



EDUCATIONAL RESOURCES

Working with Physicians and Other Referral Sources:

Pitfalls to Avoid Legal Trouble Including Federal and State Investigations

 PHARMACY



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Introduction

- In order to succeed in today's hyper-competitive environment, the pharmacy must establish its niche. It must “think outside the box.”
- The successful pharmacy must set itself apart from its competition.
- One very important way to do this is for the pharmacy to enter into relationships with physicians, hospitals, DME suppliers, home health agencies, long term care facilities, and other referral sources.
- In doing so, it is critical that the pharmacy comply with federal and state anti-fraud laws as well as fulfilling obligations imposed by PBM contracts.



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Legal Guidelines

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Legal Guidelines

- Federal Anti-Kickback Statute
- Beneficiary Inducement Statute
- Stark Physician Self-Referral Statute
- State Specific Statutes

Federal Anti-Kickback Statute

It is a felony for a health care provider to knowingly and willfully offer or pay any remuneration to induce a person/entity to refer an individual for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program (“FHCP”), or the purchase or lease or the recommendation of the purchase or lease of any item for which payment may be made under a federal health care program.

Beneficiary Inducement Statute

- This statute prohibits a provider from offering or giving anything of value to an FHCP beneficiary that the provider knows, or should know, is likely to persuade the person to purchase an item covered by a federal health care program.
- In the preamble to the regulations implementing this statute, the OIG stated that the inducement statute does not prohibit the giving of incentives that are of “nominal value.”
- The OIG defines “nominal value” as no more than \$15 per item or \$75 in the aggregate to any one beneficiary on an annual basis.
- “Nominal value” is based on the retail purchase price of the item.

Stark Physician Self-Referral Statute

- This statute provides that if a physician has a financial relationship with an entity providing “designated health services,” then the physician may not refer Medicare/Medicaid patients to the entity unless a Stark exception applies.
- Designated health services include out-patient prescription drugs; parenteral and enteral nutrients; prosthetics, orthotics and prosthetic devices and supplies; DME; and rehab therapy services.
- One of the exceptions to Stark provides that a health care provider may provide non-cash equivalent items to a physician if such items do not exceed an annual amount established by CMS. For 2021, such amount is \$429.

State Specific Laws

- All states have enacted statutes prohibiting kickbacks, fee splitting, patient brokering, or self-referrals.
- Some state anti-fraud statutes only apply when the payer is a government health care program.
- Other state anti-fraud statutes that apply regardless of the identity of the payer.
- All states have a set of statutes and regulations that are specific to pharmacies.

Safe Harbors



Safe Harbors

- Because of the breadth of the federal anti-kickback statute (“AKS”), the OIG has published a number of “safe harbors.”
- A safe harbor is a hypothetical fact situation such that if an arrangement falls within it, then the AKS is not violated.
- If an arrangement does not fall within a safe harbor, then it does not mean that the arrangement violates the AKS. Rather it means that the arrangement needs to be carefully scrutinized under the language of the AKS, applicable case law, and other published guidance

Safe Harbors- Small Investment

For investments in small entities, “remuneration” does not include a return on the investment if a number of standards are met, including the following: (i) no more than 40% of the investment can be owned by persons who can generate business for or transact business with the entity, and (ii) no more than 40% of the gross revenue may come from business generated by investors.

Safe Harbors- Space Rental

Remuneration does not include a lessee's payment to a lessor as long as a number of standards are met, including the following:

- (i) the lease agreement must be in writing and signed by the parties;
- (ii) the lease must specify the premises covered by the lease
- (iii) if the lease gives the lessee periodic access to the premises, then it must specify exactly the schedule, the intervals, the precise length, and the exact rent for each interval;
- (iv) the term must be for not less than one year; and
- (v) the aggregate rental charge must be set in advance, be consistent with fair market value, and must not take into account business generated between the lessor and the lessee.

Safe Harbors- Equipment Rental

Remuneration does not include any payment by a lessee of equipment to the lessor of equipment as long as a number of standards are met, including the following:

- (i) the lease agreement must be in writing and signed by the parties;
- (ii) the lease must specify the equipment;
- (iii) for equipment to be leased over periods of time, the lease must specify exactly the scheduled intervals, their precise length and exact rent for each interval;
- (iv) the term of the lease must be for not less than one year; and
- (v) the rent must be set in advance, be consistent with fair market value, and must not take into account any business generated between the lessor and the lessee.

Safe Harbors- Personal Services & Management Contracts

Remuneration does not include any payment made to an independent contractor as long as a number of standards are met, including the following:

- (i) the agreement must be in writing and signed by the parties;
- (ii) the agreement must specify the services to be provided;
- (iii) the term of the agreement must be for not less than one year;
- (iv) the methodology for calculating the compensation must be set in advance, be consistent with fair market value, and must not take into account any business generated between the parties; and
- (v) the services performed must not involve a business arrangement that violates any state or federal law.

Safe Harbors- Employees

Remuneration does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made, in whole or in part, under Medicare or under a state health care program.

New VBE Safe Harbors

The 3 new value-based safe harbors contain protection against potential fraud including:

- (i) a prohibition against taking into account the volume or value of referrals outside the target patient population
- (ii) limits on directed referrals

New VBE Safe Harbors

The following entities may not utilize the new value-based safe harbors:

- Pharmaceutical manufacturers
- Distributors; wholesalers
- PBMs
- Labs
- Compounding pharmacies and DME suppliers

New VBE Safe Harbors

The following are the new VBE safe harbors:

- The *Value-Based Arrangements with Full Financial Risk* safe harbor provides the greatest flexibility because it requires the assumption of the most risk.
- The *Value-Based Arrangements with Substantial Downside Risk* safe harbor protects both in-kind and monetary remuneration if the VBE participants assume a certain amount of risk.
- The *Care Coordination Arrangements* safe harbor does not require the participants to take on risk.
 - It does, however, require that the arrangement be measured based on at least one evidence-based outcome measure.

