Q. What is a “physician practice” within the definition of “physician organization” at 42 C.F.R. §411.351?

A. A “physician practice” is a medical practice comprised of two or more physicians organized to provide patient care services (regardless of its legal form or ownership). For example, a “physician practice” may be a group of physicians that practice together but do not meet all of the requirements of §411.352 for “group practices” that qualify to use the physician services and in-office ancillary services exceptions. We note that the provision of patient care services by employed or contracted physicians does not automatically cause an entity to become or be considered a “physician practice” (and, thus, a “physician organization”). For example, a hospital, which, in general terms, is an institution that provides medical, surgical, or psychiatric care and treatment for the sick or the injured, is not considered a “physician practice” or “physician organization” even though it employs or contracts with two or more physicians to provide patient care services to its inpatients and outpatients. (FAQ2327) [Last revised May 18, 2017 to clarify that the physician services and in-office ancillary services exceptions are only available to entities that qualify as “group practices” in accordance with 42 C.F.R. §411.352.]

Q. Is physician ownership a prerequisite for meeting the definition of “physician organization” or “physician practice”? In other words, must all “physician organizations” or “physician practices” have at least one physician owner?

A. No. Physician ownership is not determinative as to whether an entity (regardless of its legal form, for example, limited liability company, professional corporation, etc.) is a “physician organization.” We note that 42 C.F.R. §411.352 states that, with respect to a group practice (which is a “physician organization”), the single legal entity that is the group practice may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities. Likewise, physician ownership is not determinative as to whether an entity (regardless of its legal form, for example, limited liability company, professional corporation, etc.) is a “physician practice.” (FAQ2337)

Q. Is a federally qualified health center a “physician organization”?

A. No. A federally qualified health center (as defined at 42 C.F.R. §405.2401(b)) is not a “physician organization” as defined at §411.351. Federally qualified health centers are subject to the conditions for coverage at 42 C.F.R. Part 491. These regulations require, among other things, that the federally qualified health center have written policies and procedures, disclosure of certain information to patients, minimum staffing composition and levels, and that the federally qualified health center provides medical emergency procedures as a first response to common life-threatening injuries and acute illness. Federally qualified health centers may share some characteristics with physician medical practices. However, federally qualified health centers typically are not structured as physician medical practices in the traditional sense, nor are
physician medical practices required to meet the same conditions for coverage as federally qualified health centers. (FAQ12308)

Q. If a hospital (or other Part A provider) directly employs or contracts with physicians to provide physician services to hospital patients, does that make the hospital (or other Part A provider) a “physician organization”?

A. A hospital (or other Part A provider) is not considered to be a “physician organization” simply because it has employment or contractual arrangements with physicians for the provision of patient care services. (FAQ2329 renumbered as FAQ12310)

Q. Is a staffing company a “physician organization”?

A. A staffing company that does not directly provide and bill for patient care services, but merely facilitates the provision of physicians to hospitals and other health care providers, is not a “physician organization” as defined at 42 C.F.R. §411.351. (FAQ12312)

Q. Please provide some examples of organizations, providers, or other entities that are NOT “physician organizations” as defined at 42 C.F.R. §411.351.

A. The following are examples of organizations, providers, or other entities that are NOT physician organizations. This list is illustrative, not exclusive:

- Hospitals and other Part A providers of services
- Federally qualified health centers
- A single legal entity (that does not satisfy the requirements of a group practice for purposes of §411.352) that encompasses (that is, operates) a faculty practice plan AND either a medical school or hospital, or both
- A medical school that does not operate a faculty practice plan but employs physicians to provide clinical and academic service

(FAQ2331 renumbered as FAQ12314)

Q. Consider the following facts. A physician group practice (Group Practice 1) has a written contractual agreement with another physician group practice (Group Practice 2) for the services of a physician in Group Practice 2. Group Practice 1 would bill Medicare for the services of the physician (Physician A) as Group Practice 1 services. Must Physician A sign a contractual agreement directly with Group Practice 1 in order to be considered a “physician in the group practice” with respect to Group Practice 1 (so as to permit Group Practice 1 to bill for the services provided to its patients by Physician A)?

