I. Introduction

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.

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 the definition of "group practice" and "designated health services";
- 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.

In general, the Department has tried to reduce regulatory burdens and add flexibility by broadening exceptions using the Secretary's discretionary authority under the statute to create exceptions that pose no risk of fraud or abuse. However, the rule still contains many traps for the unwary. This article summarizes the basic Stark prohibition and the highlights of the Phase II rules. A more detailed summary of the Phase I and Phase II final rules is available at www.ascrs.org and www.jenner.com.
II. **Basic Prohibition of Stark II**

Stark II prohibits a physician from making a referral to an entity for the furnishing of "designated health services" ("DHS") 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.\(^5\)

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.

It is important to note that Stark II is a separate beast from the Medicare-Medicaid anti-kickback 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 anti-kickback statute and vice versa. 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.

III. **Highlights of Phase II Final Rules**

Phase II first provides clarifications and modifications in response to comments on the Phase I final rules. It also creates final rules for the existing statutory exceptions not covered by Phase I; and third, it establishes several new regulatory exceptions under CMS’s authority to create new exceptions that do not pose a risk of program or patient abuse. Lastly, it establishes final rules for the reporting requirements and sanction provisions of Stark II. The highlights of Phase II follow.

A. **Changes in Response to Comments on Phase I Rules**

In response to comments on the Phase I final rules, Phase II made several important changes and clarifications. Specifically, it:

- Clarifies that a financial relationship with an entity that provides DHS implicates the statute even if it is wholly unrelated to the DHS, for example where the financial relationship only involves private pay business.
• Confirms that payment may be made to a DHS entity that receives a prohibited referral if the entity did not have actual knowledge, and did not act in reckless disregard or deliberate ignorance, of the identity of the physician who made the referral, and the claim complies with all other applicable federal laws, rules, and regulations.
• Confirms that DHS personally performed by the referring physician is not covered by the definition of "referral," but clarifies that this exclusion does not apply to DHS performed by the physician’s co-owners, employees or independent contractors. One effect of this clarification is that productivity bonuses can be paid without violating Stark II for DHS personally performed by physicians. Productivity bonuses may also be based on “incident to” DHS for physicians in group practices that otherwise meet the group practice requirements.
• Excludes from 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; but declines to include A-scans and B-scans in this exception.
• Further broadens and clarifies the in-office ancillary services exception, which is designed for group practices that order, provide, and bill for DHS. Among other things, Phase II creates a more liberal test for one of the location requirements of the exception—i.e., where the services must be performed to qualify for the exception; clarifies that a solo practitioner may provide DHS through a shared facility, as long as the supervision, location, and billing requirements of the in-office ancillary services exception are satisfied; and confirms that leased employees can be members of group practices if they meet the IRS definition of employee.
• Clarifies the rules for determining whether an indirect ownership interest or compensation arrangement exists and when the indirect compensation exception applies.
• Permits percentage-based compensation arrangements if certain conditions are met and confirms that per-service, time-based, and unit-based compensation provisions are permissible under certain circumstances. This change will allow ophthalmologists to enter into personal service agreements and leases with percentage-based, per-service, and per-click compensation provisions.
• Creates specific safe-harbor methodologies for calculating an hourly payment for physician services that will be deemed to meet the fair market value requirements of various Stark II exceptions.
• Clarifies that an arrangement that meets an ownership or investment interest exception does not also have to meet a compensation exception to protect profit distributions, dividends, or interest payments on secured obligations.
• Changes the definition of “commercially reasonable,” a term used in several compensation exceptions, to “An . . . arrangement [that] would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals.”
In addition, Phase II retains the following exceptions from the Phase I final rules of special interest to ophthalmology:

- The exception for post-cataract eyewear.
- The definition of DHS excluding services provided as part of a composite rate, such as an ambulatory surgical center ("ASC") rate, but declines to create an exception for radiology procedures (including A-scans or B-scans) performed in ASCs and billed outside the composite rate.
- The exception for implants in ASC settings, including implants of intraocular lenses, and confirms that this exception applies only to facilities seeking reimbursement as part of the composite rate and not to physicians who bill for implants.
- The exception for non-monetary compensation from DHS entities to physician up to $300. Phase II agrees to index this limit for inflation.
- The exception for incidental benefits provided to hospital medical staff. Phase II will index for inflation the $25 per occurrence limit on expenditures and makes additional changes to clarify the type of benefits covered. Phase II also excepts the listing or identification of physicians on hospital websites (but advertising or promoting a physician’s private practice on the hospital’s website is not excepted), deletes the requirement that benefits be of a type offered to medical staff members at other local hospitals or by comparable hospitals in comparable regions, and clarifies that the exception applies to other institutions, such as long term care facilities, federally qualified health centers (“FQHCs”), and other health care clinics as long as they have bona fide medical staffs.

