HOW TO GET MORE REFERRALS WITHOUT BREAKING THE LAW

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Description

The market for post-acute services is highly competitive. Fierce competition has created enormous stress and tension for providers. Competition among post-acute providers has also raised a number of crucial questions such as: How can providers comply with requirements related to patients’ right to freedom of choice of providers? Can doctors write orders for specific providers? Can hospitals decide that they will work with only certain providers? What about taking lunches to physicians’ offices? The purpose of this presentation is to assist providers to understand legal requirements, including the anti-kickback statute, the Stark laws, regulatory requirements regarding patients’ right to freedom of choice and antitrust laws. The emphasis will be on practical strategies to increase referrals within the limits of the law.

Outline

I. Legal issues related to referrals.
   A. Fraud and abuse.
      1. False claims.
      2. Kickbacks and rebates.
   B. Patients’ right to freedom of choice of providers.
      1. Sources.
         a. Common law.
         b. Federal statutes.
         d. Hospital Conditions of Participation.
         e. Case law.
2. Practical application to marketing home care services.

C. Stark Laws.

1. Referrals.

2. Items of nominal value.

II. Strategies to use to increase referrals.

A. Use of coordinators/liaisons.

B. Space rental.

C. Use of preferred providers.

D. Consulting physician/medical director agreements.

E. Items of nominal value.

F. Marketing to patients/families.

Objectives

1. List three (3) requirements of the Balanced Budget Act of 1997 (BBA) related to referrals.

2. Describe the legal basis for patients' right to freedom of choice of providers.

3. Identify three (3) criteria that must be met when items of nominal value are given to physicians and other referral sources, including patients.
PHASE I STARK RULES: NON-MONETARY COMPENSATION UP TO $300.00 TO PHYSICIANS

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Providers may give physicians and/or their immediate family members noncash items that have a relatively low value and are not part of a formal, written agreement. Staff may, for example, provide lunch or snacks, such as cookies, to physicians and their personnel at their offices. Providers have also routinely left items of limited value such as coffee mugs, pens, and notepads at physicians’ offices. Managers have questioned, however, whether such items are legally acceptable.

There are two (2) areas of the law that must be considered when addressing this issue:

1) Prohibitions against illegal remuneration or kickbacks and rebates and

2) Provisions of the so-called Stark laws.

Phase I of final regulations under the Stark laws were published several years ago. These regulations directly address this issue. Specifically, the regulations indicate that free items of relatively low value are unlikely to cause overutilization if provided within reasonable limits. The regulations further state that such nonmonetary compensation will not violate the Stark laws as long as all of the following criteria are met:

- The annual aggregate value of nonmonetary gifts to a physician does not exceed $300.00.
- Providers that provide nonmonetary compensation to physicians make it available to all similarly situated physicians, regardless of whether physicians refer patients to the company for services.
- The compensation is not determined in any way that takes into account the volume or value of a physician’s referrals to the supplier.

Thus, it is now clear that agencies that meet these criteria for nonmonetary compensation can avoid violation of the Stark laws.

Providers should, however, also be aware of the following limitations:

- Protection from violations of the Stark laws is not available for gifts that are solicited by physicians or group practices. The reason for this
limitation is to prevent physicians from making such gifts a condition or expectation of doing business.

The “classic” example of solicitation of gifts is insistence by physicians that they will only meet with staff to discuss patients receiving services, etc; if staff supply lunch. Such requirements may amount to solicitation that will preclude protection for companies that supply lunch under these circumstances.

The exception for non-monetary compensation up to $300.00 only protects gifts to individual physicians. Thus, gifts given to a group practice will not qualify for this exception. Noncash gifts could, however, be given to one member, several individual members, or each member of a group practice if each such gift meets all of the conditions of the exception for non-monetary compensation up to $300.00. The exception does not apply to gifts, such as holiday parties, office equipment, or supplies that are valued at not more than $300.00 per physician in the group, but are, in effect, given or used as a group gift.

When providers comply with the above requirements and avoid these limitations, they may gain protection from allegations that they violated the Stark laws in order to encourage referrals from physicians.

