

## Structuring Physician Timeshare Arrangements: Leveraging the Stark Exception, Navigating the Limitations

WEDNESDAY, OCTOBER 18, 2017

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

Rick L. Hindmand, Member, **McDonald Hopkins**, Chicago

Kim C. Stanger, Partner, **Holland & Hart**, Boise, Idaho

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**[NOTE: THIS IS A SAMPLE TIMESHARE AGREEMENT. IT IS PROVIDED FOR EDUCATIONAL PURPOSES ONLY, AND SHOULD NOT BE USED AS A CONTRACT UNLESS AND UNTIL REVIEWED BY QUALIFIED PERSONS TO ENSURE LEGAL COMPLIANCE AND MODIFIED TO FIT THE PARTICULAR CIRCUMSTANCES OF A TRANSACTION]**

**PRACTITIONER TIMESHARE AGREEMENT  
(LICENSE FOR PERIODIC USE)**

- 1. Practitioner.** \_\_\_\_\_  
Mailing Address \_\_\_\_\_  
\_\_\_\_\_  
Phone \_\_\_\_\_  
E-mail \_\_\_\_\_
- 2. Premises.** Office suite (including the reception area, office space, \_\_\_ exam rooms, and associated common areas) located at \_\_\_\_\_  
\_\_\_\_\_  
(collectively "Space")
- 3. Equipment and Supplies.** Office and medical furniture, equipment and reasonable supplies located on the Premises and approved by Hospital, including but not limited to:  
\_\_\_\_\_  
\_\_\_\_\_  
(collectively "Equipment and Supplies"), but excluding advanced imaging equipment, radiation therapy equipment, clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests if approved by Hospital) and the following additional excluded equipment:  
\_\_\_\_\_  
\_\_\_\_\_.
- 4. Services.** Receptionist and janitorial services associated with Premises and such other services approved by Hospital, including:  
\_\_\_\_\_  
\_\_\_\_\_  
(collectively "Services"). Hospital does not provide clinical support staff or medical record services unless specified above or expressly agreed in writing by Hospital.
- 5. Fee.** \$ \_\_\_\_\_ per \_\_\_\_\_.
- 6. Period of Use.**  As needed and scheduled in advance.  
(choose applicable period)  Every \_\_\_\_\_ per \_\_\_\_\_,  
during normal business hours between \_\_\_\_ a.m. and \_\_\_\_ p.m., unless otherwise agreed by Hospital ("Period of Use").
- 7. Term.** Beginning \_\_\_\_\_, 20\_\_\_\_, and continuing until terminated pursuant to this Agreement.
- 8. Additional Terms.** Practitioner shall comply with all policies and procedures adopted by Hospital from time to time pertaining to the use of the

Premises, Equipment, Supplies and Services. The terms and conditions set forth in Sections 9 through 24 attached hereto are made a part hereof.

Reviewed and agreed by:

**Hospital:**

**Practitioner:**

By: \_\_\_\_\_  
Administrator

By: \_\_\_\_\_  
Name

Dated: \_\_\_\_\_

Dated: \_\_\_\_\_

This Practitioner Timeshare Agreement (“Agreement”) is made by and between \_\_\_\_\_ (“Hospital”), and the person identified as Practitioner on page 1 (“Practitioner”).

**9. LICENSE.** This Agreement gives Practitioner a nonexclusive license to use the Premises, Equipment, Supplies and Services identified on page 1. Practitioner understands and agrees that this Agreement does not convey an ownership or possessory leasehold interest in the Premises, Equipment or Supplies.

**10. NATURE OF RELATIONSHIP.** Nothing in this Agreement shall be construed to establish an employment, agency, partnership, joint venture or other relationship between the parties except that of independent contractors. Neither Hospital nor Practitioner shall be liable or responsible for the acts, errors or omissions of the other party.

