Executive Summary

On March 26, 2004, the Centers for Medicare & Medicaid Services ("CMS") issued the long-awaited Phase II regulations under the Stark Law. While subject to a comment period (comments are due by 5:00 p.m. on June 24, 2004), the regulations will take effect July 26, 2004. Phase I of the regulations was released on January 2, 2001 and covered only a portion of the Stark Law’s definitions and exceptions. The Phase II regulations contain the following:

• Additional changes to and comments on the Phase I regulations.
• Provisions of the Stark Law not covered by Phase I, including:
  • Exceptions to ownership/investment interests
  • Exceptions to compensation arrangements
  • Reporting requirements
  • Sanctions
• Additional regulatory definitions
• New regulatory exceptions

The Phase II regulations provide significant additional guidance and set forth new regulatory requirements for common transactions, including physician employment/compensation and recruitment arrangements. As with the Phase I regulations, the Phase II regulations are voluminous (nearly 100 pages of comments and regulations). Accordingly, we have attempted to highlight the most significant aspects of the Phase II regulations and discuss how they impact common arrangements.

Definition of DHS

The Phase II regulations include a new list of CPT codes comprising designated health services ("DHS"). Despite rumors to the contrary, the list does not include PET scans as DHS. In addition, the Phase II regulations continue the approach that the professional component of a DHS also constitutes a DHS.

Bright Line Tests

CMS reiterated its desire to create bright line tests to help practitioners with compliance. Notwithstanding this desire, CMS continued its approach of requiring compliance with the anti-kickback statute as a condition of numerous Stark Law exceptions. As a result, compliance with the Stark Law is, in many cases, now subject to compliance with the vagueness of the anti-kickback statute, including its intent requirement. This makes compliance more difficult in many instances.

Finally, despite the reliance of a number of exceptions on compliance with the anti-kickback statute, CMS rejected a broad-based incorporation of the anti-kickback safe harbor regulations as exceptions under the Stark Law. Rather, CMS reviewed those safe harbors for which no parallel exception existed under the Stark Law and decided to create exceptions for referral services and obstetrical malpractice subsidies by incorporating the safe harbors by reference.

Effective Date and Unwinding Noncompliant Arrangements

The Phase II regulations are to become effective July 26, 2004. CMS did not agree to grandfather any existing noncompliant arrangements. Instead, such arrangements must be restructured or unwound prior to the effective date.

CMS, however, created a new exception for certain arrangements that temporarily fall out of compliance. Specifically, an entity may submit claims for DHS reimbursement for a period of up to 90 days despite a noncompliant arrangement if:
(1) the financial relationship fully complied with an exception for at least 180 consecutive days prior to noncompliance; (2) the arrangement is noncompliant for reasons beyond the entity’s control and the entity promptly takes steps to cure the noncompliance; and (3) the arrangement does not violate the anti-kickback statute. This exception may be used once only in a 3-year period for any given arrangement. Finally, the exception does not apply to arrangements previously exempt under the $300 non-monetary exception or the medical staff incidental benefits exception.

Ownership or Investment Interests

Options, Convertible Securities and Secured Loans

The Phase II regulations offer clarifications regarding stock options and convertible securities which have the potential to cause some existing transactions involving such securities to be treated as ownership interests rather than compensation and, thus, affect available exceptions. In defining what constitutes a financial relationship, the Phase II regulations partially reverse CMS’s previous position with respect to the treatment of stock options and other convertible securities. Previously, stock options and convertible securities were deemed to create a compensation arrangement rather than an ownership interest. Under the Phase II regulations, if stock options or other convertible securities are originally purchased or received for money or in return for a capital contribution in whole or in part, those securities will represent ownership interests. If, however, those securities are received as compensation for services rendered, they will be treated as compensation until such time as they are exercised or converted, at which time they will become ownership interests.

In addition, loans that are secured by the assets or revenues of a DHS provider are typically deemed to be an ownership interest. In the regulations, CMS has clarified that a loan secured by only a particular piece of equipment or revenues of a particular department should not be considered an ownership interest in the DHS provider as a whole; thus, the whole hospital exception would not apply.