Providers must bear in mind, however, that the federal statute that prohibits illegal remuneration or kickbacks and rebates also applies to the issue of nonmonetary compensation to physicians who make referrals. This federal statute generally prohibits anyone from offering to give or actually giving anything to referral sources in order to induce them to make referrals. At least in theory, providers could comply with the requirements of the Stark laws regarding nonmonetary compensation to physicians, but still violate the kickback and rebate statute through their use of nonmonetary gifts to physician referral sources.

At this point, however, it seems unlikely that the Office of the Inspector General (OIG) of the U. S. Department of Health and Human Services (HHS), the primary enforcer of fraud and abuse prohibitions, will conclude that providers provided kickbacks and rebates to physicians, if the requirements of the Stark regulations as described above are met. In others words, compliance with the requirements of the new final Stark regulations will probably provide protection to providers with regard to all nonmonetary compensation provided to physicians. Stay tuned for more guidance on these issues.

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Discharge planners, case managers, and social workers certainly cannot accept cash payments from providers in exchange for referrals of patients. But what can they accept from providers who want referrals? What about non-cash items that have a relatively low value? What about acceptance of referrals to provide services in the evenings and on weekends on behalf of providers who receive referrals from discharge planners/case managers?

The key area that must be considered to answer these questions involves a federal statute that prohibits illegal remuneration or kickbacks in the Medicare and Medicaid and other federal and state health care programs. This federal statute makes it a crime for providers to offer to give or actually give anything to anyone in order to induce referrals.

Providers who are not Medicare-certified or do not participate in the Medicare program, such as so-called "private" providers, may be tempted to ignore this statute. Providers must remember that the fraud and abuse prohibitions also apply to companies that participate in Medicaid programs, including Medicaid waiver programs, as well as other federal and state health care programs, such as Tri-Care.

In addition, even if providers who want referrals do not accept payments from any federal or state health care programs, the case managers, discharge planners, and social workers who make referrals often work for organizations that do. They must comply, therefore, with fraud and abuse prohibitions and providers of all types should assist them to do so.

Case managers and providers who violate this federal statute may be guilty of criminal conduct and may go to jail or be forced to pay large amounts of money in the form of fines or civil monetary penalties. They may also be excluded from participation in the Medicare/ Medicaid and other state and federal health care programs. Licensed case managers also face loss of licensure.

The Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services, the primary enforcer of fraud and abuse prohibitions, has stated that regulations will be published that will help to define what items of nonmonetary value may be accepted from providers who receive referrals.
Until specific guidance on these issues is provided by the OIG, providers and case managers may be wise to apply final regulations under the Stark laws, even though the Stark laws technically apply only to physicians.

Specifically, the Stark regulations indicate that free items of low monetary value are unlikely to cause overutilization, if provided within reasonable limits. The regulations further state that as long as all of the following criteria are met, such non-monetary compensation will not violate the Stark laws:

- The annual aggregate value of nonmonetary gifts does not exceed $300.00.
- Providers that give nonmonetary compensation must make it available to those similarly situated, regardless of whether they refer patients to the provider for services.
- The compensation is not determined in any way that takes into account the volume or value of referrals to the provider.

Providers and case managers should also be aware of the following limitations under the Stark laws:

- Protection from violations of the Stark laws is not available for gifts that are solicited.
- The exception for non-monetary compensation up to $300.00 only protects gifts to individuals.

At least in theory, providers and case managers could comply with the requirements of the Stark laws regarding non-monetary compensation to physicians, but still violate the kickback statute described above.

It seems unlikely, however, that the OIG will conclude that case managers received kickbacks and rebates if the requirements of the Stark regulations described above are met. In other words, compliance with the requirements of the final Stark regulations may provide protection to case managers and providers with regard to non-monetary compensation received from providers by case managers, even though they may not technically apply.

Providers and case managers should, of course, monitor developments in this area; especially since the OIG has stated that specific regulations that apply to all practitioners will be published in the near future.

What about discharge planners/case managers who “moonlight” for post-acute providers in the evenings and/or weekends? Can they provide services to patients who they referred in their role as hospital discharge planners?
When discharge planners/case managers provide services to patients they referred to post acute providers in their “day job” as discharge planners, they are likely engaging in prohibited cross referral arrangements that also violate the anti-kickback statute described above.

According to the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services, the primary enforcer of fraud and abuse prohibitions, cross referral arrangements can best be described as relationships in which providers agree to refer patients to another provider in return for an agreement on the part of the provider receiving the referral to refer the patient back at a certain time or under certain circumstances. In other words, a cross referral arrangement is one in which providers agree as follows: “You send me your patients and I’ll send you mine.”

