, to ensure that all compensation exceptions with signature requirements are treated uniformly. We do not believe that allowing parties 90 days to obtain signatures while the arrangement otherwise complies with the physician self-referral law poses a risk of program or patient abuse.

The proposed regulation maintains the safeguards of the current rule. Specifically, the proposed regulation applies narrowly to the signature requirement only. To make use of the proposed revised provisions at § 411.353(g), an arrangement would have to satisfy all other requirements of an applicable exception, including the requirement that the arrangement be set out in writing. In addition, an entity may make use of the proposed regulation only once every 3 years for the same referring physician. Given these safeguards, we believe that the proposed revision poses no risk of program or patient abuse. We are finalizing our proposed revision to the special rule at § 411.353(g).

The following is a summary of the comments we received.

Comment: The vast majority of commenters on this issue supported our proposal to allow all parties up to 90 days to obtain required signatures, regardless of whether the failure to obtain the signatures was inadvertent or not inadvertent. Several commenters requested that we remove the provision at § 411.353(g)(2) that limits the use of the temporary noncompliance rule to once every 3 years for the same referring physician.

Response: We appreciate the commenters' support, and we are finalizing our proposal. However, we decline to remove the limitation on the use of the special rule to once every 3 years for the same physician. The signature requirement of certain compensation exceptions is statutory, and we believe that the requirement plays a role in preventing fraud and abuse. Among other things, the signature of the parties creates a record of the fact that the parties to an arrangement were aware of and assented to the key terms and conditions of the arrangement. Requiring parties to sign an arrangement encourages parties to monitor and review financial relationships between DHS entities and physicians. In contrast, permitting parties to make frequent use of the special rule for noncompliance with signature requirements would not incent parties to exercise diligence with our rules. (See 73 FR 48707). We believe that repeated use of the special rule (that is, use more than once in a 3-year period) for the same physician may pose a risk of program or patient abuse.

Comment: One commenter requested clarification that the temporary noncompliance provision can be used more than once every 3 years for different physicians within the same group practice. According to the commenter, a party should be permitted to use the temporary noncompliance provision for an arrangement with a group practice for the services of one physician without precluding the party from using the temporary noncompliance provision within 3 years for another arrangement with the same group practice involving the services of a different physician.

Response: The ''stand in the shoes'' provisions at § 411.354(c) determine whether a party may use the rule at § 411.353(g)(1) more than once in 3 years for physicians associated with a physician organization. Assume a physician organization consists of 2 non-titular owners (Drs. A and B), and that a DHS entity enters into a compensation arrangement with the physician organization for the services of Dr. A on January 1, 2014.

The compensation arrangement with the physician organization is deemed to be a compensation arrangement with Dr. A and a compensation arrangement with Dr. B. If the parties do not sign the arrangement until February 15, 2014, but the arrangement otherwise satisfies the requirements of § 411.353(g), the DHS entity may bill the program for DHS performed as a result of referrals by both Dr. A and Dr. B for the period from January 1, 2014 through February 14, 2014. That is to say that the special rule at § 411.353(g) affords the DHS entity protection for referrals from each of the physicians who stand in the shoes of the physician organization. For precisely this reason, however, if the DHS entity enters into a different arrangement with the physician organization on March 1, 2015 for Dr. B's services, and the parties do not sign the arrangement until May 1, 2015, the entity may not rely on the rule at § 411.353(g) for either Dr. A or Dr. B for the period of March 1, 2015 through April 30, 2015. The entity already made use of the special rule for Dr. A and Dr. B's referrals from January 1, 2014 through February 14, 2014. On the other hand, if the DHS entity entered into direct compensation

arrangements with Drs. A and B (that is, arrangements with the physicians as opposed to arrangements with the physician organization), then the DHS could use the rule at § 411.353(g) to protect referrals from Dr. A for the period from January 1, 2014 through February 14, 2014, and to protect referrals from Dr. B for the period from March 1, 2015 through April 30, 2015.

Comment: According to two commenters, a contract can be binding under State law even if it is missing the signature of one or more parties. The commenters urged CMS to adopt a similar rule for the physician self-referral law. Specifically, the commenters requested that CMS deem an arrangement to be signed, for the purposes of the physician self-referral law, even if one or more of the parties did not sign the arrangement, as long as the agreement is binding under State law. Another commenter asked CMS to establish that clear assent of the parties as to the terms of the arrangement is sufficient to satisfy the signature requirement.

Response: As noted elsewhere in this section, State contract law principles do not determine compliance with the physician self-referral law. The commenters' suggestion illustrates a problem with relying exclusively on State law principles, namely that the requirements for a contract to be enforceable under State law may differ substantively from the requirements of the physician self-referral law. By statute, the exceptions for the rental of office space, the rental of equipment, and personal service arrangements require an arrangement to be signed ''by the parties.'' (See section 1877(e) of the Act.) The commenters' suggestion that an arrangement should be deemed to comply with the signature requirement if one or more of the parties have not signed the arrangement is inconsistent with the plain language of the statute. In addition, as noted elsewhere in this section, we believe that the requirement that the parties sign an arrangement plays a role in preventing fraud and abuse. In this context, it is not enough that the course of conduct between the parties could support an inference of assent to the terms. Rather, a signature is necessary to provide a written record of the assent of the parties to the arrangement.

Comment: One commenter requested clarification as to what would satisfy the signature requirement of various compensation exceptions. The commenter specifically asked whether any of the following would satisfy the requirement that an arrangement be signed by the parties: an electronic signature; a typed name; the name of the sender in the ''from'' line of an email; the signature of the maker of a check; and the signature of a person endorsing a check. Another commenter asked CMS to explicitly allow electronic signatures. A third commenter suggested that State law principles should determine what constitutes a signed writing for the purposes of the physician self-referral law.

Response: As noted elsewhere in this section, State law principles do not determine whether a party complies with the physician self-referral law, including compliance with the signature requirement. Nevertheless, parties may look to State law and other bodies of relevant law, including Federal and State law pertaining to electronic signatures, to inform the analysis of whether a writing is signed for the purposes of the physician self-referral law. Given evolving technologies, we are concerned that a prescriptive statement on our part regarding electronic signatures may unduly limit parties' ability to comply with the physician self-referral law in the future.

We decline to state whether the examples provided by the commenter comply with the signature requirement for the following reasons: First, the exceptions require the arrangement to be signed by the parties. Even a document bearing the handwritten signature of one of the parties will not satisfy this requirement if the document, when considered in the context of the collection of documents and the underlying arrangement, does not clearly relate to the arrangement. Second, the intent of the party purportedly ''signing'' the standalone document is not clear in certain examples provided. Third, we are concerned that, by judging the examples in isolation from their context, we might unduly narrow parties' ability to comply with the signature requirement. In sum, whether an arrangement is signed by the parties depends on the facts and circumstances of the arrangement and the writings that document the arrangement.

After careful consideration of the comments, we are finalizing our proposal to remove the distinction between inadvertent and not inadvertent failure to obtain a signature at § 411.353(g). Under the final regulation, all parties have 90 days to obtain missing signatures. The regulation, as finalized, continues to limit the use of § 411.353(g) by an entity to once every 3 years for a particular physician. At this time, we believe that this limitation is necessary to prevent program or patient abuse.

8. Physician-Owned Hospitals

Section 6001(a) of the Affordable Care Act amended the rural provider and hospital ownership or investment interest exceptions to the physician self-referral law to impose additional restrictions on physician ownership and investment in hospitals. For the purposes of these exceptions, the new legislation defined a ''physician owner or investor'' as a physician, or immediate family member of a physician, who has a direct or indirect ownership or investment interest in a hospital. We refer to hospitals with direct or indirect physician owners or investors as ''physician-owned hospitals.''

Section 6001(a)(3) of the Affordable Care Act established new section 1877(i) of the Act, which imposes additional requirements for physician-owned hospitals to qualify for the rural provider or hospital ownership exceptions. In part, section 1877(i) of the Act requires a physician-owned hospital to disclose the fact that the hospital is partially owned or invested in by physicians on any public Web site for the hospital and in any public advertising for the hospital; provides that a physician-owned hospital must have had a provider agreement in effect as of December 31, 2010; and provides that the percentage of the total value of the ownership or investment interests held in a hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate cannot exceed such percentage as of March 23, 2010.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72240), we addressed many of the additional requirements that were established by the Affordable Care Act for a physician-owned hospital to avail itself of the rural provider or hospital ownership exceptions. In that final rule with comment period, among other things, we finalized regulations at § 411.362(b)(3)(ii)(C) that required a physician-owned hospital to disclose on any public Web site for the hospital and in any public advertising that the hospital is owned or invested in by physicians. We also finalized regulations at § 411.362(b)(1) that required a physician-owned hospital to have had a provider agreement in effect on December 31, 2010, and at § 411.362(b)(4)(i) to provide that the percentage of the total value of the ownership or investment interests held in a hospital (or in an entity whose assets include the hospital) by physician owners or investors in the aggregate cannot exceed such percentage as of

March 23, 2010. We also revised the rural provider and hospital ownership exceptions at § 411.356(c)(1) and § 411.356(c)(3), respectively, to provide that a physician-owned hospital must meet the requirements in new § 411.362 not later than September 23, 2011, to avail itself of the applicable exception.

a. Preventing Conflicts of Interest: Public Web site and Public Advertising Disclosure Requirement (§ 411.362(b)(3)(ii)(C))

Following publication of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72240), we received numerous inquiries about many of the additional requirements that were established by the Affordable Care Act for the rural provider and hospital ownership exceptions, including the requirement that a physician-owned hospital must disclose on any public Web site for the hospital and in any public advertising that the hospital is owned or invested in by physicians. Specifically, industry stakeholders requested additional guidance to clarify the terms ''public Web site for the hospital'' and ''public advertising for the hospital,'' the range of statements that constitute a sufficient disclosure, and the period of noncompliance for a failure to disclose. We also received disclosures through the SRDP where the disclosing parties reasonably assessed that, based on existing CMS guidance, they could not certify compliance with this disclosure requirement and, therefore, the conduct constituted a violation of the law.

Given the inquiries and disclosures that we received, we have carefully considered both the disclosure requirement's purpose and our existing regulations addressing the requirement. We believe that, in establishing this requirement, the Congress decided that the public should be on notice if a hospital is physician-owned because that fact may inform an individual's medical decision-making. We do not interpret the public Web site and advertising disclosure requirements to be prescriptive requirements for the inclusion of specific wording in an undefined range of communication. Accordingly, we proposed to provide physician-owned hospitals more certainty regarding the forms of communication that require a disclosure statement and the types of language that would constitute a sufficient statement of physician ownership or investment. We believe that our proposals would appropriately balance the industry's need for greater clarity with the public's need to be apprised of such information. Finally, we note that, in the event that a physician-owned hospital discovers that it failed to satisfy the public Web site or public advertising disclosure requirements, the SRDP is the appropriate means for reporting such overpayments. For more information, see the *Special Instructions for Submissions to the CMS Voluntary Self-Referral Disclosure Protocol for Physician-Owned Hospitals and Rural Providers that Failed to Disclose Physician Ownership on any Public Web site and in any Public Advertisement*, available on our Web site at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html*.