Timing of Availability to the Public

The publicly traded securities exception creates an exception for self-referrals of DHS by physicians to certain publicly traded entities. To qualify for the exception, the securities must be purchased on terms generally available to the public, the securities must be listed on a national or regional exchange, and the entity providing the DHS must have had stockholders’ equity exceeding $75 million at the end of its most recent fiscal year or on average during the previous three fiscal years. There is also a similar exception for mutual funds, which was unchanged by the Phase II regulations.

In response to comments, CMS reconsidered its prior position on the time at which it is determined whether securities meet these standards. The new position is that the securities must be generally available to the public at the time of the DHS referral. This new interpretation will allow physicians to maintain investments in DHS providers while they are privately held, as long as the investing physician does not make referrals until after the DHS provider becomes publicly traded and meets the other requirements.

Under the prior regulations, publicly traded companies would have been required to report all financial relationships that met the exception. Responding to comments that this reporting requirement was unduly burdensome on the publicly traded company, CMS eliminated the requirement in the Phase II regulations.

Specialty Hospitals

The Stark Law provides special exceptions for ownership interests in three types of providers: hospitals in Puerto Rico, rural providers, and ownership in other hospitals. In Phase II, CMS conformed to requirements in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 by implementing, subject to certain grandfathering provisions, an 18-month moratorium on referrals to certain so-called “specialty hospitals” beginning December 8, 2003. Unfortunately, the new regulations do not provide any additional insight into the moratorium. For example, the Phase II regulations do not define the standard as to whether a hospital is “primarily or exclusively engaged in the care and treatment of” certain specialties and, therefore, a specialty hospital.

Physician Compensation

The Phase II regulations give considerable attention to physician compensation arrangements, the highlights of which are as follows.

Indirect Compensation Arrangements and Exception

The Phase II regulations maintain the complex and confusing interrelationships of indirect compensation arrangements and the indirect compensation exception. Specifically, notwithstanding the general beneficial treatment of time-based or unit-of-service compensation arrangements (see the discussion regarding “set in advance” below), the Phase II regulations continue the approach of causing such relationships to result in indirect compensation arrangements, only to then exempt such arrangements under the indirect compensation exception.

In particular, the Phase II regulations focus on aggregate compensation in determining whether an indirect compensation
arrangement exists. If a physician’s aggregate compensation varies in any manner based upon the volume or value of referrals, including time-based or unit-of-service compensation, then the arrangement could be an indirect compensation arrangement. At the same time, however, if the time-based or unit-of-service compensation the physician receives represents fair market value (i.e., the unit is at fair market value and does reflect the volume or value of referrals), then the indirect compensation exception may apply. This is because the indirect compensation exception does not include the “aggregate” requirement. CMS admits that even though the result would be the same if such arrangements were deemed not to be indirect compensation arrangements, this is the approach the Phase II regulations take.

Specific Compensation Exceptions – Generally

The Phase II regulations devote significant time to discussing the differences among the various exceptions applicable to a physician’s compensation, whether as a member of a group practice, an employee, under a service arrangement, as part of an academic medical center (“AMC”) or generally under a fair market value arrangement. Many commenters were confused as to which standards apply to these categories of compensation relationships. Most notably, the Phase II regulations use of the following table to clarify which requirements apply to each category of relationship.