**11. USE.** Practitioner warrants and agrees that Practitioner shall use the Premises, Equipment, Supplies and Services predominantly for the provision of evaluation and management services to patients during the Period of Use. Practitioner shall not use the Premises, Equipment, Supplies and Services for any other purpose, including but not limited to performing surgery or \_\_\_\_\_ without Hospital’s written consent. Practitioner shall not use the Equipment and Supplies to furnish designated health services (as defined in 42 CFR 411.351) other than those incidental to the evaluation and management services at the time of the patient’s evaluation and management visit. Practitioner shall comply with all laws, rules, regulations, and procedures applicable to or affecting the Premises, Equipment and Supplies, and Services. Practitioner shall properly use all Equipment and Supplies consistent with manufacturer instructions and Hospital policies and procedures, and shall take no action that may damage or void warranties or violate restrictions on the use of Equipment or Supplies.

**12. NON-EXCLUSIVITY.** Practitioner understands and agrees that his/her license to use the Premises, Equipment, Supplies and Services is on a non-exclusive basis, and that Practitioner will share the Premises, Equipment, Supplies and Services with Hospital or other licensees during the Period of Use. Practitioner shall cooperate with and refrain from taking any action that unduly interferes with Hospital’s or other licensees’ use of the Premises, Equipment, Supplies and Services. Unless otherwise agreed by Hospital, those who first schedule their use of the Premises, Equipment, Supplies and Services shall have priority in such use.

**13. PAYMENT OF FEE.** In exchange for Practitioner’s use of the Premises, Equipment, Supplies and Services, Practitioner shall pay the Fee set forth on page 1. Unless otherwise agreed by Hospital, Hospital shall invoice Practitioner on a monthly basis, and Practitioner shall pay the Fee within thirty (30) days of the date of the invoice. Any payment not received when due shall accrue interest at the rate of 12% per annum from the date due until paid. Unless otherwise agreed by Hospital, Practitioner shall be liable for the Fee for the Period of Use scheduled by Practitioner regardless of whether Practitioner actually uses Premises during the Period of Use.

**14. SIGNAGE.** Practitioner shall not place or install any sign in or upon Premises without Hospital’s consent.

**15. SURRENDER OF PROPERTY.** At the end of each Period of Use, Practitioner shall leave the Premises and Equipment in reasonably good condition and ready for use by other Practitioners after basic cleaning by Hospital’s basic janitorial services. Practitioner shall also remove all of Practitioner’s property from Premises unless otherwise agreed by Hospital. Practitioner hereby releases Hospital from and waives as to Hospital any obligation to maintain, store, sell, dispose or preserve such property. If Practitioner remains in and precludes others from using part of Premises or Equipment after the end of a Period of Use without the express consent of Hospital, Practitioner may be charged the Fee for Practitioner’s additional use. The inclusion of this Section shall not be construed as Hospital’s permission for Practitioner to use the Premises, Equipment, Supplies or Services outside the Period of Use.

**16. CONFIDENTIALITY.** Practitioner acknowledges and agrees that, in the course of using the Premises, Equipment, Supplies or Services, Practitioner may intentionally or unintentionally have access

to or receive confidential information concerning Hospital's operations, including but not limited to confidential information concerning Hospital patients or personnel. Practitioner shall maintain the confidentiality of such information and shall not use or disclose such information without Hospital's prior written approval. Practitioner agrees that, in the performance of Services on behalf of Practitioner, Hospital personnel shall be acting as members of Practitioner's workforce within the meaning of the HIPAA privacy and security rules, and not as Practitioner's business associates and, accordingly, Hospital is not required to enter a business associate agreement with Practitioner.

**17. NO GUARANTEES.** Hospital makes no representation, warranty, or guarantee concerning the quality, suitability, or fitness for a particular purpose of the Premises, Equipment, or Supplies provided under this Agreement, and expressly disclaims any representation, warranty or guarantee concerning such property. Hospital makes no representation concerning the education, training, experience, or qualifications of any Hospital personnel utilized by Practitioner under this Agreement. Practitioner shall be responsible for supervising Hospital personnel while providing Services on behalf of Practitioner pursuant to this Agreement.

**18. DAMAGE TO PROPERTY.** Practitioner shall at all times properly use and act in a manner so as to protect, maintain, and preserve the Premises and Equipment in good order, and shall refrain from any action that would damage such property or impair Hospital's or other licensees' ability to use any such property as contemplated by this Agreement. Practitioner shall be responsible for replacing or repairing, at Practitioner's own cost and expense, any damage to such property caused by Practitioner's act, error, or omission, or the act, error or omission of Practitioner's employee, agent, patient, invitee, guest, or anyone acting under their supervision or control.