When “moonlighting” discharge planners are paid per visit for their services by post-acute providers for services provided to patients they referred, the OIG is likely to be extremely concerned. The more patients discharge planners refer to post-acute providers, the more money they make when they provide services to these same patients on a per visit basis.

The temptations are many but there is a great deal to be lost!

[More information about this topic is available in a book entitled *Medicare/Medicaid Fraud and Abuse: A Practical Guide for Providers*. To obtain a copy of this book, send a check for $30.00 (that includes shipping and handling) made out to Elizabeth E. Hogue, Esq. to: Fulfillment, 107 Guilford, Summerville, SC 29483.]

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Fraud and Abuse in the Form of Free Discharge Planning Services

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Hospitals are required to provide discharge planning services. Case managers who provide these types of services and providers that receive referrals from hospitals must be aware of a possible type of fraud and abuse in the form of free discharge planning services.

Specifically, there is a federal statute that governs illegal remuneration in the Medicare, Medicaid and other federal and state health care programs. This statute is often called the "anti-kickback and rebate statute." It basically says that anyone who either offers to give or actually gives anything to anyone in order to induce a referral has engaged in criminal conduct.

Possible penalties for violation of this statute include imprisonment, fines, suspension and exclusion from participation in the Medicare, Medicaid and other state and federal health care programs and civil money penalties. So the stakes are extremely high.

The Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services is the primary enforcer of fraud and abuse prohibitions. The OIG stated in a Special Fraud Alert published in August, 1995, that the activities of coordinators and liaisons supplied by providers who want referrals cannot supplant the services of discharge planners. When coordinators and liaisons perform services that discharge planners are supposed to perform, it is a kickback or rebate to referral sources in the form of free discharge planning services.

Recently, discharge planners/case managers at hospitals and longterm care facilities seem to have increased interest in entering into written agreements with post-acute providers such as longterm care facilities, home care agencies, home medical equipment (HME) and hospices to provide coordinators and liaisons. Although written agreements for the provision of coordinators/liaisons are not required, they may be acceptable if appropriately drafted.

Specifically, these agreements must be drafted very carefully in order to avoid possible kickbacks and rebates. Below are some of the potential pitfalls of such agreements that should be avoided:

(1) Agreements should not require providers to keep a coordinator/liaison in the facility on a full-time basis unless the number of referrals clearly justifies the commitment of an employee for this amount of time. Otherwise, this requirement may reinforce the
likelihood that this arrangement will be viewed by the OIG as an impermissible kickback or rebate. If the liaisons/coordinators are not providing discharge planning services, there is no need for them to be on the premises on a full-time basis. Rather, an Agreement for legitimate coordinator/liaison activities would require them to be available to receive referrals on an as-needed basis only. If providers supply liaisons and coordinators under the proposed agreements on a full-time basis, but do not receive enough referrals to justify assignment of personnel on a full-time basis, it reinforces a conclusion that liaisons and coordinators are really supplying discharge planning services in exchange for referrals.

(2) Agreement for the provision of coordinators/liaisons should not require them to "develop" and/or "implement an appropriate discharge plan" or to document these activities in patients' charts. Medicare Conditions of Participation (COP's) for hospitals make it quite clear that it is the job of discharge planners to develop and implement appropriate discharge plans.

(3) Agreement for liaisons and coordinators should not include a requirement that they must be registered nurses (RN's). It is common practice in post-acute care industries to utilize coordinators and liaisons who are not licensed professionals who perform very effectively in these positions. A reasonable interpretation of this requirement is, therefore, that liaisons and coordinators must be RN's because they will in essence be providing discharge planning services.

(4) Discharge planners/case managers should not propose agreements for use of coordinators and liaisons that include indemnification provisions. If no free discharge planning services are being provided, there is no need for indemnification.

(5) Hospitals that elect to have written agreements with providers who supply coordinators and liaisons must also be careful to handle compliance with HIPAA privacy requirements appropriately. Specifically, providers who supply coordinators and liaisons should not be required to sign business associate agreements. The Standards of Privacy of Individually Identifiable Health Information generally define a business associate as an entity that performs a service on behalf of a covered entity. The OIG is likely to conclude that the services performed by providers as business associates on behalf of hospitals are discharge planning services.