<table>
<thead>
<tr>
<th>Comp must be fair market value</th>
<th>Group Practice Physicians</th>
<th>Bona Fide Employment</th>
<th>Personal Service Arrangements</th>
<th>Fair Market Value</th>
<th>Academic Medical Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comp must be set in advance</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Scope of volume or value restriction</td>
<td>DHS referrals</td>
<td>DHS referrals</td>
<td>DHS referrals or other business</td>
<td>DHS referrals or other business</td>
<td>DHS referrals or other business</td>
</tr>
<tr>
<td>Scope of productivity bonuses allowed</td>
<td>Personally performed services and incident to, plus indirect</td>
<td>Personally performed services</td>
<td>Personally performed services</td>
<td>Personally performed services</td>
<td>Personally performed services</td>
</tr>
<tr>
<td>Are overall profit shares allowed?</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Written agreement required?</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes (except for employment)</td>
<td>Yes</td>
</tr>
<tr>
<td>Physician incentive plan exception for services to enrollees?</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

With respect to the specific criteria in the chart, the Phase II regulations provide the following clarifications.

**Fair Market Value.** The Phase II regulations create a “safe harbor” for establishing that hourly compensation paid to a physician for services personally performed is consistent with fair market value. Hourly compensation will be considered fair market value if: (1) the hourly rate is less than, or equal to, the average hourly rate for emergency room physician services in the relevant market provided that there are at least three hospitals providing emergency room services in that market; or (2) the hourly rate is determined by averaging the 50th percentile national compensation level for physicians in the same specialty as the one at issue, using at least four delineated surveys, then dividing the compensation by 2,000 hours. The delineated surveys are: Sullivan, Cotter & Associates – Physician Compensation and Productivity Survey; Hay Group – Physician Compensation Survey; Hospital and Healthcare Compensation Services – Physician Salary Survey Report; Medical Group Management Association – Physician Compensation and Productivity Survey; ECS Watson Wyatt – Hospital and Health Care Management Compensation Report; and William M. Mercer – Integrated Health Networks Compensation Survey.

**Set in Advance.** The Phase II regulations clarify which exceptions require that compensation be set in advance. With respect to the exceptions that include the set in advance requirement, the regulations permit certain percentage-based compensation arrangements. Physician compensation will be deemed “set in advance” if it includes a specific formula for calculating compensation in a written agreement before services are rendered, and the formula is not changed during the course of the agreement in any manner that reflects the

**Other Business.** A number of the exceptions include the requirement that compensation not vary based on the volume or value of referrals or other business generated. In the Phase II regulations, CMS has clarified that “other business” does
not include personally performed services. In addition, in Phase I, CMS proposed to add the further limitation in the employment exception that compensation not vary based on the volume or value of “other business” generated. CMS backtracked in the Phase II regulations and has deleted this further limitation.

**Volume or Value Standards – Productivity Bonuses.** CMS acknowledges the difficulty in having varying exception criteria that apply to physician compensation arrangements. For example, prior to the Phase II regulations, productivity bonuses were expressly permitted for employed physicians but were not for independent contractors. CMS made two revisions that enable the personal services, employee, AMC and fair market value exceptions to be more uniform and allow entities greater flexibility in compensating physicians for services. The first is the clarification on the “set in advance” standard (see above). Second, consistent with the Phase I regulations, CMS permits productivity bonuses under the bona fide employment, fair market value, personal services and AMC exceptions based on personally performed services, even if the physician’s service rendered was a self-referral. This is the case because any personally performed service is not a “referral” even if the service performed is a DHS. There remain, however, certain limitations to the productivity bonus calculation. For example, the bonus for employees or independent contractors may not include “incident to” services. CMS recognizes that this is more restrictive than what is allowed for group practices; however, the statute prohibits CMS from equalizing these provisions. Additionally, supervision is not a “personally performed” service to be considered in the productivity bonus calculation. CMS is concerned that calling “supervision” a personal service may be a proxy payment for having generated the DHS being supervised.

**Mandatory Referrals.** CMS was clear in Phase I that mandating referrals from employed physicians did not violate the “volume or value” standard if certain criteria are met (e.g., the requirement to refer did not apply if the patient expressed a different preference or the referral was not in the physician’s best medical judgment). Phase II clarifies that mandatory referrals are permissible from not only employed physicians but contracted physicians as well. The preamble, however, states that these required referrals are under “limited circumstances” and the regulation further limits the mandatory referrals by requiring that: (1) the referrals relate solely to the physician’s services covered by the scope of the written agreement for professional services; and (2) the referral requirement be reasonably necessary to effectuate a legitimate purpose. The following two examples of mandated referral patterns would not be considered a legitimate purpose. A hospital may not employ a physician on a part-time basis and mandate referrals from the physician during the non-employed time – thus from the physician’s private practice. Moreover, a hospital should not employ anesthesiologists and require their referrals for pain management services to the hospital outpatient department because the pain services may be deemed unrelated to the scope of contracted for anesthesiology services.