**19. INDEMNITY.** Practitioner shall indemnify, defend and hold harmless Hospital from and against any and all costs, attorney's fees, expenses, claims, causes of action, proceedings and liabilities arising from or relating to Practitioner's use of the Premises, Equipment, Supplies or Services and from any breach of this Agreement by Practitioner, and shall further indemnify, defend and hold Hospital harmless from and against any and all claims arising from any act or negligence of Practitioner, or any of its agents, guests, or invitees, and from and against all cost, attorney's fees, expenses and liabilities incurred in or from any such claims or any action or proceeding brought thereon.

**20. HOLD HARMLESS.** Should Hospital, without fault on Hospital's part, be made a party to any litigation instituted by Practitioner or by any third party against Practitioner, or otherwise arising out of or resulting from any act or omission of Practitioner, Practitioner covenants to defend and save and hold Hospital harmless from any judgment rendered against Hospital, and all costs and expenses, including reasonable attorney's fees, incurred by Hospital in or in connection with such litigation.

**21. INSURANCE.** Practitioner shall at all times during the term of this Agreement and at its own cost and expense procure and maintain professional liability insurance covering the acts and omissions of Practitioner and Practitioner's agents at the Premises in an amount of not less than \$1,000,000 per occurrence, \$3,000,000, general aggregate. Upon request, Practitioner shall deliver a copy of such policy or an endorsement thereto to Hospital.

**22. ASSIGNMENT.** Practitioner shall not either voluntarily or by operation of law assign, re-license, or transfer Practitioner's rights under this Agreement to any other entity without Hospital's prior written consent.

**23. TERMINATION.** Either party may terminate this Agreement without cause by giving written notice to the other party at least thirty (30) days prior to the effective date of termination. Hospital may terminate this Agreement immediately and without prior notice upon the occurrence of any of the following: (i) Practitioner fails to maintain the insurance required by this Agreement; (ii) either party is excluded from participating in government healthcare programs; (iii) Hospital determines that performance of this Agreement violates applicable laws or regulations, or may subject either party to adverse action by any government agency; (iv) Practitioner or Practitioner's agents, guests or invitees engage in any action that has damaged or may damage the Premises, Equipment, or Supplies; (v)

Practitioner or Practitioner's agents, guests or invitees engage in any action that violates Hospital's policies or procedures relating to the Premises, Equipment, Supplies or Services; or (vi) Hospital otherwise determines that Practitioner has engaged in conduct that interferes with effective Hospital operations, endangers patients or personnel, or that may otherwise expose the Hospital to liability or adversely affect Hospital's reputation.

**24 REGULATORY COMPLIANCE.** The parties intend that this Agreement comply, and the Agreement shall be interpreted to comply, with all relevant laws and regulations, including but not limited to 42 CFR 411.357(y). The parties represent and warrant that (i) this Agreement is not conditioned on the referral of patients by Practitioner to Hospital; (ii) the Agreement would be commercially reasonable even if no referrals were made between the parties; and (iii) the Fee is set in advance, consistent with fair market value, and not determined in a manner that take into account (directly or indirectly) the volume or value of referrals or other business generated between the parties.

## 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 or 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 her 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 “incidental 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



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## Physician Timeshare Arrangements: New Stark Option for Sharing Space with Visiting Specialists and Others

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Recent Stark law amendments will make it easier for physicians to share space, and for hospitals to provide space, equipment, and services to visiting specialists and other physicians on a non-exclusive, "as-needed" basis. Hospitals and physicians may want to review their current lease arrangements to determine whether the new exception is a better fit for their current or future relationships and, if so, structure their arrangements accordingly.