A. In order to be considered a “physician in the group practice,” as defined at 42 C.F.R. §411.351, an independent contractor physician must furnish patient care services 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. Under the specific factual scenario described, Physician A may either sign an agreement directly with Group Practice 1 or sign the agreement between Group Practice 1 and Group Practice 2. If the latter option is selected, the written agreement between Group Practice 1 and Group Practice 2 must identify Physician A by name and also identify the services that he or she is to perform for Group Practice 1. As set forth in our 2015 clarifying guidance, a single formal contract or agreement is not required to satisfy
the writing requirement of many of the exceptions to the physician self-referral law. (See 80 FR 41686, 41915 (Jul. 15, 2016) and 80 FR 70886, 71314-15 (Nov. 16, 2015).) If a collection of documents is used to satisfy the writing requirement, Physician A’s signature must appear in written documentation evidencing an arrangement: (i) directly between Physician A and Group Practice 1; or (ii) between Group Practice 1 and Group Practice 2. If the latter option is selected, the written documentation must identify Physician A by name and also identify the services that he or she is to perform for Group Practice 1. (FAQ10136) [Last revised May 18, 2017 to clarify the writing and signature requirements in applicable exceptions to the physician self-referral law.]

Q. Is the exception for physician recruitment in 42 C.F.R. §411.357(e) available to a hospital that wants to recruit a resident it has trained? Assume that the resident already resides in the geographic area served by the hospital (as defined in §411.357(e)(2)).

A. The exception in §411.357(e)(3) may be available to the hospital for the provision of recruitment assistance to the resident upon completion of the residency. When all of the requirements of §411.357(e) are satisfied, the exception protects remuneration provided by a hospital to a physician to induce the physician to relocate his or her medical practice into the geographic area served by the hospital in order to become a member of the hospital’s medical staff. In the case of a resident, the resident need not relocate a medical practice, provided that the resident establishes his or medical practice in the geographic area served by the recruiting hospital. However, the resident must become a member of the hospital’s medical staff.

1. Resident is not a member of the organized medical staff.

To the extent that, during his or her residency, the resident is not considered to be part of the hospital’s organized medical staff, the exception in §411.357(e) would be available to the hospital. CMS recognizes that, often, residents do not join the organized medical staff of the training hospital until their training is complete and they are able to practice without supervision. Having “privileges” or “permission” to provide patient care services only under the supervision of an attending physician (in the case of residents) is not necessarily the same as “being a member of the medical staff.” We note that this discussion is limited to residents and any activities that occur within the scope of their training programs. If a resident moonlights, he or she may be a member of the organized medical staff of the hospital at which he or she moonlights. Of course, as always, all of the requirements of an exception must be satisfied in order for remuneration to comply with the physician self-referral rules.

2. Resident is a member of the organized medical staff, but such membership is coterminous with his or her employment with the training hospital.

If the resident’s privileges terminate (for example, pursuant to a provision in the medical staff bylaws or the resident’s employment contract) at the end of his or her residency and the physician (formerly the “resident”) is not considered a member of the medical staff upon the completion of the residency, the hospital may use the exception at §411.357(e) to provide a recruitment payment to the physician, provided that all of the requirements of the exception are satisfied at the time of the arrangement. We caution that this answer is contingent upon: (1) the coterminous nature of the medical staff membership having been established prior to the parties entering into the recruitment arrangement; and (2) consideration provided by either party pursuant to the recruitment arrangement not
occurring until after the termination of the physician’s medical staff membership as a resident.

(FAQ2333)

Q. **Do the provisions regarding termination/amendment of leases apply to personal services arrangements?**

A. Yes. As stated in the Phase III final rule, “a personal service contract can be amended in the same manner as an office space or equipment lease” (72 FR 51012, 51047 (Sep. 5, 2007)). The provisions regarding termination/amendment of office space and equipment leases (see 72 FR at 51044) apply to personal service arrangements. Subsequent to the Phase III final rule, CMS revised its guidance regarding amending compensation arrangements. See 73 FR 48434, 48697 (Aug. 19, 2008). (FAQ2341) [Last revised May 18, 2017 to incorporate 2008 guidance.]