**In-Office Ancillary Services**

The Phase I regulations included significant discussion of the requirements for this exception. The Phase II regulations make few changes to Phase I, with the following notable exceptions.

**Same Building.** Many commenters criticized the Phase I regulations’ three-part test for determining if a physician furnishes services unrelated to the furnishing of DHS in the same building. In response, CMS has developed a test that requires a physician to meet one of three requirements:

1. The building is one in which the referring physician or his or her group practice has an office that is normally open to patients at least 35 hours per week, and the referring physician or one or more members of the group practice regularly practices medicine and furnishes physicians services to patients in that office at least 30 hours per week.
2. The building is one in which the referring physician or his or her group practice has an office that is normally open to patients at least 8 hours per week, and the referring physician regularly practices medicine and furnishes physicians services to patients in that office at least 6 hours per week.
3. The building is one in which the referring physician or his or her group practice has an office that is normally open to patients at least 8 hours per week, and the referring physician or a member of the group practice regularly practices medicine and furnishes physicians services to patients in that office at least 6 hours per week.

In addition, CMS defines “physician services unrelated to the furnishing of DHS” to mean physician services that are neither federal nor private pay DHS. Providing reads and interpretations of diagnostic tests do not satisfy this definition. Finally, while CMS refused to allow mobile services to satisfy the same building requirement, CMS did revise the regulations so that physicians may purchase the technical component of
mobile services and bill for such services as purchased diagnostic services.

**Primary Purpose.** Phase II continues the requirement that an entity be organized primarily for the purpose of operating a group practice. As a result, a hospital’s employment of physicians within the corporate entity of the hospital, as opposed to in a separate subsidiary formed for such purpose, will not constitute a group practice.

**Unified Business.** Phase II eliminates the requirement that a group practice have centralized utilization review.

**Bona Fide Employment Exception**
The Phase II regulations clarify that payments to “leased” employees may fit within the employee exception provided that the “leased” employee meets the IRS’s rules defining what constitutes an employee.

Employed hospital-based contracts may include exclusivity provisions and covenants not to compete without violating the volume or value standard, provided the hospital pays fair market value for these terms.

Payments to employed physicians must be for services rendered and may not incentivize physicians to meet hospital or drug utilization targets. These types of incentives are precluded as gainsharing arrangements and are only permitted through risk-sharing arrangements and physician incentive plan provisions of the personal services exception.

**Personal Services Exception**
Hospitals may now terminate an independent contractor arrangement without cause and still meet the personal services exception provided the parties do not enter into the same or substantially the same contract within the first year of the original term.

Parties no longer have to cite all other agreements between the parties within each agreement. It is permissible to maintain a master list of contracts to be made available to the Secretary of Health and Human Services, upon request. This master list may be one (e.g., maintained by in-house counsel) or several lists (e.g., a list of contracts maintained by each department chair), provided each list cross-refers to the other lists.

Physicians providing personal services and equipment to hospitals (e.g., pulmonologist furnishing services and equipment related to a sleep apnea clinic) need only have one agreement that encompasses both the services and the equipment given the similarity in the exceptions. However, CMS will analyze the fair market value of the services and the equipment separately.

Finally, many commenters requested that CMS recognize that “foundation model” organizations can qualify as group practices. Despite the apparent application of the indirect compensation arrangement definition and exception to most foundation model arrangements, CMS states that the personal services exception should apply to protect these arrangements.