For the public Web site disclosure requirement, we proposed to amend existing § 411.362(b)(3)(ii)(C) to list examples of the types of Web sites that do not constitute a ''public Web site for the hospital.'' We proposed to revise § 411.362(b)(3)(ii)(C) to specify that a ''public Web site for the hospital'' does not include certain types of Web sites, even though limited information about the hospital may be found on such Web sites. For example, we do not consider social media Web sites to be ''public Web sites for the hospital,'' and the proposed regulation would clarify this. We do not believe that a hospital's communications (such as maintaining an individual page on a Web site, posting a video, or posting messages) via a social media Web site should be construed as a Web site that is ''for the hospital,'' given that the Web site is operated and maintained by a social networking service and that a multitude of users typically can become members of such a service. Further, we note that social media communications, which are used primarily for the development of social and professional contacts and for sharing information between interested parties, differ in scope from the provision of information typically found on a hospital's main Web site, such as the hospital's history, leadership and governance structure, mission, and a list of staff physicians. We also proposed to specify at § 411.362(b)(3)(ii)(C) that a ''public Web site for the hospital'' does not include electronic patient payment portals, electronic patient care portals, or electronic health information exchanges, as these are not available to the general public. These portals are for the convenience of only those patients who have already been treated at the hospital and to whom the hospital's physician ownership likely would have already been disclosed. Our proposed examples of Web sites that do not constitute a ''public Web site for the hospital'' is not exhaustive. We recognize the difficulty in identifying every type of Web site that either currently exists or may emerge as technology develops that would not require a disclosure statement. We solicited public comments on whether our proposed examples are appropriate given the statutory language and whether we should include different or additional examples of Web sites in the list. We also solicited public comment on whether, in the alternative, we should provide an inclusive definition of what would be considered a ''public Web site for the hospital'' and, if so, we solicited recommendations for such a definition. Finally, we note that, even if a Web site does not constitute a public Web site for the hospital under our proposal, the online content may, depending on the facts and circumstances, constitute public advertising for the hospital that would require a disclosure statement.

For the public advertising disclosure requirement, we proposed to define ''public advertising for the hospital'' at § 411.362(a). We note that our existing regulations at § 411.362(b)(3)(ii)(C) reference ''public advertising'' without explicitly specifying ''for the hospital,'' which is different from the statutory language of section 1877(i)(1)(C)(iv) of the Act. We proposed to include that phrase in the definition and in the disclosure requirement to conform our regulations to the statutory language. To determine how best to clarify what we consider to be ''public advertising for the hospital,'' we consulted numerous sources for definitions of ''advertise'' and ''advertising.'' After considering the results of our research, we proposed to define ''public advertising for the hospital,'' for the purposes of the physician self-referral law, as any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital. We proposed that the definition of ''public advertising for the hospital'' does not include, by way of example, communication made for the primary purpose of recruiting hospital staff (or other similar human resources activities), public service announcements issued by the hospital, and community outreach issued by the hospital. We believe that, as a general matter, communications related to recruitment are for the primary purpose of fulfilling a hospital's basic need for staff and that communications issued via public service announcements and community outreach are for the primary purpose of providing the general public healthcare-related information.

Therefore, we proposed to specify in our regulations that these types of communications would be excluded from our proposed definition of ''public advertising for the hospital.'' We note that these types of communications do not represent an exhaustive list of what we do not consider ''public advertising for the hospital.'' We sought public comment on our proposed definition of ''public advertising for the hospital'' as well as our proposed list of examples that do not constitute ''public advertising for the hospital.''

We note that a determination as to whether a certain communication constitutes public advertising for the hospital depends on the specific facts and circumstances of the communication. In the CY 2011 OPPS/ASC final rule with comment period, commenters stated that a hospital should not be required to include disclosures in certain advertising, such as the kind found on billboards, or the kind aired via radio and television and that the requirement should be confined to print media such as newspapers, magazines, and other internally produced print material for public use (75 FR 72248). In response to the commenters, we stated that we have no flexibility to exclude certain types of advertising media, as the statute was very straightforward in its statement that the disclosure appear in ''any public advertising'' for the hospital. In the proposed rule, we clarified that the facts and circumstances of the communication, rather than the medium by which the message is communicated, determine whether a communication constitutes ''public advertising for the hospital.''

We also proposed to clarify the types of statements that constitute a sufficient statement of physician ownership or investment. Specifically, we proposed to amend § 411.362(b)(3)(ii)(C) to specify that any language that would put a reasonable person on notice that the hospital may be physician-owned is deemed a sufficient statement of physician ownership or investment. A statement such as ''this hospital is owned or invested in by physicians'' or ''this hospital is partially owned or invested in by physicians'' would certainly meet this standard. However, statements that the hospital is ''founded by physicians,'' ''managed by physicians,'' ''operated by physicians,'' or ''part of a health network that includes physician-owned hospitals'' would also meet this standard. We also believe that a hospital's name, by itself, could constitute language that meets this standard. For example, we believe that ''Doctors Hospital at Main Street, USA'' would put a reasonable person on notice that the hospital may be physician-owned. We sought public comment on our proposed revision to the public Web site and advertising disclosure requirements and on our proposed examples of language that would satisfy that standard. We also invited suggestions regarding alternative standards for deeming language sufficient for these requirements.

For the location and legibility of disclosure statements, we continue to believe, as stated in the CY 2011 OPPS/ASC final rule with comment period, that the disclosure should be located in a conspicuous place on the Web site and on a page that is commonly visited by current or potential patients, such as the home page or ''about us'' section (75 FR 72248). Further, we believe that the disclosure should be displayed in a clear and readable manner and in a size that is generally consistent with other text on the Web site. We did not propose to prescribe a specific location or font size for disclosure statements on either a public Web site or public advertising; rather, physician-owned hospitals have flexibility in determining exactly where and how to include the disclosure statements, provided that the disclosure would put a reasonable person on notice that the hospital may be physician-owned.

For those physician-owned hospitals that have identified non-compliance with the public Web site disclosure requirement, we are taking this opportunity to clarify that the period of noncompliance is the period during which the physician-owned hospital failed to satisfy the requirement. We note that September 23, 2011 is the date by which a physician-owned hospital had to be in compliance with the public Web site and advertising disclosure requirements (75 FR 72241), and, therefore, would be the earliest possible beginning date for noncompliance. For those physician-owned hospitals that have identified noncompliance with the public advertising disclosure requirement, we are clarifying that the period of noncompliance is the duration of the applicable advertisement's predetermined initial circulation, unless the hospital amends the advertisement to satisfy the requirement at an earlier date. For example, if a hospital pays for an advertisement to be included in one issue of a monthly magazine and the hospital fails to include the disclosure in the advertisement, the period of noncompliance likely would be the applicable month of circulation, even if the magazine continued to be available in the archives of the publisher, in waiting rooms of physician offices, or other public places. We sought public comment on additional guidance that may be necessary regarding the periods of noncompliance for both disclosure requirements.

We are finalizing without modification our proposals regarding the public Web site and public advertising disclosure requirement at § 411.362(b)(3)(ii)(C). The following is a summary of the comments we received.

Comment: A few commenters largely supported our proposed clarifications and regulations that articulate our existing policy concerning the public Web site and public advertising disclosure requirements. The commenters agreed that our proposed examples of statements that would constitute sufficient disclosure of physician ownership or investment interest demonstrate an appropriate approach to implementing the disclosure requirements.

Response: We appreciate the commenters' support. We are finalizing our proposal to amend § 411.362(b)(3)(ii)(C) to specify that any language that would put a reasonable person on notice that the hospital may be physician-owned is deemed a sufficient statement of physician ownership or investment, as well as our proposed examples of language that would satisfy that standard as specified in the proposed rule (80 FR 41924). We note that our goal in proposing the examples of sufficient disclosure statements was to articulate a common sense understanding of what types of statements would satisfy the requirements.

Comment: One commenter supported our proposal to amend § 411.362(b)(3)(ii)(C) to specify examples of Web sites that, consistent with our existing policy, would not constitute ''public Web sites for the hospital,'' and therefore, would not require a disclosure of physician ownership or investment. However, the commenter requested that we revise the phrase ''social media Web sites'' in proposed amended § 411.362(b)(3)(ii)(C) to read as ''social media or networking Web sites'' and that we include in the regulation specific examples of social media or networking Web sites.

Response: We are finalizing our proposal, without revision, to amend § 411.362(b)(3)(ii)(C) to specify that a public Web site for the hospital does not include, by way of example: Social media Web sites; electronic patient payment portals; electronic patient care portals; and electronic health information exchanges. We are not persuaded to explicitly include ''networking Web sites'' in

§ 411.362(b)(3)(ii)(C). We believe that it is commonly understood that networking Web sites are one form of social media and that our discussion of social media Web sites in the proposed rule is broad enough to include networking Web sites (80 FR 41924). We do not believe that additional guidance is necessary. Furthermore, we are hesitant to identify specific names of Web sites, even as examples, given the pace at which technology develops.

Comment: One commenter supported our specific proposal at § 411.362(b)(3)(ii)(C) to exclude electronic patient payment portals and electronic patient care portals from qualifying as public Web sites for the hospital, because, according to the commenter, disclosing through either type of portal would not meet the disclosure requirement's purpose of providing ownership information to the general public.

Response: We appreciate the commenter's support for our proposal to exclude such portals from qualifying as a ''public Web site for the hospital.'' We agree with the commenter's reasoning, and are finalizing the revisions as proposed.

Comment: One commenter supported our proposed definition of ''public advertising for the hospital'' at § 411.362(a), particularly our clarification in the definition that the advertisement must be ''primarily intended to persuade individuals to seek care at the hospital.'' The commenter also supported our proposed list of examples that, consistent with our existing policy, would not constitute ''public advertising for the hospital'' and therefore would not require disclosure of physician ownership or investment. However, the commenter urged CMS to add ''search engine results'' and ''online listings of area hospitals'' to our proposed list of examples given that, according to the commenter, an individual likely would not make a medical decision based on the limited information provided through either means of communication.

Response: We are finalizing our proposal, without revision, to add our proposed definition of ''public advertising for the hospital'' at § 411.362(a). We are not persuaded to add ''search engine results'' and ''online listings of area hospitals'' to our list of examples. As we noted in the preamble to the proposed rule, our list of examples is not exhaustive, and a determination as to whether a specific communication qualifies as ''public advertising for the hospital'' will depend on the facts and circumstances of the communication (80 FR 41924). We also note that under our finalized policy the standard for whether a communication qualifies as ''public advertising for the hospital'' is, in part, whether the communication ''is primarily intended to persuade individuals to seek care at the hospital'' and not whether an individual is likely to make a medical decision based on the information provided in the communication. Finally, as we noted in our proposed rule, our existing regulations at § 411.362(b)(3)(ii)(C) reference ''public advertising'' without explicitly specifying ''for the hospital,'' and we are finalizing our proposal to include the phrase ''for the hospital'' in our definition at § 411.362(a) and in the disclosure requirement to conform our regulations to the statutory language.