Q. **Does the Phase III “stand in the shoes” “grandfathering” provision apply to an arrangement that, as of September 5, 2007, did not meet the definition of an “indirect compensation arrangement” (and was not directly between a physician and a DHS entity) but would have satisfied the requirements of the exception for indirect compensation arrangements in 42 C.F.R. §411.357(p) if it had been applicable?**

A. No. The only arrangements that qualify for the “grandfathering” provision in §411.354(c)(3)(ii) are those that, as of September 5, 2007, both (1) met the definition of an “indirect compensation arrangement” set forth in §411.354; and (2) satisfied the requirements of the exception for indirect compensation arrangements in §411.357(p). If an arrangement satisfies both of these criteria, it need not be amended during its original term or the current renewal term (that is, the renewal term the arrangement is in as of September 5, 2007) to comply with the requirements of another exception. (See 72 FR 51012, 51028 (Sep. 5, 2007).) (FAQ2335) [Last revised May 18, 2017 to update citations.]

Q. **Must a physician who “stands in the shoes” of his or her physician organization (as defined at 42 C.F.R. §411.351) become a signatory to a written agreement between the physician organization and a DHS entity in order to satisfy the requirements of a direct compensation arrangement exception?**

A. No. For 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 her physician organization to have signed the written agreement when the authorized signatory of the physician organization has signed the agreement. As set forth in our 2015 clarifying guidance, a single formal contract or agreement is not required to satisfy the writing requirement of many of the exceptions to the physician self-referral law. (See 80 FR 41686, 41915 (Jul. 15, 2016) and 80 FR 70886, 71314-15 (Nov. 16, 2015).) We consider a physician who is standing in the shoes of his or her physician organization to satisfy the signature requirement of an applicable exception if the authorized signatory of the physician organization has signed at least one document in the collection of documents used to satisfy the writing requirement of the exception. (FAQ1488 renumbered as FAQ12318) [Last revised May 18, 2017 to clarify the writing and signature requirements in applicable exceptions to the physician self-referral law.]
Q. There are two references in the Phase III preamble (72 FR 51012, 51033 and 51045 (Sep. 5, 2007)) that appear to prohibit referrals for ancillary services provided in office space and using equipment that is leased other than in a block lease arrangement. May a group practice provide and bill for ancillary services provided in shared office space using shared equipment if the supervision requirement for the particular service is satisfied by a “member” of the group and the arrangement otherwise complies with Medicare coverage and reimbursement regulations?

A. Yes. Services that qualify for the in-office ancillary exception in §411.355(b) must satisfy performance, location, and billing requirements. In order to satisfy §411.355(b)(1), a service must be furnished personally by: (i) the referring physician, (ii) a physician who is a member of the same group practice as the referring physician; or (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.” A “physician in the group practice” is defined at §411.351 to include both a “member” of the group practice as well as an independent contractor during the time the independent contractor is performing services in the group practice’s facilities. Assuming that the location and billing requirements in §411.355(b) are satisfied, in-office ancillary services supervised by a member of the group practice would not be subject to the referral prohibition. (FAQ12330) [Last revised May 18, 2017 to update citations.]

Q. Where a physician-owned lithotripsy partnership contracts with a hospital to provide a lithotripter and skilled technician “under arrangements,” may the hospital pay for such services using a per-use or percentage-based compensation formula”?

A. Yes. Under certain circumstances, a hospital may use a per-use or percentage-based formula to compensate a physician-owned lithotripsy partnership that provides a lithotripter and skilled technician to the hospital on an “under arrangements” basis without violating the physician self-referral law.