**Physician Recruitment**

Substantial revisions to the physician recruitment exception should assist hospitals, federally-qualified health centers (“FQHCs”) and physicians in structuring and implementing recruitment arrangements including income guarantees. The Phase II regulations provide additional clarity and guidance regarding the geographical area where the recruited physician must relocate from (and relocate to), the recruitment of residents and physicians in practice one year or less and already in the geographical area, and the use of existing or host physician groups to recruit and retain the recruited physicians. In addition, CMS added a new exception for certain retention payments made to physicians with practices in health professional shortage areas (“HPSAs”) to retain sufficient numbers of qualified physicians in such communities.

The physician recruitment exception permits hospitals and FQHCs to provide financial assistance directly to a physician as long as it is intended to induce the physician to relocate his or her individual practice to the geographic area served by the hospital and in order for the recruited physician to become a member of the hospital’s medical staff. The physician recruitment exception also requires the arrangement be set forth in writing and signed by both parties, that it not be conditioned on the physician’s referral of patients to the hospital, nor may the hospital determine (directly or indirectly) the amount of financial assistance to be provided to the physician based on the volume or value of actual or anticipated referrals by the physician or other business generated between the parties. Additionally, the physician must be allowed to establish staff privileges at other hospital(s) and refer business to such entities. However, referrals to other entities may be restricted under a separate employment or services agreement that complies with such applicable Stark Law compensation arrangement exception. CMS recognizes in the Phase II commentary that hospitals may use reasonable credentialing restrictions on physicians becoming competitors of a hospital.

**Relocation**

To address the statutory “relocation” requirement, which CMS cites as an important safeguard against abusive financial incentives disguised as “recruitment” payments, the Phase II regulations clarify that the recruited physician’s practice location, not his or her residence, should be the relevant consideration. CMS also states that recruitment assistance is...
intended to be provided to physicians who will become members of the hospital’s medical staff and relocate their practice to the geographical area served by the hospital. In an effort to establish a bright line rule, “geographic area served by the hospital” is now defined as the area composed of the lowest number of contiguous zip codes from which the recruiting hospital draws 75 percent of its inpatients. For some hospitals, this new definition may limit recruitment activities in certain parts of a hospital’s primary and/or secondary service areas.

The recruited physician will be considered to have relocated his or her medical practice from outside the hospital’s area if one of two scenarios is met. The relocation test may be met by moving the practice a minimum distance of 25 miles or by establishing a practice with a substantial base of new patients (75 percent of the physicians’ revenues from professional services provided to patients in the relocated practice). This latter scenario will permit recruitment of physicians relocating less than 25 miles under certain circumstances. For the initial “start-up” year of the recruited physician’s practice, the 75 percent test referenced above will be met if there is a reasonable expectation that the recruited physician’s individual practice for the upcoming year will derive at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior practice site during the preceding three years.

New Physician

Hospital residents and physicians who have been in practice one year or less will not be subject to the relocation requirement because CMS recognizes that these physicians do not have established practices to relocate. Under the proposed fair market value exception, CMS previously recognized that hospital residents could be recruited to “stay” in the community if the fair market value exception was met. CMS now states that recruitment payments to community or other local physicians who do not meet the relocation requirement, as described above, will not fit in the fair market value exception. The resident or physician who has been in practice for one year or less would still need to establish his or her medical practice in the geographical area served by the hospital, however.

Recruitment to Existing Group

CMS also recognized that many new or relocating physicians prefer to join existing or host practices in the hospital’s community rather than set up a new practice due to cost, cross-coverage and professional development issues. In an attempt to balance this practice with CMS’s concern that direct or indirect payments to an existing group might create an improper financial arrangement (i.e., payment for referrals from the existing group), a new exception has been promulgated. Financial assistance provided by a hospital or FQHC to a physician indirectly through payments to another physician or physician group will be an excepted compensation arrangement if several criteria are met in addition to the criteria stated above for payments made directly to the recruited physician.