Comment: One commenter requested that we identify a more definitive period of noncompliance for a physician-owned hospital's failure to satisfy the public advertising disclosure requirement. The commenter noted that, as to our example in the proposed rule concerning a physician-owned hospital's failure to include a disclosure in a monthly magazine advertisement, we stated that the period of noncompliance would ''likely'' be the applicable month of circulation despite the fact that the magazine may continue to be available (for example, in physician waiting rooms) for a period beyond the initial circulation.

Response: We are finalizing, without revision, our clarifications regarding the periods of noncompliance associated with a failure to satisfy either the public Web site or public advertising disclosure requirements (80 FR 41925). We decline to identify a more definitive period of noncompliance for a physician-owned hospital's failure to satisfy the public advertising disclosure requirement. We believe that determining the period of noncompliance for a hospital's failure to disclose will depend on the specific facts and circumstances surrounding the hospital's public advertisement. We intended our example in the proposed rule to provide only general guidance and not to delineate a bright-line rule.

After careful review and consideration of the comments, we are finalizing our proposal, without revision, to amend § 411.362(b)(3)(ii)(C) to specify that a public Web site for the hospital does not include, by way of example: Social media Web sites; electronic patient payment portals; electronic patient care portals; and electronic health information exchanges. We are finalizing our proposal, without revision, to add our proposed definition of ''public advertising for the hospital'' at § 411.362(a). We are also finalizing, without revision, our clarifications regarding the periods of noncompliance associated with a failure to satisfy either the public Web site or public advertising disclosure requirements (80 FR 41925).

b. Determining the *Bona Fide* Investment Level (§ 411.362(b)(4)(i))

As stated above, section 6001(a)(3) of the Affordable Care Act established new requirements for physician-owned hospitals to avail themselves of either the rural provider or hospital ownership exceptions to the physician self-referral law, including the requirement that the percentage of the total value of the ownership or investment interests held in a hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate cannot exceed such percentage as of March 23, 2010. In this rule, we refer to the percentage of ownership or investment interests held by physicians in a hospital as the ''*bona fide* investment level'' and such percentage that was set as of March 23, 2010, as the ''baseline *bona fide* investment level.''

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72251), we codified the *bona fide* investment requirement at § 411.362(b)(4)(i). In that final rule we responded to commenters that stated that the *bona fide* investment level should be calculated without regard to any ownership or investment interests held by physicians who do not make any referrals to the hospital, including physicians who are no longer practicing medicine (75 FR 72250). We stated that the ownership or investment interests of non-referring physicians need not be considered when calculating the baseline physician ownership level. In our response, we noted that section 1877(i)(5) of the Act defines ''physician owner or investor'' for the purposes of that subsection to include any physician with a direct or indirect ownership or investment interest in the hospital and that, under our definition of ''indirect ownership or investment interest'' at § 411.354(b)(5), only ''referring physicians'' can have an indirect ownership or investment interest in a DHS entity. Although we did not explicitly address direct ownership or investment interests in our response, we note that only referring physicians can have a direct financial relationship under our existing regulations at § 411.354(a)(2)(i).

Following publication of the CY 2011 OPPS/ASC final rule with comment period, we received inquiries from

industry stakeholders regarding our statement that the baseline *bona fide* investment level need not be calculated as including the ownership or investment interests of non-referring physicians. First, the stakeholders stated that the statutory definition of physician owner or investor is broad and that if the Congress had intended to limit the definition to only referring physicians, the Congress would have included such qualifying language, as it did in a separate requirement established by the Affordable Care Act for physician-owned hospitals in section 1877(i)(C)(ii) of the Act. Second, the stakeholders stated that including only referring physicians in the definition of physician owner or investor for the purposes of establishing the baseline *bona fide* investment level frustrates the purpose of an explicit deadline set forth in the statute. The stakeholders noted that in the Affordable Care Act, the Congress required physician-owned hospitals that seek to avail themselves of the rural provider or hospital ownership exceptions to have had physician ownership or investment as of March 23, 2010, but allowed them until December 31, 2010 to obtain a provider agreement. The stakeholders stated that our position makes the March 23, 2010 deadline meaningless because a pre-operational physician-owned hospital that did not have a provider agreement until December 31, 2010 likely would not have had physician owners or investors referring to the hospital as of the March 23 date. The stakeholders stated that our position regarding non-referring physicians in the CY 2011 OPPS/ASC final rule with comment period, in effect, precluded pre-operational hospitals from satisfying the requirement for physician ownership as of March 23, 2010, thus preventing the hospitals from availing themselves of the hospital ownership or rural provider exceptions.

Given the inquiries that we received after publication of the CY 2011 OPPS/ASC final rule with comment period, we have reconsidered our position that our regulations at § 411.354 necessarily limit the definition of physician owner or investor for the purposes of establishing the baseline *bona fide* investment level (and any *bona fide* investment level thereafter). As we stated in the CY 2011 OPPS/ASC final rule with comment period, we recognize that the statutory definition of physician owner or investor is broad (75 FR 72250). Further, we understand the concern expressed by the stakeholders that our position may frustrate an explicit statutory deadline for certain physician-owned hospitals. We believe that the statutory revisions to the rural provider and hospital ownership exceptions must be read harmoniously and not in a way that makes any provision meaningless. Accordingly, we proposed to revise our policy articulated in the CY 2011 OPPS/ASC final rule with comment period to require that the baseline *bona fide* investment level and the *bona fide* investment level include direct and indirect ownership and investment interests held by a physician if he or she satisfies the definition of ''physician'' in section 1861(r) of the Act and in § 411.351, regardless of whether the physician refers patients to the hospital (and therefore, irrespective of whether he or she is a ''referring physician'' for the purposes of our regulatory definition of ownership or investment interest at § 411.354). Further, under our proposal, the direct or indirect ownership interests held by an individual who no longer practices medicine, as described in the comment summary above, would be counted if he or she satisfies the definition of ''physician'' in section 1861(r) of the Act and in § 411.351. We sought public comment regarding non-referring physicians and the *bona fide* investment level, including whether our proposal might alleviate the burden that some physician-owned hospitals reported when trying to determine whether a particular physician was a referring or non-referring physician for the purposes of establishing their baseline *bona fide* investment levels and the *bona fide* investment levels generally.

To support our proposal and implement the requirements of the statute, we proposed to amend our existing regulations to specify that, for the purposes of § 411.362 (including for the purposes of determining the baseline *bona fide* investment level and the *bona fide* investment level thereafter), the ownership or investment interests held by both referring and non-referring physicians are included. We proposed to effectuate this change by establishing a definition of ownership or investment interest solely for the purposes of § 411.362 that would apply to all types of owners or investors, regardless of their status as referring or non-referring physicians. Specifically, we proposed to define ''ownership or investment interest'' at § 411.362(a) as a direct or indirect ownership or investment interest in a hospital. Under the proposed revision, a direct ownership or investment interest in a hospital exists if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor, and an indirect ownership or investment interest in a hospital exists if: (1) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and (2) the hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital. We also proposed that an indirect ownership or investment interest in a hospital exists even though the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain. As used in § 411.362, the term ''physician'' would continue to have the meaning set forth in § 411.351; that is, an individual who meets the definition of ''physician'' set forth in section 1861(r) of the Act.

We believe that our proposed revision would make the prohibition set forth at § 411.362(b)(4)(i) better align with the statutory definition of ''physician owner or investor'' in a hospital without unsettling long-standing definitions in our regulations. We solicited public comments on our proposed revision to § 411.362, including whether such revision would adequately address the concerns expressed by the stakeholders after publication of the CY 2011 OPPS/ASC final rule with comment period.

We solicited public comments on an alternate proposal that we believe also supports our policy and, thereby, effectuates the statute's purpose. Specifically, we solicited public comments on whether, in the alternative, we should revise our regulations in an even more comprehensive manner and remove the references to a ''referring physician'' throughout existing § 411.354. We invited public comments on whether it would be helpful to retain the references to a ''referring physician'' for those specific provisions where the concept of a physician's referrals to a DHS entity is essential to the provision, such as our definition of an indirect compensation arrangement at § 411.354(c)(2)(ii).

Finally, in the proposed rule we recognized that some physician-owned hospitals may have relied on the position that was articulated in the CY 2011 OPPS/ASC final rule with comment period concerning non-referring physicians and the baseline *bona fide* investment level. If we

finalized one or more of the proposals described in this section of the proposed rule, these hospitals may have revised *bona fide* investment levels that exceed the baseline *bona fide* investment levels calculated under our current guidance. Therefore, we proposed to delay the effective date of the new regulation until such time as physician-owned hospitals would have sufficient time to come into compliance with the new policy. For example, we stated that we could delay the effective date for 1 year from the date of publication in the **Federal Register** of the rulemaking in which we finalize the new regulation or on a specific date, such as January 1, 2017. We solicited comments on how long we should delay the effective date. We also solicited comments on the impact of our proposed regulatory revisions on physician-owned hospitals and on the measures or actions physician-owned hospitals would need to undertake to come into compliance with our proposed revisions.

The following is a summary of the comments we received.

Comment: Four commenters disagreed with the *bona fide* investment level proposal, citing a variety of reasons. For example, two commenters stated that requiring the inclusion of ownership and investment interests held by non-referring physicians in the baseline *bona fide* investment level and every assessment of the *bona fide* investment level thereafter is inconsistent with the purpose of the physician self-referral law. One of these commenters stated that requiring the inclusion of ownership and investment interests held by non-referring physicians in the *bona fide* investment levels would stifle physician investment in physician-owned hospitals and frustrate physician recruitment to communities served by physician-owned hospitals. Another commenter asked us to refrain from finalizing the proposal until we can articulate the precise risk of fraud or abuse that excluding the ownership and investment interests held by non-referring physicians from the *bona fide* investment levels would have on the Medicare program. One commenter stated that requiring the inclusion of ownership and investment interests held by non-referring physicians in the baseline *bona fide* investment level and every assessment of the *bona fide* investment level thereafter impermissibly expands the scope of the physician self-referral law because, according to the commenter, without a ''referral,'' a physician's ownership or investment interest in an entity does not implicate the law and, thus, no applicable exception is needed. This commenter stated that we should create a special carve out for physician-owned hospitals that did not obtain a provider agreement until sometime after March 23, 2010, but by the December 31, 2010 deadline, and that these hospitals should include the ownership and investment interests held by all physicians, regardless of referral status, in the baseline *bona fide* investment level.