The Standards and related materials also make it clear that providers who receive referrals from other providers are not business associates of referring providers. Such referrals, including information shared in order to make referrals, is part of treatment, payment and healthcare operations of covered entities that does not require consent of patients to disclose.

Providers are in the proverbial "hot seat" as the marketing activities of post-acute providers and enforcement activities by the OIG "heat up." They must be careful to keep up to date on these issues.
(To obtain more information about fraud and abuse in a book entitled Medicare/Medicaid Fraud and Abuse: A Practical Guide, send a check for $30.00 that includes shipping and handling made out to Elizabeth E. Hogue, Esq. to: Fulfillment, 107 Guilford, Summerville, SC  29483.)

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Providers are increasingly concerned that physicians may violate patients' right to freedom of choice of providers.

First, it is important to note that longterm care, home health, including some services provided by private duty agencies, home medical equipment (HME) and hospice services are provided under the supervision of physicians based upon specific orders from them. Because physicians supervise these types of services, they are at risk for legal liability, along with providers and staff members, if providers supervised by physicians do not meet applicable standards.

Consequently, physicians have a clear interest in assuring the quality of care rendered by other providers to their patients. Physicians may, therefore, choose to designate in their orders which providers will render services to their patients in order to help assure quality of care and manage their risks of liability.

Nonetheless, all providers, including physicians, are required to abide by patients' right to freedom of choice of providers. There are two (2) sources of this right that apply to physicians:

1) All patients have a common law right based upon court decisions to control the care provided to them, including who renders it. Thus, when patients, regardless of payor source or type of care, voluntarily express preferences for certain providers, their choices must be honored.

2) Federal statutes of the Medicare and Medicaid Programs guarantee Medicare beneficiaries and Medicaid recipients the right to freedom of choice of providers. (Medicaid recipients may have waived this right, if they participate in waiver programs.) Consequently, when Medicare patients and non-waiver Medicaid patients voluntarily express preferences for providers, these choices must be honored.

Consequently, physicians' orders based upon quality of care concerns for specific providers should be implemented unless patients express preferences to receive services from different providers.

If, however, patients voluntarily express preferences or choose providers other than providers ordered by their attending physicians, patients' choices "trump" physicians' orders and must be honored.
Physicians may then choose whether or not they wish to supervise services and assume the risk of services provided by providers different from those they ordered.

It is at this point that physicians and their office staff members must be especially cautious. If they try to "strong arm" patients into receiving services from providers physicians' prefer instead of providers chosen by patients, consent to such services may not be voluntary. Statements by physicians or their employees, for example, that the doctor will no longer care for them if they do not accept services from the provider the doctor ordered may amount to duress which invalidates any consent by patients to such services.

Attempts to force patients to accept physicians' choices have ethical implications as well. Patients' right to act autonomously may be compromised by the insistence of physicians or staff members.

From a very practical point of view, physicians who are serious about quality of care and sound risk management should talk to patients about their preferences for providers before they write orders for specific providers. Patients will then have an opportunity to understand physicians' preferences, to express their own choices and/or to resolve any differences between physicians and patients.

Discharge planners/case managers who encounter instances in which physicians and their employees put inappropriate pressure on patients to use providers chosen by physicians should carefully document violations of patients' right to freedom of choice. Documentation should preferably be in the form of signed statements from patients. These statements should be forwarded to physicians with a letter from providers/case managers. A word to the wise should be sufficient!

Practitioners who encounter physicians who persist in pressuring patients despite their letters and documentation from patients may wish to report violations to both the central and regional offices of the Centers for Medicare and Medicaid Services (CMS). Such reports should include documentation from patients.

The competition among post-acute providers continues to "heat up." The rights of patients, however, cannot be trampled despite fierce competition among providers.
Marketing strategies utilized by post-acute providers are generating fierce competition for referrals! As a result, providers are appropriately committing more and more resources to marketing their services.

Providers, for example, are entering into agreements with referring physicians to provide consulting services to their organizations. These legitimate relationships may be misunderstood by case managers/discharge planners so that they are in a quandary about whether it is legal or ethical to refer patients to providers who have these types of arrangements.