B. Final Rules for Ownership and Compensation Exceptions

Phase II also created final rules for several ownership and compensation exceptions created by the statute or proposed rules that were not addressed by Phase I. The key changes or clarifications for these exceptions are as follows:

- **Publicly-Traded Securities and Mutual Funds.** The statutory exception for ownership in certain publicly-traded securities and mutual funds requires that the securities be available for purchase on terms generally available to the public. Phase II interpret this provision to mean availability at the time of a DHS referral rather than time of purchase of the security, as was originally proposed. This change means that stock purchased during a private offering may be eligible for the exception if the company goes public before a DHS referral is made. In addition, ownership in stock options received as compensation will not be considered to be ownership or investment interests until the time they are exercised.

- **Rural Providers and Hospital Ownership.** Phase II implements the temporary exclusion of specialty hospitals from the exception for ownership or investment interests in rural providers (defined as providers outside metropolitan statistical areas) and the exception for ownership of U.S. hospitals, as mandated by the Medicare Prescription Drug.
Improvement, and Modernization Act of 2003. Otherwise, these exceptions are unchanged.

- **Rental of Office Space and Equipment.** As noted above, Phase II clarifies that percentage-based and per click leases are permissible as long as methodology for calculating the compensation is set in advance, objectively verifiable, and does not change over the course of the arrangement in any manner that reflects the volume and value of referrals or other business generated by the referring physician. In addition, Phase II provides that

  o leases or rental agreements may be terminated with or without cause as long as no further agreement is entered into within the first year of the original lease term and any new lease between the parties meets an exception (the government believes termination without cause provisions are subject to abuse because they permit the parties to circumvent the requirement that the term of a lease, or personal services agreement, be at least one year);
  o month-to-month holdover leases are permitted for up to 6 months if they continue on the same terms and conditions as original lease;
  o there will be no distinction between capital and operating leases (the proposed rule would have excluded capital leases from this exception);
  o the requirement that the lessee have exclusive use of the property or equipment during the period of use will be met as long as the lessee or sublessee does not share the rented space or equipment with the lessor (or any entity related to the lessor) during the time it is rented or used by the lessee or sublessee; and

- **Bona Fide Employment Relationships.** This exception is unchanged from the Proposed Rule, except, consistent with the Phase II determination that services personally performed by physicians are not referrals, Phase II permits payment of productivity bonuses to employed physicians based on any services that they personally perform, including DHS. The Proposed Rule would have precluded productivity bonuses based on DHS personally performed by employed physicians. Productivity bonuses still may not be paid to employed physicians based on supervision of “incident to” DHS services, unless done so under the in-office ancillary services/group practice exception.

- **Personal Services Arrangements.** Phase II makes several clarifications to the exception for personal service agreements. Specifically, it clarifies that:

  o the exception covers services provided by the referring physician or his or her immediate family member and/or through technicians or employees (or through a wholly-owned subsidiary), but not through independent contractors; except that *bona fide* locum tenens may be used in referring physician’s absence;
  o personal services mean any kind of services personally performed, not just generic Medicare services;
  o a personal services contract can be between a DHS entity and an individual or the individual’s group practice;
  o as with leases, percentage-based, per service, or time-based compensation are permissible as long as the methodology and/or amount is set in advance and does
not vary with the volume or value of DHS referrals; hourly payments can be structured under the new safe harbor discussed above;

- as with leases, termination without cause clauses are permitted as long as the parties do not enter into the same or substantially same arrangement during the first year of the original term and any subsequent agreement fits on its own terms in an exception;

- personal service agreements may include equipment that the physician needs to provide services; separate equipment leases are not required;

- to meet the statutory requirement that the agreement cover all services provided by a physician to a DHS entity, Phase II requires either that the multiple agreements incorporate one another by reference or that each agreement cross-reference to a master list of agreements that is maintained and updated centrally. Such master lists must be made available for inspection by the Secretary upon request and the list or lists must be maintained in a manner that preserves the historical record of contractual arrangements between the parties.

- **Remuneration from Hospitals to Physicians Unrelated to Provision of DHS.** Phase II clarifies that this exception applies only to remuneration that is wholly unrelated to provision of DHS—e.g., rental of residential property. Any cost that can be allocated, in whole or in part, to Medicare or Medicaid, will be treated as related to the provision of DHS. Also, any remuneration will be treated as related to DHS if it is furnished directly or indirectly, explicitly or implicitly, to medical staff or other physicians in a position to make or influence referrals in any manner that is selective, targeted, preferential, or conditional. Phase II clarifies that this exception does not apply to remuneration to family members.