Response: We continue to believe that the revised policy articulated in the proposed rule is the only reading of the statute that fully accounts for all relevant provisions of law. We do not believe that we have the authority to continue implementing a policy that is inconsistent with the statute. Accordingly, we are finalizing our proposal, without revision, to require that the baseline *bona fide* investment level and the *bona fide* investment level include direct and indirect ownership and investment interests held by a physician if she or she satisfies the definition of ''physician'' in section 1861(r) of the Act and in § 411.351, regardless of whether the physician refers patients to the hospital (and therefore, irrespective of whether he or she is a ''referring physician'' for the purposes of our regulatory definition of ownership or investment interest at § 411.354). We also are finalizing, without revision, our proposed definition of ''ownership or investment interest'' in § 411.362 to implement our revised policy.

Comment: One commenter stated that requiring the inclusion of the ownership and investment interests held by all physicians, regardless of whether each qualifies as a ''referring'' physician, is a more faithful interpretation of the statute than the policy that we articulated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72250). The commenter stated, however, that we should implement the statute in a different manner than the proposal set forth in the proposed rule. Specifically, the commenter stated that all ownership and investment interests held by physicians as of March 23, 2010, should be included in a hospital's baseline *bona fide* investment level regardless of whether each physician was referring as of that date, but that a physician-owned hospital should be permitted to exclude the ownership and investment interests held by non-referring physicians in any calculation of the *bona fide* investment level thereafter. The commenter noted that in regulations governing provider agreements at § 489.20(u) and (v), CMS chose to not require disclosure of physician ownership interests for any physician-owned hospital that does not have at least one referring physician.

Response: We agree with the commenter that the proposal better aligns with the statute than the policy articulated in the CY 2011 OPPS/ASC final rule with comment period. However, we disagree that a physician-owned hospital should be permitted to exclude the ownership and investment interests held by non-referring physicians in any calculation of the *bona fide* investment level after March 23, 2010. We believe that the term ''physician owner or investor'' as used in the *bona fide* investment level requirement has a singular, defined meaning and that the Congress provided guidance about that meaning through its broad definition of ''physician owner or investor'' at section 1877(i)(5) of the Act, which is supported by a harmonious reading of multiple statutory provisions. Further, as we noted in the proposed rule, if the term ''physician owner or investor'' was intended to include only referring physicians in the *bona fide* investment level requirement, such qualifying language would have been included in the statute, such as in a separate requirement established by the Affordable Care Act for physician-owned hospitals in section 1877(i)(C)(ii) of the Act. Although the commenter's recommended approach would resolve the issue concerning pre-operational hospitals that we discussed in the proposed rule (80 FR 41925), we do not believe that the statute provides sufficient support for concluding that two separate standards can apply for calculating the baseline *bona fide* investment level and every *bona fide* investment level thereafter. Finally, as to the commenter's statements regarding § 489.20(u) and (v), the regulations that govern provider agreements and our regulations concerning the physician self-referral law are two distinct regulatory schemes. Although the regulations cited by the commenter mention physician-owned hospitals, we are bound by the provisions of the physician self-referral law.

Comment: One commenter requested that we clarify that a physician-owned hospital did not improperly calculate its baseline *bona fide* investment level by including the ownership and investment interests held by all physicians regardless of referral status.

Response: We confirm that a proper calculation of a physician-owned hospital's baseline *bona fide* investment level includes the ownership and investment interests held by all physicians regardless of referral status.

Comment: Two commenters stated that requiring the inclusion of ownership and investment interests held by non-referring physicians in the baseline *bona fide* investment level and the assessment of every *bona fide* investment level thereafter likely would cause financial hardship for any non-referring or retiring physicians who would need to sell their ownership interests at the current fair market value to allow a physician-owned hospital to comply with the new policy. The commenters also stated that physician-owned hospitals likely would have to restructure their governance, given the necessary ownership changes, and that such restructuring likely would be difficult and costly for the hospitals.

Response: We acknowledge the commenters' concerns regarding the potential effect that this policy may have on individual physician owners, as well as physician-owned hospitals. While we do not have the discretion to continue implementing a policy that is inconsistent with the statute, we recognize that we need to give physician-owned hospitals a reasonable amount of time to come into compliance with the revised policy. Accordingly, we are delaying the effective date of this revision for one year from the effective date of this final rule to January 1, 2017.

After consideration of the comments, we are amending our existing regulations to specify that, for the purposes of § 411.362 (including for the purposes of determining the baseline *bona fide* investment level and the *bona fide* investment level thereafter), the ownership or investment interests held by both referring and non-referring physicians are included. We are establishing a definition of ownership or investment interest solely for the purposes of § 411.362 that would apply to all types of owners or investors, regardless of their status as referring or non-referring physicians. Specifically, we are defining ''ownership or investment interest'' at § 411.362(a) as a direct or indirect ownership or investment interest in a hospital. Under the final rule, a direct ownership or investment interest in a hospital exists if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor, and an indirect ownership or investment interest in a hospital exists if: (1) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and (2) the hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital. As used in § 411.362, the term ''physician'' would continue to have the meaning set forth in § 411.351; that is, an individual who meets the definition of ''physician'' set forth in section 1861(r) of the Act.

9. Solicitation of Comments: Perceived Need for Regulatory Revisions or Policy Clarification Regarding Permissible Physician Compensation

a. Changes in Health Care Delivery and Payment Systems Since the Enactment of the Physician Self-referral Law

Since the enactment of section 1877 of the Act in 1989, significant changes in the delivery of health care services and the payment for such services have occurred, both within the Medicare and Medicaid programs and for non-federal payors and patients. For over a decade, we have engaged in efforts to align payment under the Medicare program with the quality of the care provided to our beneficiaries. Laws such as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Deficit Reduction Act of 2005 (DRA), and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) have guided our efforts to move toward health care delivery and payment reform. More recently, the Affordable Care Act required significant changes to the Medicare program's payment systems and provides the Secretary with broad authority to test models to implement these reforms. In our proposed rule, we highlighted certain provisions of the Affordable Care Act that grant the Secretary broad authority to test models implementing health care delivery and payment reform. (See 80 FR 41927–28.)

As noted in our proposed rulemaking, we are moving away from Medicare payments to providers and suppliers that do not incorporate the value of the care provided. The Secretary recently set a goal of tying 30 percent of traditional, fee-for-service Medicare payments to quality or value through alternative payment models, such as ACOs or bundled payment arrangements, by the end of 2016, and 50 percent of payments to these models by the end of 2018. The Secretary also set a goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016, and 90 percent of payments to quality or value by 2018, through programs such as the Hospital VBP Program and the Hospital Readmissions Reduction Program. (See press release titled ''Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value,'' U.S. Department of Health & Human Services (Jan. 26, 2015), *http://www.hhs.gov/news/press/2015pres/01/20150126a.html.*)

b. Financial Relationships in Alternative Delivery and Payment Systems

The physician self-referral law, by design, separates entities furnishing DHS from the physicians who refer Medicare patients to them. Evolving health care delivery and payment models, within both the Medicare and Medicaid programs and programs sponsored by non-Federal payors, are premised on the close integration of a variety of different health care providers to achieve the goals of improving the experience of care, improving the health of populations, and reducing per capita costs of health care, often referred to as the ''three-part aim.'' Entities furnishing DHS face the predicament of trying to achieve clinical and financial integration with other health care providers, including physicians, while simultaneously having to satisfy the requirements of an exception to the physician self-referral law's prohibitions if they wish to compensate physicians to help them meet the three-part aim and avoid financial penalties that may be imposed on low-value health care providers. Because all inpatient and outpatient services are considered DHS, hospitals must consider each and every service referred by a physician in their attempts to ensure that compensation paid to a physician does not take into account the volume or value of his or her referrals to the hospital. According to stakeholders, structuring incentive compensation and other payments can be particularly challenging for hospitals, even where the payments are to hospital-employed physicians.

Stakeholders have expressed concern that, outside of the Medicare Shared Savings Program or certain Center for Medicare and Medicaid Innovation-sponsored care delivery and payment models—for which we have issued waivers of the prohibitions of the physician self-referral law—the physician self-referral law prohibits financial relationships necessary to achieve the clinical and financial integration required for successful health care delivery and payment reform. These concerns apply equally to the participation of physicians and entities furnishing health care services in models sponsored and paid for solely

by non-federal payors, where care is provided solely to non-federal program patients, because the financial arrangements between the parties that result from participation in these models must satisfy the requirements of an applicable exception to the physician self-referral law to avoid the law's referral and billing prohibitions on DHS referred for and furnished to Medicare beneficiaries. We also have received numerous stakeholder inquiries, unrelated to participation in alternative health care delivery or payment models, regarding whether certain compensation methodologies would be viewed as taking into account the volume or value of a physician's referrals or other business generated between the physician and the entity furnishing DHS that provides the compensation. Many of these inquiries relate to performance-based or incentive compensation. We have not issued any formal guidance to date, either through a binding advisory opinion or rulemaking.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), enacted April 16, 2015, includes certain Medicare program integrity and fraud and abuse provisions. Notably, MACRA requires the Secretary to undertake two studies relating to the promotion of alternative payment models and to provide the Congress with a gainsharing study and report.

Section 101(e)(7) of MACRA requires the Secretary, in consultation with the Office of Inspector General (OIG), to study and report to the Congress on fraud related to alternative payment models under the Medicare program (the APM Report). The Secretary must study the applicability of the Federal fraud prevention laws to items and services furnished under title XVIII of the Act for which payment is made under an alternative payment model, identify aspects of alternative payment models that are vulnerable to fraudulent activity, and examine the implications of waivers to the fraud prevention laws to support alternative payment models. The Secretary must include in the APM Report the results of her study and recommendations for actions to reduce the vulnerabilities of Medicare alternative payment models, including possible changes in Federal fraud prevention laws to reduce such vulnerabilities. This report must be issued no later than 2 years after the enactment of MACRA.

Section 512(b) of MACRA requires the Secretary, in consultation with OIG, to submit to the Congress a report with options for amending existing fraud and abuse laws and regulations through exceptions, safe harbors or other narrowly tailored provisions, to permit gainsharing arrangements that would otherwise be subject civil money penalties in paragraphs (1) and (2) of section 1128A(b) of the Act and similar arrangements between physicians and hospitals that improve care while reducing waste and increasing efficiency (the Gainsharing Report). The Gainsharing Report must address whether the recommended changes should apply to ownership interests, compensation arrangements, or other relationships. The Gainsharing Report must also describe how the recommendations address accountability, transparency, and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care. Further, the Secretary's Gainsharing Report must consider whether a portion of any savings generated by such arrangements should accrue to the Medicare program. This report must be issued no later than 12 months after the enactment of MACRA.

c. Analysis of Comments

To help inform the APM Report and Gainsharing Report required under sections 101(e)(7) and 512(b) of MACRA, respectively, and to aid us in determining whether additional rulemaking or guidance is desirable or necessary, we solicited comments regarding the impact of the physician self-referral law on health care delivery and payment reform. On this subject, we specifically solicited comments regarding the ''volume or value'' and ''other business generated'' standards, but welcomed comments concerning any of our rules for determining physician compensation.