First, it is important to acknowledge that post-acute providers need consulting physicians’ services. Examples of services that are genuinely needed from a business perspective may include the following:

- Consultation regarding clinically complex cases;
- Assistance with the development and maintenance of specialty programs;
- Communication with physicians who provide inappropriate orders for care, do not return signed orders on time, or are unresponsive to staff members who are seeking modifications to treatment plans.

It is certainly appropriate for providers to establish consulting relationships with physicians who also make referrals to the providers with whom they have these types of arrangements.

Of course, these types of arrangements raise important legal issues related to potential violations of the federal anti-kickback and rebate statute, the federal so-called Stark laws, and state statutes that are likely to be similar to these federal statutes.

Providers are likely to avoid violations if they meet the requirements of the personal services and management contract “safe harbor” under the anti-kickback and rebate statute, and the contractual exception under the Stark laws. The safe harbor and exception generally require providers to pay consulting physicians who also make referrals to them based upon written agreements that require payments at fair market value for services actually rendered without regard to the volume or value of referrals received.
The Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) has recently started scrutinizing these types of relationships more carefully. So, from a practical point of view, providers should do the following in addition to meeting the requirements described above:

1. Providers should develop standardized or “form” agreements and use them consistently with all referring physicians who receive consulting fees from them. Providers cannot afford utilization of a variety of different agreements that may not meet the requirements described above. Staff must understand that they can use only the standard approved agreement and cannot modify it without advance written approval from a designated, knowledgeable individual.

2. Documentation of services rendered and the amount of time spent in these activities is absolutely crucial. Providers should develop and implement policies and procedures that permit payments to physicians only after appropriate documentation to support payments has been received and reviewed.

3. Providers should not have agreements for consulting services with physicians whose services they do not actually use, even if they make no payments to them. Providers should terminate the agreements if they do not need the services covered by the agreements. Otherwise, it may appear that the only purpose for the agreements is to induce referrals, as opposed to a documented need for services.

4. Although there are technically no limits on the number of consulting physicians/medical directors providers can have at any given time, a very large number is likely to invite scrutiny by regulators and should be avoided. How many is too many? The number should certainly bear some relationship to the size of the provider organization and the geographic area served. Beyond this general guideline, common sense must prevail. The “bottom line” is: Does the Agency have legitimate work for every consulting physician?

5. The commercially reasonable services consulting physicians are asked by providers to perform cannot be related to the volume and value of referrals made. Providers cannot, for example, ask referring physicians to assist with quality assurance activities that entail review by consulting physicians of the charts of patients they referred to the provider so that the more referrals made, the more money consulting physicians make.

Providers are more likely to avoid enforcement activities when they follow these practical guidelines. Violations hurt providers and referral sources alike. Expenditures of financial and other resources are certainly justified in view of the possible adverse consequences.
(To obtain more information about the fraud and abuse implications of consulting arrangements with referring physicians in a book entitled Medicare/Medicaid Fraud and Abuse: A Practical Guide for Providers, send a check for $30.00 that includes shipping and handling made out to Elizabeth E. Hogue, Esq. to Fulfillment, 107 Guilford, Summerville, SC  29483.

To obtain assistance with the development of form agreements contact Ms. Hogue as indicated above.)

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Changes to Stark Regulations: A Refresher

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As many providers already know, the so-called "Stark law" prohibits physicians from making referrals to providers who render "designated health services" (DHS) if referring physicians or their immediate family members have an ownership or investment interest in, or compensation arrangement with the provider. Designated health services generally include home health, home medical equipment (HME), infusion services, and outpatient hospital services, among others. DHS does not, however, include hospice services. Likewise, providers of DHS generally cannot bill for services provided to patients referred by physicians who have ownership or investment interests in, or compensation arrangements with them that violate the Stark law.

Exceptions to these general rules were published in the form of final regulations on January 4, 2001, the so-called "Phase I" Stark rules. On March 26, 2004, "Phase II" Stark regulations were published as interim final rules in the Federal Register. These Phase II regulations further clarified exceptions to the statute described above.

Changes to the regulations went into effect on December 4, 2007. Revisions to the regulations related to payments to consulting physicians from whom providers receive referrals, training and education, and non-monetary compensation are relevant for home health agencies.

Use of Physicians to Provide Consulting Services

The Phase II regulations provided specific guidance regarding the use of physicians to provide consulting services to physicians. Many providers utilize the services of referring physicians as consulting physicians to their organizations. These consulting physicians provide a variety of appropriate services to providers.