The primary criteria for this new exception is that other than actual costs incurred by the physician group or physician recruiting the new physician, the financial assistance is passed directly through to, or remains with, the recruited physician. Moreover, when using income guarantees, the new regulation restricts financial assistance to only the actual additional incremental costs the physician group incurs that are attributable to the recruited physician. Although many hospitals historically followed the actual additional incremental cost approach in providing income guarantee arrangements to physician groups, the new regulation definitively requires this approach to addressing practice expenses especially in the more difficult areas such as rent, staff and other similar expenses where the group practice allocates expenses on a per-physician basis. Clearly, such practice expenses will only be recognized under the recruitment arrangement if incurred solely because of the addition of the new physician.

Additionally, the Phase II regulations restrict the existing group from imposing additional practice restrictions on the recruited physician (i.e., a non-compete). Historically, where non-competes did exist to protect a group’s legitimate business interests, and the recruited physician terminated his or her relationship with the group, hospitals would then otherwise require the group to repay the financial assistance to the hospital. However, this new prohibition is a broad threshold restriction difficult to structure around.

Due to the expansion of the physician recruitment exception in the area of assistance provided to existing groups, CMS unfortunately believed it necessary to add the additional requirement that the “arrangement does not violate the anti-kickback statute,” which moves the exception further away from the bright line criteria hospitals and physicians expected, especially given that the recruitment safe harbor under the anti-kickback statute is very narrow.

Leases

CMS modified the lease exceptions to permit termination of the lease without cause, provided that the parties do not enter into another lease arrangement for the same space or equipment during the first year of the initial term. The
regulations also allow space subleases if the sublease meets the lease exception criteria. Prior to the Phase II regulations, CMS interpreted the “exclusive use” criterion to mean the exclusive use of the space by the lessee and no one else. To avoid potential abuse by the new sublease expansion, CMS required that the space be used exclusively by the lessee (or sublessee), and the space cannot be concurrently used by the physician-lessee or any affiliated-physician entity (e.g., physician-formed real estate holding company). Finally, it is permissible to have month-to-month holdover rentals for up to six months after a compliant lease expires provided the holdover terms are the same as the underlying lease.

**Isolated Transactions**

Entities entering into isolated transactions, such as purchasing physician practices or a medical office building from a physician, create compensation relationships that must meet an exception if the physician will continue to refer Medicare patients to the entity for DHS. If such transactions involve a hospital and a group practice, one should look to the indirect compensation exception. However, if a solo physician practice or sole owner of purchased space is at issue, parties may now rely on the isolated transaction exception even if installment payments are used provided that the aggregate compensation is: (1) set in advance before the first payment is made; (2) the amount does not take into account the volume or value of referrals; and (3) the balance is guaranteed by a secured note or guaranteed third party. This last criterion ensures that the physician receives the guaranteed payment regardless of future referrals to the purchaser.

**AMC Exception**

Commenters made it clear that the Phase I AMC exception, while a step in the right direction, did not go far enough to protect common, albeit complex, financial arrangements among AMC components. Despite some liberalization in the Phase II regulations, it remains true that the indirect compensation exception may provide greater protection for the varied financial arrangements than does the AMC exception.

Most of the comments requested broader protection for compensation arrangements to physicians, e.g., percentage-based compensation arrangements. CMS made these changes as discussed above, but made other changes specific to AMC exception, which are discussed below.

In general, remuneration flowing among component parts of AMCs (e.g., subsidizations of faculty practice plans (“FPP”)) will not preclude referrals of DHS to the hospital AMC component provided the AMC exception (or indirect compensation arrangement exception) is met. The AMC exception requires that the AMC be comprised of component parts as defined in the regulation, and the referring physician and the physician compensation meet certain enumerated criteria.

**AMC Definition**

CMS altered the definition of an AMC by removing the requirement that it have an accredited medical school as a component. Rather, an AMC may include either a medical school or a hospital or health system that sponsors four or more approved medical education programs – known as an “accredited academic hospital.” The accredited academic hospital and the AMC affiliated hospital may be one in the same.