We received a number of thoughtful comments on the issues raised in the solicitation. We thank the commenters for their input, and we will carefully consider their comments as we prepare the reports to Congress required under sections 101(e)(7) and 512(b) of MACRA and determine whether additional rulemaking on these issues is necessary. We would like to note that our silence in this rule should not be viewed as an affirmation of any commenter's interpretations or views.

10. Technical Corrections

We have become aware that some of the manual citations listed in our regulations are no longer correct. We therefore proposed to update regulations at § 411.351, definitions of ''entity'', '' 'incident to' services or services 'incident to' '', ''parenteral and enteral nutrients, equipment, and supplies'', and ''physician in the group practice'', with the correct citations. We also proposed to modernize the regulatory text by changing ''Web site'' to ''Web site'' in § 411.351, definition of ''list of CPT/HCPCS Codes'', § 411.357(k)(2), (m)(2) through (m)(3), and (m)(5), § 411.362(c)(2)(iv) through (v) and (c)(5), and § 411.384(b). Lastly, we are removing the hyphen from ''publicly-traded'' at § 411.356(a) and § 411.361(d), and we are correcting a minor typographical error at § 411.357(p)(1)(ii)(A).

After the proposed rule went on display, the term ''Web site'' was inadvertently changed to ''Web site.'' Our intention in the proposed rule was to change all instances of the term ''Web site'' to ''Web site.'' We are making this change in the final rule.

11. Comments Outside the Scope of This Rulemaking

Comment: We received several comments, including suggestions on policy changes that are outside the scope of this rulemaking. For example, one commenter requested revisions to the in-office ancillary services exception. Another commenter requested that we make regulatory protections for electronic health records permanent. We also received a few requests that the physician self-referral law be eliminated entirely. In addition, some commenters described their interpretations of various physician self-referral issues or asked questions about existing regulations.

Response: Although we appreciate the commenters taking the time to present these positions, these comments are beyond the scope of this rulemaking and are not addressed in this final rule with comment period. We express no view on these issues; our silence should not be viewed as an affirmation of any commenter's interpretations or views. If these issues are addressed in the future, we will publish a notice of proposed rulemaking that will be open to public comment at that time. Finally, we refer readers to the final rule regarding our exception for electronic health records at § 411.357(w), published December 27, 2013 (78 FR 78751).

O. Private Contracting/Opt-out

1. Background

Effective January 1, 1998, section 1802(b) of the Act permits certain physicians and practitioners to opt out of Medicare if certain conditions are met, and to furnish through private contracts services that would otherwise be covered by Medicare. For those

physicians and practitioners who opt out of Medicare in accordance with section 1802(b) of the Act, the mandatory claims submission and limiting charge rules of section 1848(g) of the Act do not apply. As a result, if the conditions necessary for an effective opt-out are met, physicians and practitioners are permitted to privately contract with Medicare beneficiaries and to charge them without regard to Medicare's limiting charge rules.

a. Provisions of the Regulation

The private contracting/opt out provisions at section 1802(b) of the Act were recently amended by section 106(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10). Prior to the MACRA amendments, the law specified that physicians and practitioners may opt out for a 2-year period. Individuals that wished to renew their opt-out at the end of a 2-year opt-out period were required to file new affidavits with their MAC. Section 106(a) of the MACRA amends section 1802(b)(3) of the Act to require that opt-out affidavits filed on or after June 16, 2015, automatically renew every 2 years. Therefore, physicians and practitioners that file opt-out affidavits on or after June 16, 2015, will no longer be required to file renewal affidavits to continue their opt-out status. The amendments further provide that physicians and practitioners who have filed opt-out affidavits on or after June 16, 2015, and who do not want their opt-out status to automatically renew at the end of a 2-year opt-out period may cancel the automatic extension by notifying us at least 30 days prior to the start of the next 2-year opt-out period.

We proposed to revise the regulations governing the requirements and procedures for private contracts at 42 CFR part 405, subpart D so that they conform with these statutory changes. Specifically, we proposed to revise the following:

- The definition of ''Opt-out period'' at § 405.400 so that opt-out affidavits automatically renew unless the physician or practitioner properly cancels opt-out.
- Sections 405.405(b); 405.410(c)(1) and (2); 405.415(h), (m), and (o); 405.425; 405.435(a)(4); 405.435(b)(8); 405.435(d); and 405.445(b)(2) so those sections conform with the revised definition of ''Opt-out period''.
- Section 405.445(a) so that proper cancellation of opt-out requires a physician or practitioner to submit written notice, not later than 30 days before the end of the current 2-year opt-out period, that the physician or practitioner does not want to extend the application of the opt-out affidavit for a subsequent 2-year period.
- Section 405.450(a) so that failure to properly cancel opt-out is included as an initial determination for purposes of § 498.3(b).

To update the terminology in our regulations, we also proposed to amend §§ 405.410(d), 405.435(d), and 405.445(b)(2) so that the term ''carrier'' is replaced with ''Medicare Administrative Contractor''.

We received 13 comments on our private contracting/opt-out proposal.

Comment: Many commenters supported the proposed rule.

Response: We appreciate the commenters' support.

Comment: One commenter proposed that the rule be modified to permit cancellation of opt-out (with a 30-day notice) any time after the physician's or practitioner's initial 2-year opt-out period concludes. The commenter stated that a physician who cancels opt-out and later chooses to opt-out again should be subject to another initial 2-year opt-out period. The commenter contended that such a standard would be sufficient to prevent abuse without requiring the perpetual monitoring of opt-out renewal dates.

Response: We appreciate the comment, but note that the commenter's proposal is inconsistent with the requirements of section 106(a)(1) of MACRA. As noted earlier in this preamble, the MACRA amendments permit physicians and practitioners who have filed opt-out affidavits on or after June 16, 2015, and who do not want their opt-out status to automatically renew at the end of a 2-year opt-out period to cancel the automatic extension by notifying us at least 30 days prior to the start of the next 2-year opt-out period. The MACRA amendments changed the procedures for renewing the opt-out period; it now renews automatically unless we receive written notice requesting otherwise. The MACRA amendments, however, did not change the requirement that physicians and practitioners opt-out in 2-year intervals. Therefore, because MACRA does not provide any flexibility to cancel opt-out before the 2 year opt-out period actually ends, we are not modifying the rule based on this comment.

To effectuate the changes made by the MACRA, we are finalizing these provisions of the rule as proposed with the exception of minor editorial changes to § 405.445. These changes clarify this section consistent with plain language principles but do not alter the meaning of the proposal.

P. Physician Self-Referral Prohibition: Annual Update to the List of CPT/HCPCS Codes

1. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Outpatient speech-language pathology services.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

2. Annual Update to the Code List

a. Background

In § 411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The DHS categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs furnished in or by an ESRD facility (§ 411.355(g)).
- Preventive screening tests, immunizations, or vaccines (§ 411.355(h)).

The definition of DHS at § 411.351 excludes services for which payment is made by Medicare as part of a composite rate (unless the services are specifically identified as DHS and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not DHS and are not listed among the drugs that could qualify for the exception at § 411.355(g) for EPO and other dialysis-related drugs furnished by an ESRD facility.

Drugs for which there are no injectable equivalents or other forms of administration were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, there have been several delays of the implementation of payment of these drugs under ESRD PPS. Most recently, on December 19, 2014, section 204 of the Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) was enacted and delayed the inclusion of these drugs under the ESRD PPS until 2025. Until that time, such drugs furnished in or by an ESRD facility are not paid as part of a composite rate and thus, are DHS. For purposes of the exception at § 411.355(g), only those drugs that are required for the efficacy of dialysis may be identified on the List of CPT/HCPCS Codes as eligible for the exception. As we have explained previously in the CY 2010 PFS final rule with comment period (75 FR 73583), we do not believe any of these drugs are required for the efficacy of dialysis. Therefore, we have not included any such drugs on the list of drugs that can qualify for the exception.

The Code List was last updated in Tables 90 and 91 of the CY 2015 PFS final rule with comment period (79 FR 67973–67975).

b. Response to Comments

We received three public comments relating to the Code List that became effective January 1, 2015.

Comment: All of the commenters requested the removal of two disposable negative pressure wound therapy (NPWT) codes, 97607 and 97608. The commenters stated that the definition of ''referral'' does not include services personally performed by the referring/ordering physician and that a typical patient provided with a disposal NPWT device will require significant clinical interaction from the physician to thoroughly clean a wound prior to application of such a device.

Response: We are aware that there are some circumstances under which these codes will not be considered therapy services. The codes in question are not considered therapy services when: (1) It is not appropriate to bill the service under a therapy plan of care; and (2) they are billed by practitioners/providers of services who are not therapists, such as physicians, CNSs, NPs and psychologists; or they are billed to MACs by hospitals for outpatient services which are performed by non-therapists. However, these and certain other codes can also be furnished as therapy services, specifically under a physical therapy, occupational therapy, or speech-language pathology plan of care in accordance with section 1861(p) of the Act. We note that determinations should be made on a case-by-case basis with respect to whether the physician self-referral law is implicated when using these codes. Please refer to the billing rules associated with these codes to avoid violating the physician self-referral law.

c. Revisions Effective for CY 2016

The updated, comprehensive Code List effective January 1, 2016, is available on our Web site at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html*.

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II, and to changes in Medicare coverage policy and payment status.

Tables 50 and 51 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2016. Tables 50 and 51 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

We will consider comments regarding the codes listed in Tables 50 and 51. Comments will be considered if we receive them by the date specified in the ''DATES'' section of this final rule with comment period. We will not consider any comment that advocates a substantive change to any of the DHS definitions in § 411.351.