**Prior Law.** The federal Ethics in Patient Referrals Act ("Stark") generally prohibits physicians from referring patients for certain designated health services ("DHS") payable by Medicare to entities with which the physician has a financial relationship unless the relationship is structured to fit within a regulatory safe harbor. (42 USC 1395nn; 42 CFR 411.353). Providing space or equipment to a referring physician generally creates a financial relationship that triggers Stark<sup>1</sup>; consequently, such arrangements generally needed to be structured to satisfy Stark safe harbors for leases of space or equipment. Unfortunately, those safe harbors required, among other things, that the physician enter a formal lease that provided for exclusive use of the leased premises or equipment during defined lease terms (42 CFR 411.357(a)-(b)); the physician and lessor were generally **not** permitted to share space or equipment during the lease term, nor could the lease be on an "as needed" basis. Traditional timeshare arrangements in which physicians share space or equipment on a non-exclusive basis did not satisfy Stark, thereby forcing physicians and their landlords to enter formal, inefficient, and sometimes impractical lease arrangements.

**New Timeshare Safe Harbor.** Effective January 1, 2016, a new Stark exception, 42 CFR 411.357(y), permits physicians and hospitals or other physician groups to share "space, equipment, personnel, items, supplies or services" through non-exclusive timeshare arrangements 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's group) and (i) a hospital; or (ii) a physician organization of which the visiting physician is not an owner, employee, or contractor. The new exception will not apply to DHS entities other than physicians, physician organizations, and hospitals (e.g., independent diagnostic testing facilities ("IDTFs") or labs. (80 FR 71329).

(3) The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used (i) predominantly for the provision of evaluation and management ("E/M") services to patients; and (ii) on the same schedule.

The purpose of the new provision is to increase access to care, not to facilitate the physician's ability to provide DHS in supplemental medical practices sites; accordingly, "the use of office space by the physician *solely* or *primarily* to furnish DHS to patients (as opposed to E/M services) would not be protected by the new exception." (80 FR 71330).

(4) The equipment covered by the arrangement is (i) located in the same building where the E/M services are furnished (*i.e.*, the same U.S. Postal Service address); (ii) not used to furnish DHS other than those incidental to the E/M services furnished at the time of the patient's E/M 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). CMS reasoned that advanced imaging and the other excluded equipment were likely already available onsite and, therefore, allowing the physician to use such equipment and bill for such use would not promote access, and could create a potential for fraud or abuse. (See 80 FR 71330-31).

(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.

Thus, the new exception only applies if the compensation is based on forms such as a flat-fee or time-based formula (*e.g.*, per-hour or per-day); timeshare arrangements based on a percentage of compensation, per-unit of service, or "per click" compensation formulas are not protected due to their potential to incentivize overutilization and patient steering. (80 FR 71331-32).

(7) The arrangement would be commercially reasonable even if no referrals were made between the parties. Arrangements that are above or below fair market value, or that do not make business sense except for inducing referrals, would be suspect.

(8) The arrangement does not violate the federal anti-kickback statute ("AKS") or any federal or state law or regulation governing billing or claims submission. The AKS is generally violated if "one purpose" of the transaction is to generate referrals for items or services payable by federal programs between the parties unless the transaction is structured to fit within an AKS exception, including the lease or services safe harbors. (See 42 CFR 1001.952(b)-(d)). Although providers should carefully analyze the AKS implications in each case, arrangements based on fair market value for needed space, items, or services should pose relatively little risk, especially when they promote access to care in the area.

(9) The arrangement does not convey a possessory leasehold interest in the space or equipment that is the subject of the arrangement. In other words, the arrangement only grants permission ("license") for the visiting physician ("licensee") to use the space, equipment and and/or other items of the hospital or physician organization ("licensor"); it does not grant to the licensee a possessory leasehold or similar interest to use or occupy the space or equipment, *i.e.*, the licensor retains the right to control the property. (80 FR 71327-28). CMS warned,

We do not intend [that the new exception] 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.

(80 FR 71328).

**Conclusion.** Of course, physicians, physician organizations and/or hospitals may still use the lease safe harbors where appropriate; however, this timeshare exception creates a new opportunity for hospitals and other entities to share space, equipment, personnel, and services without violating Stark. Accordingly, hospitals and other physician organizations that are currently sharing or want to share space, equipment, personnel or other items should consider revising their current agreements or entering new timeshare arrangements consistent with the new rules.

For questions regarding this update, please contact:

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<sup>1</sup>The prohibition would generally not apply to situations where, e.g., a hospital allowed medical staff members to use hospital space and equipment but each party billed payers for their respective services. (See 80 FR 71321).