An AMC must still include an FPP, but that FPP need not be a tax-exempt entity (so a professional corporation is permissible). Moreover, AMCs may now have more than one FPP, and the FPP may be affiliated with the hospital and not medical school.

A not-for-profit supporting organization with the primary purpose of supporting the teaching mission of the AMC also may be considered an AMC component. Thus, transfers of funds from a foundation to a FPP implicate the Stark Law because this could be indirect remuneration to physicians who refer to the hospital component of the AMC. However, now that a support organization is expressly included as an AMC component, it is more clear that referrals may be protected if all of the AMC exception criteria are met, even with foundation support to FPPs.

AMC affiliated hospitals are still required to have a majority of the physicians on its medical staff be faculty members and a majority of all hospital admissions be made from these physician/faculty members. There were numerous objections to this criterion, but CMS responded that because the AMC exception is so broad, “it is important to ensure that the relationship between the components is sufficiently focused on the AMC’s core mission” and that “the tests for affiliated hospital faculty and admissions . . . are strong indicators of that core relationship.” In reaching the threshold that a majority of the hospital’s medical staff be medical school faculty, CMS is allowing hospitals to include courtesy and volunteer faculty from any affiliated medical school or accredited academic hospital. Residents and non-physician professionals do not need to be included as medical staff.

**Referring Physician**

The referring physician must be a bona fide employee of any component of the AMC (i.e., not necessarily an employee of
the medical school). The physician must provide either “substantial academic services or substantial clinical teaching services” for which the physician is paid as an employee of an AMC component. Rather than providing the requested bright line test for determining the “substantial” portion of the criterion, CMS included a “safe harbor” providing that physicians who spend at least 20 percent of their professional time, or eight hours per week, providing academic services or clinical teaching services (or a combination thereof) will meet the “substantial” threshold. As with the anti-kickback law’s safe harbors, failure to meet this 20% or eight hour test does not preclude a physician from qualifying under the AMC exception. Rather, the parties must have other documentation showing that the substantial criterion is met.

Other AMC Criteria
The relationship among the AMC components must be in writing, in a form that has been adopted by the governing body of each component. This does not mean that the entire affiliation must be set forth in one document. Rather, the affiliation could include various agreements (e.g., administrative and teaching agreements, staffing agreements, medical directorship/department chair agreements) as well as policies or other documents that establish a course of conduct supporting the affiliation of the components. If the AMC is one legal entity, financial reports documenting transfers of funds will be sufficient.

Physicians Purchasing Items and Services from DHS Entities
This fairly simple exception permits payments by physicians for clinical laboratory services or to DHS entities for items and services, provided that the payment is consistent with fair market value. This exception applies only when no other exception is available. CMS is concerned that a broader application of this exception would usurp the protections of the other compensation exceptions. For example, physicians leasing space from a hospital must meet the lease exception, and thus the exclusivity provision rather than simply making the rental payments fair market value.

Arrangements Unrelated to DHS
The Phase II regulations take an extremely narrow view of the unrelated to the provision of DHS exception. The exception is available for arrangements that in no way take DHS into consideration. An arrangement is deemed to take DHS into consideration if it involves an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles, is furnished directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals, or otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

Incidental Medical Staff Benefits
CMS modified this exception to provide that the benefit need not be provided to the entire medical staff, but instead could be provided to all members of the medical staff practicing in the same specialty.

New Regulatory Exceptions
The following new exceptions are set forth in the Phase II regulations:

Professional Courtesy Exception. CMS promulgated a new professional courtesy discount exception to permit an entity, such as a hospital or physician group practice, to provide free or discounted health care items or services to a physician or his or her immediate family members or office staff. Specifically, the courtesy must meet the following requirements:

1. It must be offered to all physicians on the medical staff without regard to their referrals or other business;
2. It must be on routinely offered items or services;
3. There must be a written policy setting out the courtesy that is approved by the entity’s governing body;
4. The courtesy is not offered to federal health program beneficiaries unless there is a good faith showing of financial need;
5. If the courtesy involves a reduction in commercial coinsurance, the insurer is informed of such in writing; and
6. The arrangement does not violate the anti-kickback law.

