provided certain additional elements (based largely on the physician recruitment exception) are satisfied.[133]

10. Professional courtesy, 42 C.F.R. § 411.357(s)

As amended by the Phase III final rule, § 411.357(s) no longer requires an entity to notify an insurer when the professional courtesy involves a reduction of any coinsurance obligation. It also makes clear that the professional courtesy exception may be used only by hospitals or other providers with a formal medical staff.[134]

11. Retention payments in underserved areas, 42 C.F.R. § 411.357(t)

The Phase III final rule expanded the exception for retention payments in underserved areas, § 411.357(t), to make it available to rural health clinics, as well as federally qualified health centers and hospitals, and to make the exception available in the same manner for the three types of entities. In addition, in certain circumstances, retention payments are permitted to be made to a physician who does not have a bona fide written recruitment or employment offer. Under new § 411.357(t)(2), the physician must certify that he or she has a bona fide opportunity for future employment that would require the physician to relocate his or her medical practice at least 25 miles *and* outside of the geographic area served by the entity (which is the same requirement applicable to a written recruitment or employment offer).

According to CMS, the modifications also added flexibility. Under revised § 411.357(t)(3)(i), retention payments may be made to a physician if 75 percent of the physician's patients reside in a medically underserved area or are members of a medically underserved population, in addition to a physician who practices in a rural area, a HPSA (regardless of physician specialty), or an area with a demonstrated need for the physician (as determined in an advisory opinion).[135]

I. Disclosure Requirements for Financial Relationships Between Hospitals and Physicians

1. Disclosure of relationships to patients

CMS revised the regulations governing Medicare provider agreements in the final FY 2009 IPPS rule to require disclosure to patients of physician ownership or investment in physician-owned hospitals.[136]

Specifically, a physician-owned hospital[137] must give written notice to each patient at the beginning of the patient's hospital stay or outpatient visit that the hospital is a physician-owned hospital and the hospital must include in

---

[133] The additional requirements are:

- the arrangement is set out in writing, is signed by the physician and the hospital (or other entity) providing the payment, and specifies the payments and terms of payment;
- the arrangement is not conditioned on the physician's referrals;
- the payment is not determined (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;
- the physician is allowed to establish staff privileges at any hospital (or other entity) and to refer business to any other entity (except as restricted under an employment arrangement or services contract that complies with 42 C.F.R. § 411.354(d)(4));
- the payment is made to a person or organization (other than the physician) that provides malpractice insurance (including a self-funded organization);
- the physician treats obstetrical federal health care program patients in a nondiscriminatory manner;
- the insurance is a bona fide malpractice insurance policy or program, and any premium is calculated based on a bona fide assessment of the liability risk covered under the insurance;
- for each coverage period, which may not exceed one year, at least 75 percent of the physician's obstetrical patients treated under the malpractice coverage during the prior one-year period: (1) resided in a rural area, HPSA, medically underserved area, or an area with a demonstrated need, as determined in an advisory opinion; or (2) were part of a medically underserved population (this requirement is met for the initial coverage period, which may not exceed one year, if the physician certifies that he or she has a reasonable expectation that it will be met); and
- the arrangement does not violate the anti-kickback statute or other federal or state law or regulation governing billing or claims submission.

[134] *See* Phase III Preamble § IX.S., 72 Fed. Reg. at 51064.

[135] *See* Phase III Preamble § IX.T., 72 Fed. Reg. at 51065.

[136] *See* FY 2009 IPPS Final Rule Preamble § VII, 73 Fed. Reg. at 48686.

In the CY 2011 Hospital Outpatient Prospective Payment System rulemaking, CMS considered amending the provider agreement disclosure requirements to make them consistent with newly adopted 42 C.F.R. § 411.362(b)(3), which incorporated the additional disclosure requirements for physician ownership and investment in hospitals imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6001(a)(3) (Mar. 23, 2010). 75 Fed. Reg. 46170, 46435 (Aug. 3, 2010). Persuaded by commenters who suggested that the additions and amendments made to the whole hospital and rural provider exceptions were sufficient to provide the necessary guidance to physician-owned hospitals, CMS did not finalize the proposed conforming language. 75 Fed. Reg. 71800, at 72252-72253 (Nov. 24, 2010). However, because it addressed patient health and safety concerns, CMS did make final an amendment to 42 C.F.R. § 489.20(w)(2) that requires a hospital to obtain a signed acknowledgment from a patient, before admission or the provision of an outpatient service, that the patient understands that a physician may not be present during all hours services are furnished to the patient.

