QUESTIONS AND ANSWERS ON
FINAL STARK II RULES

PLEASE NOTE: ASCRS and ASOA cannot provide specific legal advice as to whether an individual ophthalmology practice complies with the self-referral ban. We urge ASCRS and ASOA members to contact an attorney knowledgeable in this area for further guidance on compliance with the law and proposed rules.

The Centers for Medicare and Medicaid Services (“CMS”) of the U.S. Department of Health and Human Services recently issued its long-awaited Phase II regulations on the Stark II physician self-referral law. These regulations, which were issued as an interim final rule with a 90-day comment period, supplement the Phase I final rules that were issued in January, 2001. The rules contain many significant changes and several new exceptions from the proposed rules issued in January, 1998 and the Phase I rules. The effective date of the Phase II rules is July 24, 2004.

Stark II prohibits a physician from making a referral to an entity for the furnishing of "designated health services" covered by Medicare if the physician (or an immediate family member of the physician) has a financial relationship with that entity, unless a statutory exception exists. The statute also prohibits an entity from submitting a claim to Medicare, or to any other person or entity, for DHS provided pursuant to a prohibited referral. Other sections of the Social Security Act apply the self-referral ban to Medicaid services.

The statute lists 11 categories of DHS, including radiology services (e.g., A-scans and B-scans); prosthetic devices and supplies (e.g., post-cataract eyewear); outpatient prescription drugs; and inpatient and outpatient hospital services.

A financial relationship is defined to be a direct or indirect ownership interest or compensation arrangement. Violations of Stark II carry severe monetary penalties and in some cases exclusion from Medicare. The statute contains numerous exceptions that apply to ownership and compensation arrangements, and some that apply to both.

The Phase I rules covered the following provisions of the Stark statute:

- the general prohibition on physician self-referrals;
- the definitions of key terms, including “group practice” and “designated health services”;

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5 With the exception of prepaid health plans, Phase II does not include provisions elaborating on the application of Stark II to Medicaid. CMS indicated that it will publish rules on this issue at a future date.
- the general exceptions that apply to both ownership and compensation relationships, including the in-office ancillary services exception and a regulatory exception for post-cataract eyewear.

The Phase II rules cover:

- responses to and changes based on public comments on the Phase I regulations;
- the remaining provisions of the statute, including exceptions for ownership and investment interests and compensation arrangements such as personal service agreements and space and equipment leases, reporting requirements, and sanctions;
- additional definitions; and
- additional new regulatory exceptions, including an exception for professional courtesy.

This set of questions and answers is designed to assist ASCRS and ASOA members in complying with the final rules. A companion summary of the specific provisions of the rules has been posted on the ASCRS/ASOA website (www.ascrs.org).

It is important to note that Stark II is separate from the Medicare-Medicaid antikickback law, which broadly precludes payments in exchange for referrals of program-related items or services. Compliance with Stark II does not necessarily ensure compliance with the antikickback statute and vice versa. For instance, Stark II generally does not apply to referrals involving the furnishing of physician services; the antikickback law does. In addition, Phase II declines to adopt a blanket Stark II exception for conduct that meets an antikickback safe harbor, although it does create some specific exceptions that effectively adopt certain antikickback safe harbors. Compliance with the antikickback law is also a condition for meeting several Stark II exceptions. ASCRS and ASOA have previously circulated questions and answer documents on compliance with the antikickback law. Copies of those summaries are available upon request. For further information, contact Nancey McCann at (703) 591-2220.

Optical Shops

1. Do the Stark II rules cover referrals by optometrists as well as ophthalmologists?

Yes. The Medicare Act defines “physician” to include optometrists, podiatrists, dentists, and chiropractors, as well as M.D.s and D.O.s such as ophthalmologists. Referrals by optometrists of Medicare-covered designated health services to entities with which they have a financial interest are covered by Stark II unless an exception applies. Phase II does not change the definition of physician.
2. Can ophthalmologists refer their Medicare cataract patients to optical shops owned by their group practice?

Yes. Stark II defines “designated health services” to include prosthetic devices, including post-cataract eyeglasses and contact lenses. So, these referrals must qualify for an exception. In response to ASCRS’s comments on the 1998 proposed rules, the Phase I final rule established (and Phase II retained) an exception for post-cataract eyewear if the following conditions are met:

- The eyewear is provided in accordance with the applicable Medicare coverage and payment rules;
- The arrangement for furnishing the eyewear does not violate the federal antikickback law, and billing and claims submission for the eyewear complies with all federal and state laws and regulations.