According to the Phase II regulations, there is an exception for personal service arrangements that may include payments to referring physicians for consulting services. In order to meet the requirements of this exception, providers must ensure that:

- They enter into a written agreement with physicians that is signed by providers and physicians, which specifies the services covered by the arrangement.
- The arrangement must cover all of the services to be furnished by referring physicians to providers.
Aggregate services provided by consulting physicians do not exceed those that are reasonable and necessary for the legitimate business purposes of providers.

The term of each arrangement is for at least one year. To meet this requirement, if an arrangement is terminated during the initial term of the agreement, with or without cause, the parties may not enter into the same or substantially the same arrangement during the remainder of the first year of the original term of the agreement.

Compensation paid over the term of the agreement is set in advance, does not exceed fair market value, and 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.

As described above, providers must pay for services from consulting physicians at fair market value. Many providers have asked how they should determine fair market value.

Previously, the Stark II rules made it clear that fees paid to referring physicians for their services were considered to be at fair market value only if hourly payments were calculated using either of the following two methodologies:

- The hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market.

- If there are fewer than three hospitals that provide emergency room services in the geographic area where the provider operates, or if providers choose to do so, they may pay physicians at an hourly rate that is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty or, if the specialty is not identified in the survey, for general practice in at least four of the following surveys divided by 2,000 hours. The surveys are:
  - Sullivan, Cotter and Associates, Inc. - Physician Compensation and Productivity Survey
  - Hay Group - Physicians 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
  - William M. Mercer - Integrated Health Networks Compensation Survey
As of December 4, 2007, the above formulas no longer apply. Nonetheless, providers must be able to demonstrate, using some reasonable basis, that compensation paid to consulting physicians who also make referrals is at fair market value.

Providers could, for example, conduct what amounts to a “salary survey” of providers that operate in the same geographic area regarding the amount per hour that other providers pay consulting physicians. Such a survey is likely to produce a range of hourly rates. Providers should document the results of these surveys and pay physicians at rates that do not exceed the highest end of the range.

The above described change with regard to the use of formulas to calculate compensation at fair market value is an appropriate and welcome change. The formulas proved difficult, if not impossible, for home care providers to use. Providers can now avoid the frustration of trying to comply and breathe a sigh of relief.

**Training and Education**

The Phase II Stark rules also include an exception for "compliance training," which appears to allow organizations to provide a variety of types of training and education to physicians from whom they receive referrals.

Previously, according to this exception, providers could provide such training to physicians, their immediate family members, and office staff who practice in the provider's local community or service area so long as the training is held in the local community or service area. "Compliance training" means:

- Training regarding the basic elements of a compliance program, such as establishing policies and procedures, training of staff, internal monitoring, or reporting;
- Specific training regarding the requirements of Federal and State health care programs, such as billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements; or
- Training regarding other Federal, State or local laws, regulations, or rules governing the conduct of the party for whom the training is provided.

This exception did not, however, include medical education.

As of December 4, 2007, compliance training may include programs that offer continuing medical education credits, provided that compliance training is the primary purpose of the program.
Non-monetary Compensation

According to another exception under the Stark laws, providers may give physicians and/or their immediate family members non-cash items that have a relatively low value and are not part of a formal, written agreement. Staff may, for example, provide lunch or snacks, such as cookies, to physicians and their personnel at their offices. Providers have also routinely left items of limited value, such as coffee mugs, pens, and notepads at physicians’ offices.

Previously, the regulations indicated that non-monetary compensation did not violate the Stark laws as long as all of the following criteria are met:

- The annual aggregate value of non-monetary gifts to a physician does not exceed $300.00. (This amount increases each year if the consumer price index rises.)
- Providers that give non-monetary compensation to physicians make it available to all similarly situated physicians, regardless of whether physicians refer patients to the company for services.
- The compensation is not determined in any way that takes into account the volume or value of a physician’s referrals to the supplier.

Thus, it is clear that agencies that meet these criteria for non-monetary compensation can avoid violation of the Stark laws.

Providers should, however, also be aware of the following limitations:

- Protection from violations of the Stark laws is not available for gifts that are solicited by physicians or group practices. The reason for this limitation is to prevent physicians from making such gifts a condition or expectation of doing business.