[137] 42 C.F.R. § 489.3 provides:

> Physician-owned hospital means any participating hospital (as defined in § 489.24) in which a physician, or an immediate family member of a physician (as defined in § 411.351 of this chapter), has an ownership or investment interest in the hospital. The ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in the hospital. This definition does not include a hospital with physician ownership or investment interests that satisfy the requirements at § 411.356(a) or (b) of this chapter.

ISSN 1087-7185

that notice that a list of owners and investors who are physicians or immediate family members of physicians is available upon request and must be provided at the time requested by or on behalf of the patient.[138]

In addition, all physicians who are members of the hospital's medical staff are required to agree, as a condition of continued medical staff membership or admitting privileges, to disclose in writing to all patients who they refer to the hospital any ownership or investment interest in the hospital held by themselves or by immediate family members at the time of the referral.[139]

These requirements do not apply if the hospital attests that none of the physicians owning (or who have immediate family members owning) an interest in the hospital refer patients to the hospital.[140]

Failure to make the required disclosures is grounds for termination of the hospital's Medicare provider agreement.[141]

2. Disclosure of relationships to CMS

The final FY 2009 IPPS rule also addressed the Disclosure of Financial Relationships Report, CMS's instrument to collect information concerning the ownership and investment interests and compensation arrangements between hospitals and physicians, which is intended to assist CMS in enforcing the physician self-referral statute and implementing regulations.[142]

At that time, CMS intended to proceed with its proposal to send the DFRR to 500 hospitals (both general acute care hospitals and specialty hospitals), finalizing both the type and amount of information requested in the DFRR and the timeframe of 60 days to complete, certify, and return the DFRR.[143]

In a significant change from the proposal, CMS decided not to adopt a regular reporting or disclosure process, and thus, use the DFRR as a one-time collection effort. CMS stated, however, that it might, depending on the information received on the DFRR and other factors, propose future rulemaking to use the DFRR or some other instrument as a periodic or regular collection instrument.

Note: Ultimately, CMS determined that mandating hospitals to complete the DFRR may duplicate some of the reporting obligations related to physician ownership and investment enacted by the Patient Protection and Affordable Care Act with respect to hospitals qualifying for the rural provider and hospital exception to the ownership or investment prohibition[144] and decided to focus on implementation of Affordable Care Act § 6001 instead of implementing the DFRR.[145] CMS stated, however, that it remains interested in analyzing physicians' compensation relationships with DHS entities and that, after collecting and examining information related to ownership and investment interests under Affordable Care Act § 6001, it will determine if it is necessary to capture information related to compensation arrangements.[146]

J. In-Office Ancillary Services Exception

The IOAS exception, which is codified at 42 U.S.C. § 1395nn(b)(2), allows the HHS Secretary to impose additional requirements to prevent program or patient abuse. The Affordable Care Act amended this provision by adding the following sentence:

> Such requirements shall, with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services specified under subsection (h)(6)(D) [i.e., imaging services] that the Secretary determines appropriate, include a requirement that the referring physician inform the individual in writing at the time of the referral that the individual may obtain the services for which the individual is being referred from a person other than a person described in subparagraph (A)(i) [i.e., the referring physician or his or her group practice] and provide such individual with a written list of suppliers (as defined in section 1861(d) [42 U.S.C. 1395x(d)])

---

[138] 42 C.F.R. § 489.20(u)(1). For purposes of the disclosure requirement, the hospital stay or outpatient visit begins with the provision of a package of information about scheduled preadmission testing and registration for a planned hospital admission for inpatient care or an outpatient service. The prior regulations required the hospital to furnish written notice that it is physician-owned to a patient at the beginning of the patient's hospital stay or outpatient visit and to furnish a list of physician owners or investors, but did not specify a time for the latter disclosure.