Currently, lithotripsy is not considered a designated health service (DHS) for purposes of the physician self-referral law. Therefore, if the physician owners of the lithotripsy partnership make referrals to the hospital for lithotripsy services ONLY, the physician self-referral law would not be implicated, and a per-unit or percentage-based compensation formula for the compensation arrangement is considered to be a lease of equipment (and other items or personnel).

If the physician owners of the lithotripsy partnership refer Medicare patients to the contracting hospital for DHS, the compensation arrangement between the lithotripsy partnership and the hospital must comply with an applicable exception to the physician self-referral law. Where a compensation arrangement between the hospital and the physician-owned lithotripsy partnership is considered to be a lease of equipment, a per-unit or percentage-based compensation formula would fail to satisfy the requirements of any of the potentially applicable exceptions for the lease of equipment found in §411.357(b), §411.357 (l), or §411.357(p).

In Phase II, we recognized the common practice of many contractors to provide the tools of their trade in connection with service contracts (69 FR 16054, 16091 (Mar. 26, 2004)). There, we did not require the use of the exception in §411.357(b) for the lease of equipment whenever equipment was provided as part of a service contract. The same applies in the case of lithotripsy services provided “under arrangements” to a hospital. Provided that a lithotripsy partnership is actually furnishing a service (or a package of services) to the hospital, and not merely leasing equipment over which the hospital would have dominion and control, the hospital may
compensate the lithotripsy partnership using a per-unit or percentage-based compensation formula, as long as all of the requirements of a relevant exception are satisfied.

The answer provided addresses only the specific question presented and compliance with the physician self-referral rules. It does not address compliance with any other Medicare rules and regulations, including those regarding services provided “under arrangements” to a hospital. (FAQ9780) [This FAQ was initially issued following the publication of the FY 2009 IPPS final rule (73 FR 48434 (Aug. 19, 2008)). It was revised on May 18, 2017 to update citations.]

Q. The List of Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) Codes (the Code List) identifies all the items and services included within certain categories of designated health services (DHS). The Code List includes a section which lists the CPT/HCPCS codes that are eligible for use with the exception at 42 C.F.R. § 411.355(h) for preventive screening tests, immunizations, and vaccines. Some of the CPT/HCPCS codes in this section are only eligible for the exception at 42 C.F.R. § 411.355(h) when billed with certain ICD-9-CM codes. If an entity furnishing DHS billed for the services using the ICD-10-CM code that corresponds to the ICD-9-CM code identified on the Code List, are these CPT/HCPCS codes eligible for use with the exception at 42 C.F.R. § 411.355(h) for preventive screening tests, immunizations, and vaccines?

A. Yes. CMS required the use of ICD-10-CM codes for services furnished on or after October 1, 2015. See https://www.cms.gov/Medicare/Coding/ICD10/index.html. Although the Code Lists for calendar year (CY) 2015, CY 2016, CY 2017, and CY 2018 did not provide the ICD-10-CM codes that correspond to the ICD-9-CM codes, if an entity furnishing DHS billed using the ICD-10-CM code that corresponds to the ICD-9-CM code identified on the Code List on or after October 1, 2015, the code would be eligible for use with the exception at 42 C.F.R. § 411.355(h) for preventive screening tests, immunizations, and vaccines. We remind parties seeking to utilize the exception at 42 C.F.R. § 411.355(h) that all the requirements of the exception must be satisfied in order for the prohibition on referrals set forth in 42 C.F.R. § 411.353 not to apply to the service for which protection is sought. Crosswalks for ICD-9-CM and ICD-10-CM codes can be found on the CMS webpage identifying the General Equivalence Mapping for the applicable years: https://www.cms.gov/Medicare/Coding/ICD10/2015-ICD-10-CM-and-GEMs.html (CY 2015); https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-CM-and-GEMs.html (CY 2016); https://www.cms.gov/Medicare/Coding/ICD10/2017-ICD-10-CM-and-GEMs.html (CY 2017); and https://www.cms.gov/Medicare/Coding/ICD10/2018-ICD-10-CM-and-GEMs.html (CY 2018). [Published January 10, 2019]

Q. Where the Secretary has granted a physician-owned hospital (“POH”) an exception to the prohibition on facility expansion under section 1877(i) of the Social Security Act (the “Act”) and 42 C.F.R. § 411.362(c), does the physician self-referral law prohibit the POH from relocating operating rooms, procedure rooms, or beds that were licensed on March 23, 2010 from its main campus to a remote location of the POH before implementing the approved facility expansion on the POH’s main campus?