The effect of this exception is to permit ophthalmologists to refer Medicare patients to optical shops in which they have ownership interests without triggering any Stark II scrutiny. However, these referrals still need to comply with the federal antikickback statute. To the extent that optical shops are part of or wholly-owned by a medical practice, there will be no antikickback liability risk. Antikickback risks could arise if an optical shop is co-owned by ophthalmologists, or ophthalmologists and optometrists, who are not part of the same group practice. (See Question 3 below.)

Referrals by a bona fide group practice to a wholly-owned optical shop might also qualify for the in-office ancillary services exception if the practice meets the location, billing, and supervision requirements of that exception, as well as the Stark requirements for a group practice. Generally, it will be simpler to meet the post-cataract eyewear exception than the in-office ancillary services exception.

3. Can an ophthalmologist make referrals for post-cataract eyewear to an in-office optical shop that the ophthalmologist jointly owns with other ophthalmologists or optometrists who are not in the same group practice as the referring ophthalmologist?

The post-cataract eyewear exception would protect these referrals as long as they do not violate the antikickback law. The in-office ancillary services exception would not apply to a joint venture that is not part of or wholly-owned by a single physician or group practice.

Referrals of cataract patients to a joint venture optical shop owned by physicians and/or optometrists that are not in the same group practice would implicate the antikickback statute because of the potential that ownership interests in the optical shop could be used to induce or lock-in referrals from the investing physicians/optometrists. This means that the joint venture must either meet a safe harbor to the antikickback statute, or the venture must be able to show that the joint venture is not in violation of the antikickback law. For instance, if all returns to investors are proportionate to their capital contributions, investors are not required to refer to the
optical shop, and there are no other inducements to refer, a strong argument can be made that the antikickback statute would not be violated. However, the only way to gain complete protection from antikickback risk would be to seek an advisory opinion from the HHS Office of Inspector General or not permit physician investors to refer Medicare patients to the joint venture optical shop.

4. **Does the answer to Question 3 change if the optical shop is owned by the ophthalmologist’s wife?**

No. Ownership or compensation interests of family members are treated the same as interests directly held by the physician. An “immediate family member” means a spouse, a child, parent, or sibling (by blood or adoption), including stepparents, stepchildren, and stepsiblings, a grandparent or grandchild, the spouse of a grandparent or grandchild, and a parent-in-law, sibling-in-law, and child-in-law.

5. **Can an ophthalmologist who is a member of a group practice make referrals for post-cataract eyewear to an in-office optical shop that is wholly owned by the ophthalmologist, but not by other members of the group?**

Yes, the exception for post-cataract eyewear would apply here because referrals from an individual physician to an optical shop wholly-owned by that physician would not violate the antikickback statute. This also assumes the physician does not provide anything of value to the other members of the group practice to encourage referrals to his optical shop.

6. **If an optical shop is jointly owned by two members of a five-physician group practice, can the other members of the group practice who do not have an ownership interest in the optical shop still refer patients to the optical shop for post-cataract eyewear?**

The post-cataract eyewear exception would apply here, as long as the arrangement did not violate the antikickback statute. It is unlikely that referrals from one member of a group practice to an entity owned by another member of the group practice would violate the antikickback law, especially if there was no separate payment or other inducement to make such a referral.

7. **Can an ophthalmologist refer Medicare patients to an optical shop that the ophthalmologist owns for the furnishing of eyewear not covered by Medicare?**

Yes. Stark II applies only to items and services covered by Medicare. A separate statute applies Stark II to certain Medicaid services, but CMS did not address Medicaid referrals in either Phase I or Phase II, but has promised to cover this issue in a future rulemaking.
8. Can an ophthalmologist avoid Stark II liability by not directly referring Medicare patients to an optical shop owned by the ophthalmologist?

As long as the ownership structure of the optical shop does not violate the antikickback law, the referrals of post-cataract eyewear will be exempt from Stark II. If the ownership structure of the optical shop raises antikickback concerns, the risk of liability could be reduced by not directing Medicare patients to the optical shop. Stark II applies only to program referrals by physicians to an entity with which the physician has a financial relationship. Therefore, if the physician does not specifically refer the patient to a particular entity, the referral prohibition should not apply. On this score, the Phase I final rules created an exception for indirect and oral referrals, which Phase II retained. When there is no written order or other documentation for the referral, CMS will look to see whether the DHS provider knew or had reason to suspect the identity of the physician who made the referral for DHS.

9. Can the ophthalmologist refer a Medicare patient to the ophthalmologist’s optical shop if the patient is covered by a Medicare HMO and the physician has a contract with the HMO?