[139] 42 C.F.R. § 489.20(u)(2).

[140] 42 C.F.R. § 489.20(v). The hospital must retain the attestation in its records.

[141] 42 C.F.R. § 489.53(c).

[142] *See* FY 2009 IPPS Final Rule Preamble § IX., 73 Fed. Reg. at 48740. CMS had solicited comments on the DFRR in the FY 2009 IPPS Proposed Rule. 73 Fed. Reg. at 23695-23698. Appendix C of the proposed IPPS rulemaking contains the DFRR form (eight Excel Worksheets) and instructions. 73 Fed. Reg. at 23923-23938, *reproduced* in the Web version of the series.

[143] 73 Fed. Reg. at 48741. CMS revised its estimate of the cost of compliance, increasing the amount of time it will take hospitals to complete the DFRR from 31 hours to 100 hours, and the costs associated with completing the DFRR from $1,550 to $4,080 per hospital.

[144] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § § 6001 and 10602 (Mar. 23, 2010), as amended by the Health and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1106 (Mar. 30, 2010), amending 42 U.S.C. § 1395nn(d)(2) and (3) and enacting 42 U.S.C. § 1395nn(i). Consistent with the terminology used by the federal agencies charged with implementing the comprehensive reform law, the two acts together are hereinafter referred to as the Affordable Care Act.

[145] *See* CMS Postpones Hospital Reporting of Disclosure of Financial Relationships Report (DFRR), *at* http://www.cms.gov/PhysicianSelfReferral/70_Disclosure.asp.

[146] *Id.*

ISSN 1087-7185

> who furnish such services in the area in which such individual resides.[147]

To implement the new requirements, CMS amended the IOAS exception in the regulations by adding 42 C.F.R. § 411.355(b)(7),[148] applicable to magnetic resonance imaging (MRI), computed tomography (CT), and positron emission tomography (PET) services furnished on or after January 1, 2011.[149]

The regulation requires the physician referring MRI, CT, or PET services to provide to the patient, at the time of the referral, written notice that the patient may receive the same services from a person other than the referring physician or his or her group practice. The notice must be written in a manner that is sufficient to be reasonably understood by all patients.

The regulation also requires that the notice include:

- a list of at least five other suppliers located within a 25–mile radius of the referring physician's office location who provide the services for which the patient is being referred;
- if there are fewer than five other suppliers located within a 25–mile radius of the physician's office, a list of all other suppliers of the imaging service within that area; or
- if there are no alternate suppliers within the 25-mile radius of the physician's office, no list of alternate suppliers (but the basic notice that the patient may receive the services from another supplier is still required).

For each alternate supplier on the list, the notice must include, at a minimum, the supplier's name, address, and telephone number.

CMS did not adopt as final a proposal to require the physician to maintain a record of the disclosure notification, signed by the patient, as a part of the patient's medical record. CMS stated, however, that ''the physician could document in the patient's chart that the notice was given to the patient.''[150]

As in the proposed regulation, the term ''suppliers'' is defined by reference to 42 C.F.R. § 400.202, which is the definition contained in Social Security Act § 1861(d).[151] ''Suppliers'' accordingly include physician practices and independent diagnostic testing facilities (IDTFs), but do not include hospitals and other ''providers of services,'' as defined in Social Security Act § 1861(u). CMS reiterated its position in the proposed rulemaking that the Affordable Care Act does not ''allow physicians to satisfy the disclosure requirement by furnishing a list that includes hospitals and other providers.''[152] In a change from the proposal, however, ''physicians are not precluded from listing hospitals in the disclosure notice as long as *the required number of suppliers* is also included.''[153]

CMS stated that physicians could create the list of alternate suppliers within the 25-mile radius by ''any reasonable means,'' including internet searches, but that it would not publish a standard form or publicly available database, nor would it require Medicare contractors to publish lists of entities providing the services.[154] CMS did not require that the notice include any indication of supplier quality or accreditation status, but said that physicians would not be prohibited from ''furnishing a list that designates a supplier's credentialing status.''[155]