Charitable Donations by a Physician. Bona fide charitable donations by a physician to a tax-exempt entity are protected if the donation is not solicited or made based on the volume or value of referrals or other business and the arrangement does not violate the anti-kickback law.

Community-Wide Information Systems. An entity may provide information technology items or services to a physician that enable the physician to access and share electronic health care information and records. The technology must be provided to the physician to enable him or her to participate in a community-wide health information system, they must be offered in a manner that does not take into account the volume
or value of referrals or other business generated by the physician, the technology must be provided to all providers who desire to participate in the network, and the arrangement must not violate the anti-kickback law. In addition, the entity may not provide items and services above and beyond those which are necessary to enable the physician to participate in the health information system.

**Referral Services.** CMS has incorporated the safe harbor under the anti-kickback statute for referral services into a new Stark Law exception. Referral services that meet the safe harbor conditions are protected. Among the conditions, the referral service may not be exclusionary. In addition, the referral service must make certain disclosures related to the relationship between the physician participant and the service, as well as the selection process of the referral service.

**OB Malpractice Subsidies.** As with the exception for referral services, CMS has incorporated the safe harbor under the anti-kickback statute for obstetrics malpractice insurance subsidies into a new exception under the Stark Law. This exception is limited, as it applies only to obstetrical services provided in a primary care HPSA. There are several conditions which must be met under the exception. Most notably, the practitioner must certify that he or she has a reasonable basis for believing that at least 75% of the obstetrical patients treated under the coverage of the malpractice insurance will either reside in a HPSA or a medically underserved area, or be part of a medically underserved population.

**Retention Payments in Underserved Areas.** CMS also created a new exception for retention payments made to a physician with a practice located in a HPSA (regardless of whether the HPSA is specifically designated for the physician’s particular specialty) to retain the physician in the community and assist in defeating another hospital’s or FQHC’s attempt to lure him or her away. In addition to the HPSA requirement, the physician must have a firm written recruitment offer from an unrelated hospital or FQHC that specifies the remuneration being offered and that would require the physician to move his or her practice at least 25 miles and outside of the geographic area served by the hospital or FQHC making the retention payment. With the written recruitment offer, the regulation then requires hospitals and FQHCs address and ensure they limit the retention payment to the lower of: (1) the difference between the physician’s current income and the income he or she would receive in the recruitment offer or (2) the reasonable amounts that the hospital or FQHC would otherwise need to expend to recruit a new physician to the community. A hospital or FQHC may not enter into a retention arrangement with a physician more frequently than once every five years, and the new exception does not protect payments made indirectly to a retained physician through a group practice.

CMS similarly recognizes a legitimate need for retention payments to physicians in areas outside a HPSA that are otherwise underserved by health care professionals or areas serving underserved patient populations; however, CMS will only permit retention arrangements in such areas on a case-by-case basis through their advisory opinion process. CMS expects to approve retention payments in advisory opinions only in unusual and compelling circumstances, especially given the potential implication of and need to comply with the anti-kickback statute.

**Intra-Family Rural Referrals.** A new exception has been added that protects both investment interests and compensation arrangements related to intra-family referrals in rural areas. Specifically, a physician may refer a patient to an entity in which his or her immediate family member has a financial relationship if the patient being referred resides in a rural area and there are no other available providers or suppliers of the DHS in the area able to furnish the DHS in a timely manner in light of the patient’s condition. Generally, this will mean that there is no in-home services provider or other provider available within 25 miles of the patient’s residence. In addition, the referring physician or his or her immediate family member must make reasonable inquiries as to the availability of other DHS providers, and in making a determination as to the availability thereof, quality is not a factor to be considered. CMS indicates that reasonable inquiries involve consulting telephone directories, professional associations, known providers or Internet resources. Finally, the relationship must not violate the anti-kickback statute.