A. The physician self-referral law does not prohibit the relocation of operating rooms, procedure rooms, or beds that were licensed on March 23, 2010 from a POH’s main campus to a remote location. However, because the regulation at 42 C.F.R. § 411.362(c)(6) provides that any increase in the number of operating rooms, procedure rooms, or beds permitted by the
Secretary through an exception may occur only in facilities on the POH’s main campus, any operating rooms, procedure rooms, or beds added as a result of the Secretary’s approval can be located only on the main campus of the POH and may not subsequently be relocated from the main campus.

We note that all hospitals must comply with applicable federal and state laws and regulations regarding, among other things, the licensure, location, construction, and use of operating rooms,

procedure rooms, and beds. These laws and regulations may impose additional requirements or limitations on a POH that wishes to relocate operating rooms, procedure rooms, or beds from its main campus. [Published April 19, 2018]

Q. For purposes of the physician self-referral prohibition in section 1877 of the Social Security Act (SSA), does an “immediate family member” of a physician include the lawfully married same-sex spouse of a physician and family members that result from the lawful marriage of same-sex individuals?

A. Yes. The physician self-referral regulations define an “immediate family member or member of a physician’s immediate family” to mean the following:

- 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.

In United States v. Windsor, 570 U.S. 744, 113 S. Ct. 2675 (2013), the Supreme Court ruled that section 3 of the Defense of Marriage Act is unconstitutional. In light of this decision, the Department has instituted a policy of treating same-sex marriages on the same terms as opposite-sex marriages to the greatest extent reasonably possible. This FAQ clarifies Windsor’s application to the physician self-referral prohibition under section 1877 of the SSA. Effective June 26, 2013, the date of the Windsor decision, the same-sex spouse of a physician and the family members that result from same-sex marriages meet the definition of “immediate family member or member of a physician’s immediate family” if the state or other jurisdiction, whether foreign or domestic, where the couple was married recognizes the marriage under its laws, or if the state(s) or other jurisdiction(s) where the couple lives recognizes the marriage as a legally valid marriage. [Published October 2013]

Q: If a state’s hospital licensure laws and regulations provide that a hospital may increase its licensed bed complement by a certain amount without prior approval of the state’s licensing agency, what would CMS consider the number of beds for which the hospital was licensed on March 23, 2010 for purposes of section 1877(i)(1)(B) of the Social Security Act (the “Act”) and 42 CFR 411.362(b)(2)?
A: As a general matter, neither section 1877 of the Act nor the physician self-referral regulations (42 CFR 411.350 through 411.389) preempt state licensure laws and regulations. In interpreting and applying the physician self-referral law, CMS defers to state law with respect to the determination of whether a bed is licensed as of a certain date. If the state would consider a bed to be “licensed” or within a hospital’s “bed complement” on March 23, 2010, CMS would also consider the bed to be “licensed” or within a hospital’s “bed complement” as of that date, regardless of the exact number printed on the hospital’s physical license.

To illustrate, assume that a state does not require prior approval from its licensing agency for a hospital to increase its bed complement by not more than ten beds or 10 percent of the total bed capacity, whichever is less, during a period of a license. However, the state requires notification of the change and that the hospital must at all times meet the physical plant, staffing, and all other requirements set forth in state law and regulations if additional beds are added. The license issued to the hospital on January 1, 2009 indicated that the hospital’s bed complement was 100 beds. If the hospital increased its bed complement by 9 beds (to 109 beds) on January 1, 2010 and made no further changes to its bed complement prior to March 23, 2010, its baseline number of licensed beds on March 23, 2010 would be 109 for purposes of section 1877(i)(1)(B) of the Act and 42 CFR 411.362(b)(2), provided that the hospital made the appropriate notification to the state and the hospital at all times met the physical plant, staffing, and all other requirements set forth in state law and regulations after increasing its bed complement. The same would apply to any beds that a state considered to be licensed under its specific licensure scheme on March 23, 2010.