In a somewhat internally inconsistent statement, CMS said that ''referring physicians are not obligated to list only suppliers that are accepting new Medicare patients,'' but that ''referring physicians should make a reasonable effort to ensure that the suppliers listed in the disclosure are viable options for all of their patients for the services being referred.''[156] CMS ''suggest[ed] that the list of suppliers should be reviewed annually for accuracy and updated at that time, if necessary.''[157]

CMS emphasized that

> the disclosure must be presented to the patient each time one of the listed advanced imaging services is referred . . . not just for the initial service. . . . For subsequent referrals made via phone call, the written disclosure must still be provided to the patient and adequately documented . . . . Mailing or e-mailing the disclosure to the patient would be acceptable if verbal notification has also occurred.[158]

CMS declined to expand the disclosure requirement beyond the imaging services specifically listed in the statute

---

[147] Affordable Care Act § 6003, adding the final sentence in 42 U.S.C. 1395nn(b)(2), applicable to services furnished on or after Jan. 1, 2010.

[148] The regulation was part of the Physician Fee Schedule rulemaking for calendar year 2011. 75 Fed. Reg. 73170 (Nov. 29, 2010). Text of the regulation appears at 75 Fed. Reg. at 73616. CMS's preamble explanation begins at 75 Fed. Reg. at 73443.

[149] 75 Fed. Reg. at 73443. In the proposed rulemaking, CMS considered whether, consistent with the terms of Affordable Care Act § 6003, the regulatory disclosure requirement should apply retroactively to services furnished on or after Jan. 1, 2010, but rejected that option, ″[g]iven the structure of the amended in-office ancillary services exception and the statute as a whole.″ 75 Fed. Reg. 40040, 40142 (July 13, 2010).

[150] 75 Fed. Reg. at 73447.

[151] 42 U.S.C. § 1395x(d).

[152] 75 Fed. Reg. at 73446.

[153] *Id.* (emphasis supplied).

[154] 75 Fed. Reg. at 73446.

[155] 75 Fed. Reg. at 73447.

[156] 75 Fed. Reg. at 73447. CMS further stated: ''The referring physician should list suppliers that are able to perform the services for which the patient is being referred. Listing suppliers that are unable to perform the needed test does not provide the patient with meaningful choices about his or her care.'' *Id.*

[157] 75 Fed. Reg. at 73447.

[158] 75 Fed. Reg. at 73445.

ISSN 1087-7185

(i.e., MRI, CT and PET).[159] It also confirmed that the disclosure requirement would not apply to specific MRI, CT, or PET services that either are not ''radiology and certain other imaging services'' on the list of CPT/HCPCS Codes or are not the subject of a ''referral.''[160]

Comment: CMS substantially reduced the burden associated with the disclosure by defining the geographic area within which alternative suppliers must be listed by reference to the referring physician's office location, rather than by reference to ''the area in which such individual resides,'' as used in the Affordable Care Act. CMS also lessened the burden on physicians by relaxing a number of proposed requirements, as discussed above, and, particularly, by reducing from 10 to five the number of suppliers required to be listed.

Because Stark is a strict liability statute, physicians must be very careful to ensure that the disclosure notice satisfies the many technical requirements CMS prescribed. The requirement that the lesser of five or all suppliers within a 25-mile radius of the referring physician's office be listed and the exclusion of hospitals from ''suppliers'' may make compliance particularly difficult in rural or small urban areas. These areas may not contain five freestanding imaging centers (i.e., IDTFs). In addition, it may not be clear which physician practices in the area both offer the specific test ordered and would provide it to the referring physician's patients.

[159] CMS stated: X-ray and ultrasound services in particular are much more likely to be performed on the same day as the original visit compared to many advanced imaging services. Therefore, disclosures related to these additional services would not be as useful to the patient. 75 Fed. Reg. at 73444.

[160] 75 Fed. Reg. at 73444.

ISSN 1087-7185