Stark II has a specific exception for services provided by Medicare HMOs to their enrollees. The Phase I final rules interpreted this exception to cover not only services furnished by the organizations themselves, but also those furnished to the organization’s enrollees by outside physicians, providers, or suppliers under contract with these organizations. The exception would also cover services furnished to enrollees by those with whom the outside physicians, providers, or suppliers have contracted. These provisions were unchanged by Phase II.

Thus, referrals of Medicare HMO patients by an ophthalmologist under contract with that HMO for the furnishing post-cataract eyeglasses or contacts by an optical shop in which the physician has an ownership interest would not violate Stark II as long as the provision of the eyeglasses or contacts were part of the covered services required to be provided by the physician under the agreement. For instance, the exception would clearly apply if the eyewear were covered by the physician’s capitation arrangement. Alternatively, if the optical shop were under subcontract with the physician or had a separate contract with the HMO for the provision of post-cataract eyewear, the HMO exception should still apply.

A-Scans, B-Scans, and Echo Eye Exams

10. Are A-Scans, B-Scans, and Echo Eye Exams covered by Stark II?

Yes. A-scans and B-scans fall within the Stark II definition of radiology procedures and therefore are designated health services. The Phase II final rules exclude from the definition of radiology services those radiology procedures that are integral to the performance of a nonradiological medical procedure, either during the procedure, or immediately following the procedure to confirm placement of an item positioned during the procedure. However, CMS refused to include either A-scans and B-scans in this exception even though it acknowledged that B-scans are used in certain cataract surgeries to view the posterior segment or retina of the eye to
determine if a structural pathology is present. The agency views A-scans and B-scans as essentially the same as any other radiology services ordered in conjunction with other surgeries, but did not explain why. It also said it was not convinced that A-scans and B-scans “pose no risk of abuse.” However, it did opine that in many cases the in-office ancillary services test could shield these tests from Stark liability.

Echo eye exams are included in the codes listed at the end of the final rule. These codes represent a non-exhaustive list of services covered by Stark II.

11. **Can ophthalmologists perform A-scans and echo eye exams in their office without violating Stark II?**

As noted above, A-scans and echo eye exams are considered to be designated radiology services covered by Stark II. If these tests are personally performed by the treating ophthalmologist, there will be no prohibited referral. However, if the tests are performed by another group practice member, an employee, or independent contractor, there will be a referral to an entity with which the referring physician has a financial relationship (i.e., his or her group practice). To avoid Stark II liability, the group must meet the definition of a group practice and the location, supervision, billing and other criteria for the ancillary services exception. In addition, the rural provider exception might apply if the practice is located outside a metropolitan statistical area and at least 75 percent of its services are furnished to patients within the rural area.

The final rule states that, for purposes of the in-office ancillary services exception, independent contractors are not included as members of the group practice, but are now treated as physicians in the group who can supervise the provision of DHS. The proposed rules set forth a very restrictive supervision standard, which would have required the supervising physician to be "present in the office suite in which the services are being furnished throughout the time they are being furnished, and immediately available to provide assistance and direction." Both the Phase I and Phase II final rules confirm that the services only need to be provided in accordance with the existing supervision standards under the applicable Medicare coverage and payment rules, such as the supervision standards for diagnostic tests. Thus, for A-scans and echo eye exams, ophthalmology practices need only comply with the level of supervision standard established as a condition of reimbursement for these services.

**Ambulatory Surgical Centers and IOLs**

12. **Do referrals of Medicare patients to ambulatory surgical centers owned in part or in whole by the referring physician violate Stark II?**

No. Stark II generally does not cover referrals for physician services. For instance, the performance of cataract surgery itself is not a designated health service covered by the statute. However, because cataract surgery includes the provision of other items or services that are designated health services, the statute would be implicated by such referrals. For instance, the proposed rules explicitly include prosthetic devices (including IOLs) as one of the eleven designated health items and services. In addition, A-scans and B-scans are regularly performed.
in conjunction with cataract surgery. Accordingly, referrals of Medicare cataract patients to ASCs with which the referring physician has a financial relationship would violate Stark II in the absence of an exception. Fortunately, the final rules define designated health service not to include services that are included as part of a composite payment rate to an ASC. There is also a new exception for implants of IOLs in ASCs if the following conditions are met:

- The implant is furnished by the referring physician or a member of the referring physician’s group practice in a Medicare-certified ASC with which the referring physician has a financial relationship.

- The implant is inserted in the patient during a surgical procedure performed in ASC and paid by Medicare to the ASC as an ASC procedure.