Section 1877(i)(1)(B) of the Act limits the expansion of facility capacity of a hospital that wishes to qualify for the rural provider or hospital exceptions to the law’s ownership or investment prohibition. (See section 1877(d)(2) and (3); 42 CFR 411.356(c)(1) and (3).) Specifically, section 1877(i)(1)(B) of the Act states that, among other things, to qualify for the rural provider or hospital exceptions, the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after March 23, 2010 is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010. For purposes of applying this provision of the physician self-referral law, we refer to the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 as the hospital’s “baseline.” As stated above, CMS defers to state law with respect to the determination of whether a bed is licensed as of a certain date. However, in extraordinary circumstances, CMS may include additional beds when determining a hospital’s “baseline” for purposes of section 1877 of the Act. See, for example, CMS-AO-2020-01 (https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions).

[Published March 2020]

Q: Where are items considered to be “furnished” for purposes of the “location requirement” of the exception for in-office ancillary services at 42 C.F.R. §411.355(b)(2)? If prosthetic or orthotic devices, such as intermittent catheters, are mailed to the patient from a location that qualifies as a “same building” or “centralized building,” are they considered to be furnished in a location that satisfies the requirement at 42 C.F.R. §411.355(b)(2)?

A: As we explained in the January 4, 2001 final rule with comment period entitled Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (“Phase I”), in general, we believe that the Congress intended to exclude from the reach of section 1877 of the Social Security Act (the “Act”) only items and services provided (or used, as the case may be) in the physician’s office (66 Fed. Reg. 856, 882 (Jan. 4, 2001)). In that rulemaking, we finalized with modification our proposal to define where an item or service is “furnished” for purposes of the “location requirement” at 42 C.F.R. §411.355(b)(2). We
proposed that: (1) a service would be considered furnished where it is performed on the patient; and (2) an item would be considered furnished where the patient receives and begins using the item. However, commenters objected to the proposed policy’s application to items that are provided to a patient in the physician’s office (or delivered to a patient’s home) that are meant to be used at home rather than in the physician’s office. We recognized that, as noted by the commenters, the proposed rule did not make sense in the case of outpatient prescription drugs, which are commonly dispensed to patients in the office for later consumption at home (66 Fed. Reg. at 882). In response, we clarified that, for purposes of the in-office ancillary services exception, services are considered “furnished” 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 Medicare billing and coverage rules” (66 Fed. Reg. at 882). We revised the regulation text at 42 C.F.R. §411.355(b)(5) to reflect this narrow accommodation for outpatient prescription drugs dispensed in a physician office, external ambulatory infusion pumps filled or serviced in a physician’s office, and other items that are dispensed directly to the patient in a physician’s office even though the patient may use the item at home (see 66 Fed. Reg. at 882, 884).

Our policy has not changed since the effective date of the Phase I final rule. The “location requirement” at 42 C.F.R. §411.355(b)(2) requires that the patient receive the item in the physician’s office. Put another way, items that are designated health services to which the exception is applicable, such as intermittent catheters (which are prosthetic devices), fall within the scope of the exception for in-office ancillary services only when a patient directly receives the item in the physician’s office and in a manner that is sufficient to meet applicable Medicare billing and coverage rules. The “location requirement” at 42 C.F.R. §411.355(b)(2) would not be satisfied if a patient receives an item by mail outside the physician’s office, as it would not be dispensed to the patient in the office. This is true regardless of whether Medicare coverage and payment rules would permit the supplier to mail the item to the patient and bill the Medicare program for the item.

Beneficiaries should be directed to www.medicare.gov or 1-800-Medicare for information about where to get items and supplies that are not furnished in the physician office.

[Published September 20, 2021]