  The “classic” example of solicitation of gifts is insistence by physicians that they will only meet with staff to discuss patients receiving services if the staff supplies lunch. Such requirements may amount to solicitation that will preclude protection for companies that supply lunch under these circumstances.

- The exception for non-monetary compensation up to $300.00 only protects gifts to individual physicians. Thus, gifts given to a group practice will not qualify for this exception. Non-cash gifts, however, could be given to one member, several individual members, or each member of a group practice if each such gift meets all of the conditions of the exception for non-monetary compensation up to $300.00. The exception does not apply to gifts, such as holiday parties, office equipment, or supplies that are valued at not more than $300.00 per physician in the group, but are, in effect, given or used as a group gift.
As of December 4, 2007, Stark provides for a limited exception when providers inadvertently provide nonmonetary compensation to physicians who make referrals to them in excess of the above limit. Such compensation is deemed to be within the limit if:

- The value of the excess non-monetary compensation is no more than 50% of the limit; and

- Physicians return to providers who receive referrals the excess non-monetary compensation or an amount equal to the value of the excess non-monetary compensation by the end of the calendar year in which the excess non-monetary compensation was received, or within 180 consecutive calendar days following the date the excess non-monetary compensation was received by physicians, whichever is earlier.

The above changes should generally be welcomed. At the same time, it is important to master them in order to achieve and maintain compliance.

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Some hospitals and skilled nursing facilities (SNF’s) refer to post-acute providers as “vendors” and require them to follow the policies and procedures related to “vendors.” These may include, for example, a requirement for representatives of post-acute providers to sign in when they arrive at hospitals and SNF’s to coordinate services in hospitals’ Purchasing Departments.

On the contrary, post-acute providers such as home health agencies, home medical equipment (HME) companies, hospices and private duty home care agencies are not “vendors” and should not be treated like “vendors.” They are, instead, fellow providers. Vendors are manufacturers and distributors of supplies and equipment that are utilized by hospitals and SNF’s on the premises of institutions. Post-acute providers rarely sell equipment and supplies that are used by facilities on the premises. In fact, the users of post-acute providers are patients, not hospitals and SNF’s.

When hospitals and SNF’s lump post-acute providers in with equipment and supply vendors they are, at the least, being disrespectful of these types of providers. Such treatment may be demeaning to post-acute providers.

Some hospitals are asking post-acute providers who are categorized as vendors to pay fees to hospitals in order to appear on a vendor list. Such payments are likely to constitute illegal kickbacks in exchange for referrals and cannot be required.

In addition, restrictions that hospitals and SNF’s may appropriately put on the activities of vendors while on the premises are inapplicable to post-acute providers. Vendors may, for example, be prohibited from going to other areas of institutions besides purchasing departments unless they are accompanied by staff of facilities.

No such restrictions should be applied to post-acute providers. In fact, it is inappropriate to restrict the activities of post-acute providers who:

- Have received referrals of patients; or
- Cared for patients immediately prior to their admission to institutions

Under these circumstances, post acute providers should be permitted access to patients, their families, and information about them as part of the discharge planning process.
It is important to note that referrals for post-acute services do not have to come from physicians. They may come from patients, their families, physicians, case managers/discharge planners, or other sources. Referrals may also be received by post-acute providers, either verbally or in writing. When post-acute providers are acting on verbal referrals, they should, however, document the name of the person who made the referral and the date and time at which it was received.

Of course, patients have the right to freedom of choice of providers. This right to freedom of choice of providers includes the right to self-refer to any type of post-acute provider. There are a number of sources of this right, as follows:

1) All patients have a common law right, based upon court decisions, to control the care provided to them, including who renders it. Thus, when patients, regardless of payor source or type of care, voluntarily express preferences for providers, their choices must be honored.

2) Federal statutes of the Medicare and Medicaid programs guarantee Medicare beneficiaries and Medicaid recipients the right to freedom of choice of providers. (Medicaid recipients may have waived this right if they participate in a waiver program.) Consequently, when Medicare patients and non-waiver Medicaid patients voluntarily express a preference for a home health agency, these choices must be honored.

3) The Balanced Budget Act of 1997 (BBA) requires hospitals to develop a list of home health agencies that are:

   a) Medicare certified;

   b) Provide services in the geographic areas where patients reside, and;

   c) Ask to be on the list.