- The arrangement for furnishing the implant does not violate the federal antikickback statute, and the billing and claims submissions for the implants complies with all federal and state laws and regulations.

- All billing and claims submission for the implant comply will all applicable federal and state laws or regulations.

This exception applies only to the physician's financial relationship with the ASC. Phase II also confirms that this exception applies only to facilities seeking reimbursement and not to physicians who bill for implants.

13. **Are A-scans, B-scans, or echo eye exams performed in ASCs covered by the “ASC exception.”**

These tests are covered by the ASC exception if they are billed by the facility as part of the composite rate. Otherwise, a referral of A-scans or B-scans to an ASC by a physician that has a financial relationship with the ACS would be prohibited unless covered by another exception (e.g., the in-office ancillary services exception or rural provider exception).

14. **May a physician order an IOL from a company with which the physician has an ownership interest or compensation arrangement?**

Yes, as long as the supplier does not receive direct reimbursement from Medicare it is not considered to be a entity that furnishes DHS and is not covered by Stark II. If the IOL company is reimbursed directly by Medicare, the purchase should still be covered by the exception for payments made by physicians for items and services if the purchase price is at fair market value. This exception does not apply if the purchase is covered by another Stark II exception.
Sale of Practice

15. Does the sale of a physician’s practice to a physician violate Stark II if the parties continue to refer patients to each other after the sale?

The sale of a physician’s practice falls under the isolated transaction exception finalized in Phase II. An isolated transaction means one involving a single payment between two or more persons or entities or a transaction that involves integrally related installment payments provided that—

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

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

The compensation exchanged as part of the isolated transaction will be exempt from Stark II if:

- The amount of remuneration under the isolated transaction is: (i) consistent with the fair market value of the transaction; and (ii) not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician or other business generated between the parties.

- The remuneration is provided under an agreement that would be commercially reasonable even if the physician made no referrals.

- There are no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that meet another Stark exception and except for commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician.

The allowance of installment payments and post-closing adjustments are concessions by CMS, which originally proposed to prohibit such payments and modifications. The sale of a practice might also meet the new fair market value exception.
Discounts from Suppliers

16. **Is Stark II violated if an ophthalmologist accepts a discount from a supplier?**

A discount from a supplier will not implicate Stark II as long as the supplier does not furnish DHS items or services directly to Medicare beneficiaries and does not receive reimbursement directly from Medicare. Discounts received from entities that do furnish DHS to Medicare beneficiaries will be covered by the exception for payments made by physicians for items and services if the discount is at fair market value. This exception does not apply if the purchase is covered by another Stark II exception. Discounts must also be evaluated under the antikickback statute.

Gifts from Suppliers

17. **Does Stark II preclude physicians from accepting gifts from manufacturers or suppliers?**

As noted above, manufacturers and suppliers are not covered by Stark II unless they furnish DHS directly to Medicare beneficiaries and receive reimbursement from Medicare directly. However, Stark II would apply to gifts from laboratories and hospitals. The final rules create an exception for non-monetary compensation that does not exceed an aggregate of $300 per year. This exception is modified from the *de minimis* exception in the proposed rules. It allows the physician to receive gifts or free goods like free samples of drugs, training sessions for the physician or his staff, note pads, coffee mugs, etc. Cash equivalents, such as gift certificates or frequent flier miles are not allowed. The criteria for this exception are as follows:

- The compensation is not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. So providing gifts only to physicians who refer a certain level of business would violate not meet this exception.

- The compensation is not solicited by the referring physician or the physician’s practice, including employees and staff.

- The compensation does not violate the antikickback law or any federal or state law or regulation governing billing or claims submission.

Note that this exception applies only to gifts to individuals, not group practices. Under Phase II, the $300 limit will be indexed for inflation. The new limits will be posted on the CMS website at:

ASCRS members should also strive to comply with the AMA guidelines on gifts to physicians, as well as the comparable guidelines issued by PhRMA, the latter of which has been blessed by the HHS Office of Inspector General in its Compliance Guidance for the Pharmaceutical Industry.