TABLE 50—ADDITIONS TO THE PHYSICIAN SELF-REFERRAL LIST OF CPT[1]/HCPCS CODES

CLINICAL LABORATORY SERVICES
G0475 HIV combination assay
G0476 HPV combo assay CA screen
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
{No additions}
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
72081 X-ray exam entire spi 1 vw
72082 X-ray exam entire spi 2/3 vw
72083 X-ray exam entire spi 4/5 vw
72084 X-ray exam entire spi 6/> vw
73501 X-ray exam hip uni 1 view
73502 X-ray exam hip uni 2–3 views
73503 X-ray exam hip uni 4/> views
73521 X-ray exam hips bi 2 views
73522 X-ray exam hips bi 3–4 views
73523 X-ray exam hips bi 5/> views
73551 X-ray exam of femur 1
73552 X-ray exam of femur 2/>
74712 Mri fetal sngl/1st gestation
78265 Gastric emptying imag study
78266 Gastric emptying imag study
C9457 Lumason contrast agent
C9458 Florbetaben F18
C9459 Flutemetamol F18
G0297 LDCT for Lung CA screen
RADIATION THERAPY SERVICES AND SUPPLIES
0394T Hdr elctrnc skn surf brchytx
0395T Hdr elctr ntrst/ntrcv brchtx
77767 Hdr rdncl skn surf brachytx
77768 Hdr rdncl skn surf brachytx
77770 Hdr rdncl ntrstl/icav brchtx
77771 Hdr rdncl ntrstl/icav brchtx
77772 Hdr rdncl ntrstl/icav brchtx
C2645 Brachytx planar, p-103
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No additions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
G0475 HIV combination assay
G0476 HPV combo assay CA screen

[1] CPT codes and descriptions only are copyright 2015 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 51—DELETIONS FROM THE PHYSICIAN SELF-REFERRAL LIST OF CPT[1]/HCPCS CODES

CLINICAL LABORATORY SERVICES
0103T Holotranscobalamin
G0431 Drug screen multiple class
G0434 Drug screen multi drug class
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
{No deletions}
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
72010 X-ray exam of spine
72069 X-ray exam of trunk spine
72090 X-ray exam of trunk spine
73500 X-ray exam of hip
73510 X-ray exam of hip
73520 X-ray exam of hips

TABLE 51—DELETIONS FROM THE PHYSICIAN SELF-REFERRAL LIST OF CPT[1]/HCPCS CODES—Continued

73540 X-ray exam of pelvis & hips
73550 X-ray exam of thigh
RADIATION THERAPY SERVICES AND SUPPLIES
0182T HDR elect brachytherapy
77777 Apply interstit radiat inter
77787 HDR brachytx over 12 chan
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No deletions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
90669 Pneumococcal vacc 7 val im

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IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

In the CY 2016 PFS proposed rule (80 FR 41930 through 41937) we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements. PRA-related comments were received as indicated below under section IV.B.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (*www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 52 presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

TABLE 52—ESTIMATED HOURLY WAGES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Billing and Posting Clerks	43–3021	17.10	9.58*	26.68
Business Operations Specialists	13–1000	33.69	33.69	67.38
Computer Systems Analysts	15–1121	41.98	41.98	83.96
Medical and Health Services Managers	11–9111	49.84	49.84	99.68
Medical Secretaries	43–6013	16.12	16.12	32.24
Physicians and Surgeons	29–1060	93.71	93.71	187.48

* For fringe benefits, we are using the December 2014 Employer Costs for Employee Compensation (*http://www.bls.gov/news.release/archives/ecec_03112015.pdf*).

Except where noted, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Information Collection Requirements (ICRs) Carried Over From the CY 2016 Proposed Rule

1. ICRs Regarding 42 CFR part 405, subpart D

Section 106(a) of MACRA indicates that valid opt-out affidavits filed on or after June 16, 2015, automatically renew every 2 years. Previously, physicians and practitioners wanting to renew their opt-out were required to file new valid affidavits with their Medicare Administrative Contractors (MACs).

To be consistent with section 106(a), we revised 42 CFR part 405, subpart D, governing the submission of opt-out affidavits. We estimate that 150 physicians/practitioners will submit new affidavits at 2 hr per submission or 300 hr (total). Previously, we estimated that 600 physicians/practitioners would submit renewal affidavits at 2 hr per submission or 1,200 hr (total). In this regard, the burden will decrease by −900 hr (300 hr − 1,200 hr) when physicians and practitioners no longer need to submit renewal affidavits starting on June 16, 2017. We also estimate that a medical secretary will perform this duty at $32.24/hr for a savings of −$29,016 (−900 hr × $32.24/hr).

Under § 405.445(a), physicians and practitioners that file valid opt-out affidavits on or after June 16, 2015 and do not want to extend their opt-out status at the end of a 2 year opt-out period may cancel by notifying us at least 30 days prior to the start of the next 2 year opt-out period. The burden associated with this new requirement is the time to draft, sign and submit the written request to the MAC. We estimate it will take 60 physicians/practitioners approximately 10 min each for a total of 10 hr. We also estimate that a medical secretary will perform this duty at $32.24/hr for a total cost of $322.40 (10 hr x $32.24/hr).

We did not receive any public comments regarding the proposed requirements or burden and are adopting them without change. The requirements and burden will be submitted to OMB under control number 0938–0730 (CMS–R–234).

2. ICRs Regarding the Payment for RHC and FQHC Services (§ 405.2462) and What Constitutes a Visit (§ 405.2463)

For a clinic that was billing as if it were provider-based to an IHS hospital as of April 7, 2000, and is now a tribally-operated clinic contracted or compacted under the ISDEAA, §§ 405.2462(d) and 405.2463(c)(4) provides that the clinic may seek to become certified as a grandfathered tribal FQHC. To become certified, an eligible tribe or tribal organization must submit an enrollment application (CMS–855A, OMB control number 0938–0685) and all required documentation, including an attestation of compliance with the Medicare FQHC Conditions for Coverage at part 491, to

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TABLE 65: 2016 VM AMOUNTS UNDER QUALITY-TIERING—Continued

Cost/quality	Low quality	Average quality	High quality
High Cost	−2.0%	−1.0%	+0.0%

* Groups of physicians eligible for an additional +1.0x if (1) reporting Physician Quality Reporting System quality measures and (2) average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

To ensure budget neutrality, we first aggregate the Category 1 groups' downward payment adjustments under quality-tiering, in Table 65 with the Category 2 groups' −2.0 percent automatic downward payment adjustments. Using the aggregate downward payment adjustment amount, we then calculate the upward payment adjustment factor (x). These calculations will be done after the performance period has ended.

On September 8, 2015, we made the 2014 Annual QRURs available to all groups and solo practitioners based on their performance in CY 2014. We also completed a preliminary analysis (prior to accounting for the informal review process) of the impact of the VM in CY 2016 on physicians in groups with 10 or more EPs based on their performance in CY 2014 and present a summary of the findings below. Please note that the impact of the policies for the CY 2018 VM finalized in this final rule with comment period will be discussed in the PFS rule for CY 2018.

Based on the methodology codified in § 414.1210(c), there are 13,785 groups of 10 or more EPs (as identified by their Taxpayer Identification Numbers (TINs)) whose physicians' payments under the Medicare PFS will be subject to the VM in the CY 2016 payment adjustment period. Of these 13,785 groups subject to the CY 2016 VM, preliminary results show that 8,357 groups met the criteria for inclusion in Category 1 and are subject to the quality-tiering methodology in order to calculate their CY 2016 VM. Of the 8,357 groups in Category 1, there are 7,639 groups of physicians with between 10 and 99 EPs and 718 groups of physicians with 100 or more EPs. As noted in this section, these are preliminary numbers and may be subject to change as a result of the informal review process. We release the actual number of upward and downward adjustments, along with the adjustment factor after the conclusion of the informal review process.

Of the 7,639 groups of physicians with between 10 and 99 EPs, preliminary results found that 110 groups are in tiers that will result in an upward adjustment of between +1.0x and +3.0x; 42 of those groups qualify for the additional +1.0x adjustment to their Medicare payments for treating high-risk beneficiaries; and 7,529 groups are in tiers that will result in a neutral adjustment to their payments in CY 2016. Of the 718 groups of physicians with 100 or more EPs, our preliminary results showed that 9 groups are in tiers that will result in an upward adjustment of between +1.0x and +3.0x, with 4 of those groups qualifying for the additional +1.0x adjustment to their Medicare payments for treating high-risk beneficiaries; 54 groups are in tiers that will result in a downward adjustment of between −1.0 and −2.0 percent; and 655 groups are in tiers that will result in a neutral adjustment to their payments in CY 2016. We will announce the final quality-tiering results along with the upward payment adjustment factor (x) in the late 2015 on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html.* Tables 66 shows the preliminary distribution of the groups with between 10 and 99 EPs in Category 1 into the various quality and cost tiers. Tables 67 shows the preliminary distribution of the groups with 100 or more EPs in Category 1 into the various quality and cost tiers.

TABLE 66—PRELIMINARY DISTRIBUTION USING 2014 DATA OF QUALITY AND COST TIERS FOR GROUPS WITH BETWEEN 10 TO 99 EPS (7,639 GROUPS)

Cost/quality	Low quality	Average quality	High quality
Low Cost	0.0% (6)	+[1.0/2.0]x (50)	+[2.0/3.0]x (1)
Average Cost	0.0% (589)	0.0% (6,700)	+[1.0/2.0]x (59)
High Cost	0.0% (32)	0.0% (201)	0.0% (1)

TABLE 67—PRELIMINARY DISTRIBUTION USING 2014 DATA OF QUALITY AND COST TIERS FOR GROUPS WITH 100 OR MORE EPS (718 GROUPS)

Cost/Quality	Low Quality	Average Quality	High Quality
Low Cost	0.0% (0)	+[1.0/2.0]x (6)	+[2.0/3.0]x (0)
Average Cost	−1.0% (31)	0.0% (655)	+[1.0/2.0]x (3)
High Cost	−2.0% (0)	−1.0% (23)	0.0% (0)

Of the 13,785 groups subject to the CY 2016 VM, preliminary results found that 5,428 groups met the criteria for inclusion in Category 2. As noted above, Category 2 includes groups that do not fall within Category 1. Groups in Category 2 will be subject to a −2.0 percent payment adjustment under the VM during the CY 2016 payment adjustment period.

In CY 2016, only the physicians in groups with 10 or more EPs will be subject to the VM.

We note that in the 2014 QRUR Experience Report, which we intend to release in early 2016, we will provide a detailed analysis of the impact of the 2016 VM policies on groups of 10 or more EPs subject to the VM in CY 2016, including findings based on the data contained in the 2014 QRURs for all groups and solo practitioners.

14. Physician Self-Referral Updates

The physician self-referral update provisions are discussed in section III.N. of this final rule with comment period. We did not receive any comments on the physician self-referral updates regulatory impact section of the proposed rule.

Physicians and Designated Health Services (DHS) entities have been complying with the requirements set forth in the physician self-referral law for many years, specifically in regard to clinical laboratory services since 1992 and to referrals for all other DHS since 1995. The majority of the physician self-

referral update provisions in this final rule with comment period will reduce burden by clarifying previous guidance. We believe these provisions will allow parties to determine with greater certainty whether their financial relationships comply with an exception.

We are also issuing new exceptions and a new definition that will accommodate legitimate financial arrangements while continuing to protect against program and patient abuse:

• In section III.N.2.a of this final rule with comment period, we discuss a limited new exception for hospitals, FQHCs, and RHCs that wish to provide remuneration to physicians to assist with the compensation of a nonphysician practitioner. This new exception would promote access to primary medical and mental health care services, a goal of the Secretary and the Affordable Care Act.

• In section III.N.2.b of this final rule with comment period, we describe the new definition of the geographic area served by an FQHC or RHC we are adding to physician recruitment exception. This new definition will provide certainty to FQHCs and RHCs that their physician recruitment arrangements satisfy the requirements of the exception.

• In section III.N.7 of this final rule with comment period, we discuss a new exception that will protect timeshare arrangements that meet certain criteria. This new exception will help ensure beneficiary access to care, particularly in rural and underserved areas.

To the extent that the new exceptions and definition permit additional legitimate arrangements to comply with the law, this rule will reduce the potential costs of restructuring such arrangements, and the consequences of noncompliance may be avoided entirely.