- **Physician Recruitment.** This exception allows for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital so as to be a member of the hospital’s medical staff. Phase II creates a new test for determining relocation eligibility, which changes the focus from the relocation of the physician’s residence to the relocation of his or her practice. Among other things, Phase II also permits, in limited circumstances, payments to medical groups, rather than individual physicians, and retention payments for physicians who practice in health professional shortage areas. Hospitals making recruitment payments cannot prevent physician from obtaining staff privileges at, and/or referring to, other hospitals, but hospitals may still have reasonable credentialing restrictions with respect to numbers of procedures performed at the hospital, etc.

- **Isolated Transactions.** This exception permits isolated transactions, such as a one-time sale of property or a practice, in certain circumstances. Phase II reverses the proposed rule by permitting these transactions to include installment payments if the total aggregate payment is set before the first installment payment is made and does not take into account, directly or indirectly, referrals or other business generated by the referring physician. In addition, the outstanding balance must be secured by a third party, promissory note, or other mechanism to guarantee payment. Post closing adjustments are permitted within 6 months of date of the purchase or sale transaction if they are
commercially reasonable and not dependent on referrals or other business generated by the referring physician. Phase II also clarifies that this exception covers any isolated transaction, not just those that involve DHS or Medicare.

- **Payments Made by Physician for Items and Services.** This exception protects items or services purchased by physicians from DHS entities at a price consistent with fair market value. Phase II extends this exception to cover purchases by a physician’s family members. It also removes a proposed exception for items or services purchased by physicians at a discount.

C. **New Regulatory Exceptions**

Phase II creates several new exceptions intended to protect practices that are not considered to be improper or abusive. For instance, the new rule

- **Noncompliance Grace Period.** Creates a 90-day grace period for certain arrangements involving temporary noncompliance for reasons beyond the control of the entity furnishing DHS, and the entity promptly takes steps to come back into compliance. The exception may only be used by an entity once every 3 years with respect to the same referring physician. It also does not apply to arrangements that previously complied with the exceptions for non-monetary compensation up to $300 or incidental medical benefits.

- **Professional Courtesy.** Creates a narrow exception for professional courtesy offered by a DHS entity to a physician or a physician’s immediate family member or office staff if the professional courtesy is offered to all physician’s on the entity’s medical staff or in the entity’s local community or service area without regard to the volume or value of referrals or other business generated between the parties, is not offered to a federal health care program beneficiary unless there has been a good faith showing of financial need, and several other conditions are met.

- **Intrafamily Referrals in Rural Areas.** Creates a new exception for certain referrals from a referring physician to a DHS entity with which his or her immediate family member has a financial relationship, if the patient being referred resides in a rural area and there is no DHS entity available in a timely manner in light of the patient’s condition to furnish the DHS to the patient in his or her home (for DHS furnished to patients in their homes) or within 25 miles of the patient’s home (for DHS furnished outside the patient’s home).

- **Antikickback Safe Harbors.** Adopts the Medicare antikickback safe harbors for referral services and obstetrical malpractice insurance as new Stark II exceptions.6

- **Other New Exceptions.** Creates new exceptions for retention payments to physicians in underserved areas, charitable donations by physicians, and community-wide information systems.

D. **Reporting Requirements and Sanctions**

The final rule generally requires entities that provide DHS to retain reportable information and furnish it to HHS upon request. This is a substantial improvement from the Proposed Rule,
which would have imposed very onerous affirmative reporting requirements on DHS entities that would have applied with or without a government request. Still, the regulations will require medical practices to maintain specified information on each of its physicians’ ownership or compensation relationships that are covered by Stark II, except for shareholder information relating to ownership interests that satisfy the exceptions for publicly-traded securities and mutual funds. The specific requirements are included in Section 411.361 of the rule and listed in the detailed summary available at www.ascrs.org or www.jenner.com. The failure to respond to a request for information from the Secretary within 30 days are subject to a fine of up to $10,000 per day.

Phase II makes no change in the sanctions for Stark II violations, which include nonpayment of claims resulting from prohibited referrals or require refunds of amounts paid on prohibited claims. Individuals or entities that knowingly violate the prohibition are subject to civil monetary penalties.

IV. Conclusion

The Phase II final rule contains many changes that should be helpful to physicians and entities that furnish DHS in their efforts to comply with this law. However, the final rules are still enormously detailed and complex, creating many traps for the unwary. Physicians and DHS providers should take care to consult with experienced legal counsel before entering into any business or professional arrangements that implicate the statute.

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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.
6 See 42 C.F.R. § 1001.952(f) and (o).