**Lease of Space or Equipment**

18. **Can a general ophthalmologist rent space to a retina specialist if the parties make referrals to each other that involve DHS?**

Yes, if the parties enter into a written space lease that meets the following conditions:

- The agreement is set out in writing, is signed by the parties, and specifies the premises it covers.
- The term of the agreement is at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.
- The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.
- The rental charges over the term of the agreement are set in advance and are consistent with fair market value.
- The rental charges over the term of the agreement are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

The parties would also want to meet the conditions of the antikickback safe harbor for leases. The HHS OIG has issued an alert on how to calculate lease payments so they are consistent with fair market value and take into account common areas. See http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm.
19. **Can an ophthalmologist who performs cataract surgery (which is a DHS referral) at a hospital lease a Yag laser to the hospital for use in it’s outpatient surgery center?**

Yes, if the parties enter into a written lease that meets the following requirements:

- has at least a one-year term that describes the equipment covered;
- the equipment is reasonable and necessary for the hospital’s legitimate business purposes (i.e., this is not a sham transaction to put money in the physician’s pocket);
- the equipment is used exclusively by the lessee-hospital and is not shared with or used by the lessor-physician or any entity related to the physician while the hospital is using it;
- the rental charges over the term of the agreement are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;
- the agreement would be commercially reasonable even if no referrals were made between the parties;
- if the agreement is terminated during the term, with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement;
- a holdover, month-to-month rental for up to 6 months immediately following an agreement of at least 1 year that met all of the above conditions will be permitted provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.

This exception will not be met if the physician uses the laser to perform post-op Yag laser capsulotomies while the machine is being rented by the hospital. However, the hospital presumably may perform these procedures on the physician’s patients if the hospital bills for the procedure on its own.

20. **Can the rental charge in Question 19 be set on a per procedure or per click basis? How about a percentage of collections basis?**

Yes, per service or per click arrangements, as well as percentage-based agreements, are permitted if the methodology is set in advance, is objectively verifiable, and does not vary over the course of the agreement with the volume or value of DHS referrals.

**Personal Services Agreements and Employee Bonuses**

21. **Can an ophthalmology practice hire a cataract and refractive surgeon or retinal specialist as an independent contractor and pay him or her a percentage of collected revenues for which he or she is responsible?**

Yes. As with space and equipment leases, percentage-based compensation is permissible for independent contractor agreements if the methodology is set in advance, is objectively verifiable, and does not vary over the course of the agreement with the volume or value of DHS referrals. In this case, the physician contractor will likely be referring patients to the practice for A-scans, B-scans, and echo eye exams, so any compensation to the physician will implicate Stark II,
unless the DHS is performed personally by the referring physician. Assuming that is not the case, the practice can still pay the physician on a percentage of collections basis if it meets all of the requirements for the personal services exception:

- Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.
- The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. A physician or family member can “furnish” services through employees whom they have hired for the purpose of performing the services; through a wholly owned entity; or through locum tenens physicians.
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).
- The term of each arrangement is for at least 1 year. To meet this requirement, if an arrangement is terminated during the term with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement.
- The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

If there are multiple agreements between the parties, the requirement that the agreement cover all services to be provided by the physician to the DHS entity will be met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of contracts.
22. **Can the practice in Question 21 pay the physician a productivity bonus?**

Yes, as long as the bonus is based on services personally performed by the physician. Group practices may also pay bonuses to physicians, whether independent contractors or employees, based on services incident to the physician’s services, as long as the bonus is not tied to the volume or value of referrals of DHS by the physician to the practice. Outside group practice settings, physician bonuses may only be paid based on DHS personally performed by the physician.

23. **Is a separate lease agreement required if the independent contractor physician provides his own equipment to perform the agreed to services?**

No, Phase II clarifies that personal service agreements may include equipment that the physician needs to provide the services, and that separate equipment leases are not required in such cases; however, both the services and the equipment must be set at fair market value separately, rather than collectively.

**Professional Courtesy**

24. **May an ophthalmology group practice provide free or discounted services to ophthalmologists and optometrists (and their family members) who refer patients (including cataract patients) to the practice?**

Yes, but only if the conditions of the professional courtesy exception established by Phase II are met. Specifically,

- The professional courtesy must be offered to all physicians on the entity’s bona fide medical staff or in the entity's local community without regard to the volume or value of referrals or other business generated between the parties;
- The health care items and services provided must be of a type routinely provided by the entity;
- The entity's professional courtesy policy must be set out in writing and approved in advance by the governing body of the health care provider;
- The professional courtesy must not offered to any physician (or immediate family member) who is a Federal health care program beneficiary (e.g., Medicare or Medicaid), unless there has been a good faith showing of financial need;
- If the professional courtesy involves any whole or partial waiver of any coinsurance obligation, the insurer is informed in writing of that reduction so that the insurer is aware of the arrangement.
- The professional courtesy arrangement does not violate the anti-kickback statute or any billing or claims submission laws or regulations.

These conditions are sufficiently onerous and limiting that many physicians will likely use this exception as a reason *not* to provide professional courtesy.