In addition, if a hospital places the name of an agency on the list in which it has discloseable financial interests, the relationship between the hospital and the agency must be disclosed on the list.

This list must be presented to all patients who may benefit from home health services, regardless of payor source, so that they can choose the home health agency that they wish to provide services to them.

4) Hospital Conditions of Participation (COP’s) that became effective on October 1, 2004, include the basic requirements of the BBA described above.

5) Court decisions, such as the opinion in Assured Home Health, Inc. v. Providence Health System, also support patients’ right to freedom of choice of providers. In this case, Assured claimed that the hospitals in the System regularly violated
patients’ right to freedom of choice and “steered” patients to agencies owned by the System. This case was settled when the System agreed to institute additional safeguards to protect patients’ rights, including monitoring of the hospital’s practices by outside third parties.

A patient who received services from a post-acute provider immediately prior to admission to an institutional setting may, of course, choose to receive services from a different provider upon discharge. If a patient does not choose another provider, his or her care should be continued by the same provider with which the patient is likely to have a continuing provider-patient relationship.

Likewise, patients who are referred to post-acute providers may, of course, choose different providers any time they wish to do so.

Patients greatly value the services that post-acute providers offer. Hospitals and SNF’s, therefore, should not treat them like “vendors.”

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PhRMA, a trade association whose members are pharmaceutical research and biotechnology companies, recently updated its Marketing Code. The revised Code is applicable as of January 1, 2009. Although the Code applies only to members of PhRMA who voluntarily agree to follow it, the Code may help providers to understand changing standards regarding acceptable marketing practices.

With regard to taking lunches to physicians’ offices, for example, the revised Code says that PhRMA members who elect to adhere to the Code may present information to healthcare professionals and their staff members during the workday, including at mealtimes. In connection with such presentations or discussions, the Code also says that it is appropriate for occasional meals to be offered as a business courtesy to the participants. The presentations must, however, provide scientific or educational value, and meals must meet the following standards:

- Modest, by local standards;
- Not part of an entertainment or recreational event;
- Provided in a manner conducive to informational communication; and
- Limited to in-office or in-hospital settings.

With regard to entertainment and recreation, the Code says that members who decide to abide by the Code may not provide any entertainment or recreational items to any healthcare professional who is not a salaried employee of the company providing the items. Examples of these items are tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips. According to the Code, entertainment or recreational benefits should not be offered, regardless of:

- The value of the items;
- Whether the company engages the healthcare professional as a speaker or consultant; or
- Whether the entertainment or recreation is secondary to an educational purpose.
Home health agencies, hospices, private duty agencies, and home medical equipment (HME) companies may be especially interested in what the Code says about payments to healthcare consultants, including physicians. The Code recognizes a legitimate need for providers to obtain information or advice from medical experts. The Code also points out, however, that decisions regarding the selection or retention of healthcare professionals as consultants should be made based on defined criteria, such as general medical expertise and reputation, or knowledge and experience regarding particular therapeutic areas. In addition to legal requirements included in applicable criteria of the safe harbors of the federal anti-kickback statute and exceptions to the Stark laws, the Code requires members of PhRMA who voluntarily adhere to it to meet the following additional requirements:

- The number of health professionals retained is not greater than the number reasonably necessary to achieve identified purposes of the services;

- Providers that pay consultants maintain records concerning and make appropriate use of the services provided by consultants; and

- The venue and circumstances of any meeting with consultants are conducive to the consulting services, and activities related to the services are the primary focus of the meeting. Resorts are inappropriate venues, according to the Code.

Providers may also be interested to know that the Code also includes a blanket prohibition on giving healthcare professionals any items that do not advance disease or treatment education; including pens, note pads, mugs, and similar “reminder” items with company or product logos. Members of PhRMA who decide to voluntarily adhere to the Code may, however, offer items designed primarily for the education of patients or healthcare professionals if the items are not of substantial value (i.e. $100.00 or less) and do not have value to healthcare professionals outside of their professional responsibilities. Examples of permitted items include anatomical models for use in examination rooms for the education of patients.

*Although the Code described above applies only to members of PhRMA who voluntarily agree to adhere to it,* providers may have been told by physicians and their staff members that they can no longer accept mugs, sticky notes, etc. and may have wondered about the basis for this new standard. In addition, to the extent that the Code represents a “window” on what standards may become in the future, it is helpful for all providers to know about them.

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