• In section III.N.9.b of this final rule with comment period, we discuss the requirement that the physician-owned hospital baseline bona fide investment level and the bona fide investment level include direct and indirect ownership and investment interests held by a physician regardless of whether the physician refers patients to the hospital. We recognize that some physician-owned hospitals may have relied on earlier guidance that the ownership or investment interests of non-referring physicians need not be considered when calculating the baseline bona fide physician ownership level and may have revised bona fide investment levels that may exceed the baseline bona fide investment levels calculated under our previous guidance. As discussed in section III.N.9.b, while we do not have the discretion to continue implementing a policy that is inconsistent with the statute, we recognize that we need to give physician-owned hospitals a reasonable amount of time to come into compliance with the revised policy. Accordingly, we are delaying the effective date of this revision for one year from the effective date of this final rule to January 1, 2017.

15. Opt Out Change

We revised the regulations governing the requirements and procedures for private contracts at part 405, subpart D so that they conform with the statutory changes made by section 106(a) of the MACRA. We anticipate no or minimal impact as a result of these revisions.

F. Alternatives Considered

This final rule with comment period contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered.

G. Impact on Beneficiaries

There are a number of changes in this final rule with comment period that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through revisions to the inputs used to calculate payments under the PFS will have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

Most of the aforementioned policy changes could result in a change in beneficiary liability as relates to coinsurance (which is 20 percent of the fee schedule amount, if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in Table 63, the CY 2015 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $109.60, which means that in CY 2015, a beneficiary would be responsible for 20 percent of this amount, or $21.92. Based on this final rule with comment period, using the CY 2016 CF, the CY 2016 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 63, is $109.28, which means that, in CY 2016, the proposed beneficiary coinsurance for this service would be $21.86.

H. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf),* in Table 66 (Accounting Statement), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2015 to CY 2016 based on the FY 2016 President's Budget baseline. Note that subsequent legislation changed the updates for 2016 from those shown in the 2016 President's Budget baseline.

TABLE 66—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2016 Annualized Monetized Transfers.	Estimated increase in expenditures of $0.0 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.
CY 2016 Annualized Monetized Transfers.	Estimated increase in payment of $0.0 billion.
From Whom To Whom?	Federal Government to eligible professionals who satisfactorily participate in the Physician Quality Reporting System (PQRS).

TABLE 67—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2016 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.0 billion
From Whom to Whom?	Federal Government to Beneficiaries.

I. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

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management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by clinical staff. The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services

* * * * *

■ 21. Section 410.41 is amended by revising paragraph (b) to read as follows:

§ 410.41 Requirements for ambulance suppliers.

* * * * *

(b) *Vehicle staff.* A vehicle furnishing ambulance services must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished, and at least one of the staff members must, for:

(1) *BLS vehicles.* (i) Be certified at a minimum as an emergency medical technician-basic by the State or local authority where the services are furnished; and

(ii) Be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle;

(2) *ALS vehicles.* (i) Meet the requirements of paragraph (b)(1) of this section; and

(ii) Be certified as a paramedic or an emergency medical technician, by the State or local authority where the services are being furnished, to perform one or more ALS services.

* * * * *

■ 22. Section 410.78 is amended by adding paragraph (b)(2)(ix) to read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) * * *

(2) * * *

(ix) A certified registered nurse anesthetist as described in § 410.69.

* * * * *

■ 23. Section 410.160 is amended by revising paragraph (b)(8) to read as follows:

§ 410.160 Part B annual deductible.

* * * * *

(b) * * *

(8) Beginning January 1, 2011, for a surgical service, and beginning January 1, 2015, for an anesthesia service, furnished in connection with, as a result of, and in the same clinical encounter as a planned colorectal cancer screening test. A surgical or anesthesia service furnished in connection with, as a result of, and in the same clinical encounter as a colorectal cancer screening test means—a surgical or anesthesia service furnished on the same date as a planned colorectal cancer screening test as described in § 410.37.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 24. 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).

■ 25. Section 411.351 is amended by—

■ a. In the definition of ''Entity'', revising paragraph (3).

■ b. Revising the definitions of '' 'Incident to' services or services 'incident to' '', ''List of CPT/HCPCS Codes'', and ''Locum tenens physician''.

■ c. In the definition of ''Parenteral and enteral nutrients, equipment, and supplies'', revising paragraphs (1) and (2).

■ d. Revising the definition of ''Physician in the group practice''.

■ e. In the definition of ''Remuneration'', revising paragraph (2).

The revisions read as follows:

§ 411.351 Definitions.

* * * * *

Entity * * *

(3) For purposes of this subpart, ''entity'' does not include a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with § 414.50 of this chapter and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.9.

* * * * *

''Incident to'' services or services ''incident to'' means those services and supplies that meet the requirements of section 1861(s)(2)(A) of the Act, § 410.26 of this chapter, and Pub. 100–02, Medicare Benefit Policy Manual, Chapter 15, Sections 60, 60.1, 60.2, 60.3, and 60.4.

* * * * *

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually, as published in the **Federal Register**, and is posted on the CMS Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp#TopOfPage*.

Locum tenens physician (or substitute physician) is a physician who substitutes in exigent circumstances for another physician, in accordance with section 1842(b)(6)(D) of the Act and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.11.

* * * * *

Parenteral and enteral nutrients, equipment, and supplies * * *

(1) *Parenteral nutrients, equipment, and supplies*, meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in Pub. 100–03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2, as amended or replaced from time to time; and

(2) *Enteral nutrients, equipment, and supplies*, meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in Pub. 100–03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2.

* * * * *

Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under § 411.352(g) (or the contract must satisfy the requirements of the personal service arrangements exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules in § 424.80(b)(2) of this chapter (see also Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.7, as amended or replaced from time to time). Referrals from an

independent contractor who is a physician in the group practice are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b).

* * * * *

Remuneration * * *

(2) The furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely for one or more of the following purposes:

(i) Collecting specimens for the entity furnishing the items, devices or supplies;

(ii) Transporting specimens for the entity furnishing the items, devices or supplies;

(iii) Processing specimens for the entity furnishing the items, devices or supplies;

(iv) Storing specimens for the entity furnishing the items, devices or supplies;

(v) Ordering tests or procedures for the entity furnishing the items, devices or supplies; or

(vi) Communicating the results of tests or procedures for the entity furnishing the items, devices or supplies.

* * * * *

■ 26. Section 411.353 is amended by revising paragraphs (g)(1)(i) and (ii) to read as follows:

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

* * * * *

(g) * * *

(1) * * *

(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in § 411.355, § 411.356, or § 411.357, except with respect to the signature requirement in § 411.357(a)(1), (b)(1), (d)(1)(i), (e)(1)(i), (e)(4)(i), (l)(1), (p)(2), (q) (incorporating the requirement contained in § 1001.952(f)(4) of this title), (r)(2)(ii), (t)(1)(ii) or (t)(2)(iii) (both incorporating the requirements contained in § 411.357(e)(1)(i)), (v)(7)(i), (w)(7)(i), (x)(1)(i), or (y)(1); and

(ii) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant (without regard to whether any referrals occur or compensation is paid during such 90-day period) and the compensation arrangement otherwise complies with all criteria of the applicable exception.

* * * * *

■ 27. Section 411.354 is amended by revising paragraphs (c)(3)(i), (d)(1), (d)(4) introductory text, (d)(4)(i), (d)(4)(iv)(A), and (d)(4)(v) to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

* * * * *

(c) * * *

(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv) of this section, a physician who ''stands in the shoes'' of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. When applying the exceptions in §§ 411.355 and 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the ''parties to the arrangements'' are considered to be—

(A) With respect to a signature requirement, the physician organization and any physician who ''stands in the shoes'' of the physician organization as required under paragraph (c)(1)(ii) or (c)(2)(iv)(A) of this section; and

(B) With respect to all other requirements of the exception, including the relevant referrals and other business generated between the parties, the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians).

* * * * *

(d) * * *

(1) Compensation is considered ''set in advance'' if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

* * * * *

(4) A physician's compensation from a bona fide employer or under a managed care contract or other arrangement for personal services may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets all of the following conditions. The compensation arrangement:

(i) Is set in advance for the term of the arrangement.

* * * * *

(iv) * * *

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

* * * * *

(v) The required referrals relate solely to the physician's services covered by the scope of the employment, the arrangement for personal services, or the contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, arrangement for personal services, or contract.

■ 28. Section 411.356 is amended by revising paragraphs (a) introductory text and (a)(1)(i) and (ii) and adding paragraph (a)(1)(iii) to read as follows:

§ 411.356 Exceptions to the referral prohibition related to ownership or investment interests.

* * * * *

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and (2) of this section.

(1) * * *

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis;

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers; or

(iii) Listed for trading on an electronic stock market or over-the-counter quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.

* * * * *

■ 29. Section 411.357 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(1) through (4), (a)(5) introductory text, (a)(6) and (7), (b)(1) through (3), (b)(4) introductory text, (b)(5) and (6), (c)(3), (d)(1)(iii), (iv)

and (vii), (e)(1)(iii) and (iv), (e)(4)(i) and (iv), (e)(6), (f)(2), (k)(2), (l) introductory text, (l)(1) and (2), (m)(1) through (3), (m)(5), (p)(1)(ii)(A), (p)(2), (r)(2)(iv) and (v), (s)(1), (t)(2)(iv)(A).

■ b. Adding paragraphs (x) and (y).

The revisions and additions read as follows:

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

* * * * *

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if the arrangement meets the following requirements:

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The duration of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same space during the first year of the original lease arrangement.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the lease arrangement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the lease arrangement are not determined—

* * * * *

(6) The lease arrangement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of paragraph (a) of this section if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (a)(1) through (6) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (a)(1) through (6) of this section.

(b) * * *

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor).

(3) The duration of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same equipment during the first year of the original lease arrangement.

(4) The rental charges over the term of the lease arrangement are set in advance, are consistent with fair market value, and are not determined—

* * * * *

(5) The lease arrangement would be commercially reasonable even if no referrals were made between the parties.

(6) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of paragraph (b) of this section if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (b)(1) through (5) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding lease arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (b)(1) through (5) of this section.

(c) * * *

(3) The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer.

* * * * *

(d) * * *

(1) * * *

(iii) The aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The duration of each arrangement is for at least 1 year. To meet this requirement, if an arrangement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement.

* * * * *

(vii) If the arrangement expires after a term of at least 1 year, a holdover arrangement immediately following the expiration of the arrangement satisfies the requirements of paragraph (d) of this section if the following conditions are met:

(A) The arrangement met the conditions of paragraphs (d)(1)(i) through (vi) of this section when the arrangement expired;

(B) The holdover arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(C) The holdover arrangement continues to satisfy the conditions of paragraphs (d)(1)(i) through (vi) of this section.

* * * * *

(e) * * *

(1) * * *

(iii) The amount of remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties; and

(iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment or services arrangement that complies with § 411.354(d)(4)).

* * * * *

(4) * * *

(i) The writing in paragraph (e)(1) of this section is also signed by the physician practice.

* * * * *

(iv) Records of the actual costs and the passed-through amounts are maintained for a period of at least 6 years and made available to the Secretary upon request.

* * * * *

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(ii) The ''geographic area served'' by a federally qualified health center or a rural health clinic is the area composed of the lowest number of contiguous or noncontiguous zip codes from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center or rural health clinic may include one or more zip codes from which the federally qualified health center or rural health clinic draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients.

(f) * * *

(2) The remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity.

* * * * *

(k) * * *

(2) The annual aggregate nonmonetary compensation limit in this paragraph (k) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI–U_Updates.asp.*

* * * * *

(l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.352) for the provision of items or services (other than the rental of office space) by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in writing.

(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

* * * * *

(m) * * *

(1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(2) Except with respect to identification of medical staff on a hospital Web site or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital Web site or in hospital advertising, meets the ''on campus'' requirement of this paragraph (m).

* * * * *

(5) 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). The $25 limit in this paragraph (m)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–I for the 12 month period and the new limits on the physician self-referral Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.*

* * * * *

(p) * * *

(1) * * *

(ii) * * *

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

* * * * *

(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 writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

* * * * *

(r) * * *

(2) * * *

(iv) The hospital, federally qualified health center, or rural health clinic does not determine the amount of the payment in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the physician or any other business generated between the parties.

(v) The physician is allowed to establish staff privileges at any hospital(s), federally qualified health center(s), or rural health clinic(s) and to refer business to any other entities (except as referrals may be restricted under an employment arrangement or services arrangement that complies with § 411.354(d)(4)).

* * * * *

(s) * * *

(1) The professional courtesy is offered to all physicians on the entity's bona fide medical staff or in such entity's local community or service area, and the offer does not take into account the volume or value of referrals or other business generated between the parties;

* * * * *

(t) * * *

(2) * * *

(iv) * * *

(A) An amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months), using a reasonable and consistent methodology that is calculated uniformly; or

* * * * *

(x) *Assistance to compensate a nonphysician practitioner.* (1) Remuneration provided by a hospital to a physician to compensate a nonphysician practitioner to provide patient care services, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by the hospital, the

physician, and the nonphysician practitioner.

(ii) The arrangement is not conditioned on—

(A) The physician's referrals to the hospital; or

(B) The nonphysician practitioner's referrals to the hospital.

(iii) The remuneration from the hospital—

(A) Does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); and

(B) Is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by—

(1) The physician (or any physician in the physician's practice) or other business generated between the parties; or

(2) The nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.

(iv) The compensation, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the patient care services furnished by the nonphysician practitioner to patients of the physician's practice.

(v) The nonphysician practitioner has not, within 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under § 411.354(c))—

(A) Practiced in the geographic area served by the hospital; or

(B) Been employed or otherwise engaged to provide patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished services at the medical practice site located in the geographic area served by the hospital.

(vi)(A) The nonphysician practitioner has a compensation arrangement with the physician or the physician organization in whose shoes the physician stands under § 411.354(c); and

(B) Substantially all of the services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services.

(vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide patient care services in the geographic area served by the hospital.

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

(2) Records of the actual amount of remuneration provided under paragraph (x)(1) of this section by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(3) For purposes of this paragraph (x), ''nonphysician practitioner'' means a physician assistant as defined in section 1861(aa)(5) of the Act, a nurse practitioner or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, a certified nurse-midwife as defined in section 1861(gg) of the Act, a clinical social worker as defined in section 1861(hh) of the Act, or a clinical psychologist as defined in § 410.71(d) of this subchapter.

(4) For purposes of paragraphs (x)(1)(ii)(B) and (x)(1)(iii)(B)(2) of this section, ''referral'' means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the nonphysician practitioner.

(5) For purposes of paragraph (x)(1) of this section, ''geographic area served by the hospital'' has the meaning set forth in paragraph (e)(2) of this section.

(6) For purposes of paragraph (x)(1) of this section, a ''compensation arrangement'' between a physician (or the physician organization in whose shoes the physician stands under § 411.354(c) and a nonphysician practitioner—

(i) Means an employment, contractual, or other arrangement under which remuneration passes between the parties; and

(ii) Does not include a nonphysician practitioner's ownership or investment interest in a physician organization.

(7)(i) This paragraph (x) may be used by a hospital, federally qualified health center, or rural health clinic only once every 3 years with respect to the same referring physician.

(ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, or rural health clinic to a physician to compensate a nonphysician practitioner to provide patient care services if—

(A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide patient care services with the physician (or the physician organization in whose shoes the physician stands) within 1 year of the commencement of the employment or contractual arrangement; and

(B) The remuneration provided to the physician is provided during a period that does not exceed 2 consecutive years as measured from the commencement of the compensation arrangement between the nonphysician practitioner who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

(8)(i) This paragraph (x) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(ii) The ''geographic area served'' by a federally qualified health center or a rural health clinic has the meaning set forth in paragraph (e)(6)(ii) of this section.

(y) *Timeshare arrangements.* Remuneration provided under an arrangement for the use of premises, equipment, personnel, items, supplies, or services if the following conditions are met:

(1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement.

(2) The arrangement is between a physician (or the physician organization in whose shoes the physician stands under § 411.354(c) and—

(i) A hospital; or

(ii) Physician organization of which the physician is not an owner, employee, or contractor.

(3) The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used—

(i) Predominantly for the provision of evaluation and management services to patients; and

(ii) On the same schedule.

(4) The equipment covered by the arrangement is—

(i) Located in the same building where the evaluation and management services are furnished;

(ii) Not used to furnish designated health services other than those incidental to the evaluation and management services furnished at the time of the patient's evaluation and management visit; and

(iii) Not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).

(5) The arrangement is not conditioned on the referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.

(6) The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined—

(i) In a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(7) The arrangement would be commercially reasonable even if no referrals were made between the parties.

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

(9) The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

■ 30. Section 411.361 is amended by revising paragraph (d) to read as follows:

§ 411.361 Reporting requirements.

* * * * *

(d) *Reportable financial relationships.* For purposes of this section, a reportable financial relationship is any ownership or investment interest, as defined at § 411.354(b) or any compensation arrangement, as defined at § 411.354(c), except for ownership or investment interests that satisfy the exceptions set forth in § 411.356(a) or § 411.356(b) regarding publicly traded securities and mutual funds.

* * * * *

■ 31. Section 411.362 is amended by—

a. In paragraph (a):

■ i. Effective January 1, 2017, adding the definition of ''Ownership or investment interest'' in alphabetical order; and

■ ii. Adding the definition of ''Public advertising for the hospital'' in alphabetical order.

■ b. Revising paragraphs (b)(3)(ii)(C), (c)(2)(iv) and (v), and (c)(5) introductory text.

The additions and revisions read as follows:

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) * * *

Ownership or investment interest means for purposes of this section, a direct or indirect ownership or investment interest in a hospital.

(1) A direct ownership or investment interest in a hospital exists if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor.

(2) An indirect ownership or investment interest in a hospital exists if—

(i) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(ii) The hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital.

(3) An indirect ownership or investment interest in a hospital exists even though the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

* * * * *

Public advertising for the hospital means any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital.

(b) * * *

(3) * * *

(ii) * * *

(C) Disclose on any public Web site for the hospital and in any public advertising for the hospital that the hospital is owned or invested in by physicians. Any language that would put a reasonable person on notice that the hospital may be physician-owned would be deemed a sufficient statement of physician ownership or investment. For purposes of this section, a public Web site for the hospital does not include, by way of example: social media Web sites; electronic patient payment portals; electronic patient care portals; and electronic health information exchanges.

* * * * *

(c) * * *

(2) * * *

(iv) *Average bed capacity.* Is located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine a State's average bed capacity and the national average bed capacity. CMS will provide on its Web site State average bed capacities and the national average bed capacity. For purposes of this paragraph (c)(2)(iv), ''sufficient number'' means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(2)(iv) would not materially change after additional hospital data are reported.

(v) *Average bed occupancy.* Has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate. A hospital must use filed hospital cost report data to determine its average bed occupancy rate. CMS will provide on its Web site State average bed occupancy rates. For purposes of this paragraph (c)(2)(v), ''sufficient number'' means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(2)(v) would not materially change after additional hospital data are reported.

* * * * *

(5) *Community input and timing of complete request.* Upon submitting a request for an exception and until the hospital receives a CMS decision, the hospital must disclose on any public Web site for the hospital that it is requesting an exception and must also provide actual notification that it is

requesting an exception, in either electronic or hard copy form, directly to hospitals whose data are part of the comparisons in paragraphs (c)(2)(ii) and (c)(3)(ii) of this section. Individuals and entities in the hospital's community may provide input with respect to the hospital's request no later than 30 days after CMS publishes notice of the hospital's request in the **Federal Register**. Such input must take the form of written comments. The written comments must be either mailed or submitted electronically to CMS. If CMS receives written comments from the community, the hospital has 30 days after CMS notifies the hospital of the written comments to submit a rebuttal statement.

* * * * *

■ 32. Section 411.384 is amended by revising paragraph (b) to read as follows:

§ 411.384 Disclosing advisory opinions and supporting information.

* * * * *

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

* * * * *

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

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

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

■ 34. Section 414.90 is amended by—

■ a. Adding paragraphs (j)(8) and (9).

■ b. Revising paragraphs (k) introductory text and (k)(2).

■ c. Redesignating paragraphs (l)(4) and (l)(5) as (k)(4) and (l)(4), respectively.

■ d. Adding paragraph (k)(5).

The additions and revisions read as follows:

§ 414.90 Physician Quality Reporting System (PQRS).

* * * * *

(j) * * *

(8) *Satisfactory reporting criteria for individual eligible professionals for the 2018 PQRS payment adjustment.* An individual eligible professional who wishes to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via claims.* (A) For the 12-month 2018 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional will report on at least 1 measure contained in the proposed cross-cutting measure set. If less than 9 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

(*ii*) [Reserved]

(*2*) [Reserved]

(B) [Reserved]

(ii) *Via qualified registry.* (A) For the 12-month 2018 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional will report on at least 1 measure contained in the proposed cross-cutting measure set. If less than 9 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable to the eligible professional, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies.

(*ii*) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients.

(*2*) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(B) [Reserved]

(iii) *Via EHR direct product.* For the 12-month 2018 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For the 12-month 2018 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional would be required to report all of the measures for which there is Medicare patient data. An eligible professional would be required to report on at least 1 measure for which there is Medicare patient data.

(9) *Satisfactory reporting criteria for group practices for the 2018 PQRS payment adjustment.* A group practice who wishes to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* For the 12-month 2018 PQRS payment adjustment reporting period, for a group practice of 25 or more eligible professionals, report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In some instances, the sampling methodology will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 eligible professionals. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

(ii) *Via qualified registry.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report at least 9 measures, covering at least 3 of the NQS domains. Of these measures, if a group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would report on at least 1

Pages Intentionally Omitted

(Pages Not Relevant to Stark Law Redacted)

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