NEW PATIENT ENGAGEMENT & SUPPORT SAFE HARBOR

- This new safe harbor provides protection for certain patient engagement tools.
- Its protection is limited to in-kind remuneration provided by VBE participants to patients.
- Examples of in-kind patient engagement tools are:
 - Health-related technology
 - Patient health-related monitoring tools
 - Support services designed to address a patient's social determinants of health
- The safe harbor does not protect the giving of cash, cash equivalents, and certain types of gift cards.

NEW PATIENT ENGAGEMENT & SUPPORT SAFE HARBOR

- The aggregate value of the patient engagement tools and supports cannot exceed \$500 per year.
- The safe harbor does not apply to certain VBE participants including pharmaceutical manufacturers, distributors, and wholesalers; PBMs; labs; compounding pharmacies; certain DME manufacturers; and DME suppliers.

Modifications of Existing Safe Harbors

- *Local Transportation* safe harbor. The OIG expanded the mileage limits up to 75 miles for residents in rural areas. There is no distance requirement for transporting inpatients to their residence upon discharge.
- *Warranty* safe harbor. Protection is afforded to a bundle of one or more items and related services, provided that they are paid for by the same TPP and under the same payment.

Modifications of Existing Safe Harbors

Personal Services and Management Contracts and Outcomes-Based Payments safe harbor. This safe harbor now includes the protection of certain outcome-based payment arrangements. Outcomes measures related solely to patient satisfaction and/or internal cost savings are excluded from safe harbor protection. Safe harbor protection under this new provision is not available to pharmaceutical manufacturers, distributors and wholesalers; PBMs; labs; compounding pharmacies; certain DME manufacturers, and DME suppliers.

Modifications of Existing Safe Harbors

In addition, the OIG removed the current safe harbor requirement that the aggregate payment for a management or services arrangement be set out in advance. Going forward, only the methodology needs to be set in advance. This makes the safe harbor consistent with the parallel Stark exception. The OIG also removed the requirement that a part-time arrangement have a schedule of services specifically set out in the written agreement.

Modifications of Existing Safe Harbors

ACO Beneficiary Incentive Program safe harbor. The Balanced Budget Act of 2018 included a statutory provision excluding incentive payments, made to a beneficiary who receives the payments as part of the ACO Beneficiary Incentive Program, from the definition of remuneration.

Modifications of Existing Safe Harbors

- CMS and the OIG finalized changes to the EHR exception to Stark and the EHR safe harbor to the AKS.
- The final rules:
 - Remove the sunset provision
 - Allow the recipient to pay its portion of the EHR at reasonable intervals
 - Delete the prohibition on donating replacement technology
 - Delete the prohibition on the donor taking any action to limit or restrict the use, compatibility, or interoperability of the items or services with other e-prescribing or electronic health record systems.



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Applicability to Pharmacies

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Applicability to Pharmacies

- Certain components of the final rules do not directly apply to pharmacies. There are two reasons for this. First, at present most pharmacies are not integrated into the VBC arena; most pharmacies are paid on an FFS basis. Secondly, several of the changes specifically exclude pharmacies
- On the other hand, other components of the final rules do directly apply to pharmacies. These include:

Applicability to Pharmacies

- Modification to the *Personal Services and Management Contracts* safe harbor to the AKS by removing the requirement that the aggregate payment for a management or services arrangement be set out in advance (i.e., only the methodology needs to be set out in advance).
- Modification to the *Personal Services and Management Contracts* safe harbor to the AKS by removing the requirement that a part-time arrangement have a schedule of services specifically set out in the written agreement.

Applicability to Pharmacies

Modification to the Stark definition of “commercial reasonableness” clarifying that:

- the key question is whether the arrangement makes sense as a means to accomplish the parties’ goals and
- commercial reasonableness is not one of valuation - it is expressly not based on whether the arrangement is profitable or not.

Applicability to Pharmacies

- Clarification to the Stark “volume or value standard and other business generated standard” by stating that the amount of compensation will be considered to take into account the volume or value of referrals or other business generated only when the formula used to calculate compensation to or from a physician includes the volume or value of referrals or other business generated.
- Clarification that the Stark definition of “fair market value” means the value in an arm’s length transaction consistent with the general market value of the subject transaction (i.e., the intended use of the equipment or facility space is not taken into consideration and the proximity to a referral source lessor is not taken into consideration).

Applicability to Pharmacies

- The ability of the parties to a transaction (that implicates Stark) to sign documents (memorializing the arrangement) within 90 days of the beginning of the arrangement.
- The modification to the Stark definition of “set in advance” to allow the modification of compensation during the term of an agreement where the modified compensation is not based on the volume or value of referrals.

Applicability to Pharmacies

- These modifications and clarifications bring Stark and the AKS into line with each other.
- The modifications to Stark and the AKS show that CMS and the OIG recognize that Stark and the AKS were too limited in today's health care climate. The modifications provide additional freedom to pharmacies to enter into collaborative arrangements with physicians, hospitals and other providers when the arrangements are designed to improve patient outcomes.

Referral Sources



Types of Referral Sources

- Independent Contractors
 - Typically involves percentage-based compensation arrangements involving 1099 independent contractor sales agents
- Marketing Companies
- Physicians
 - What we will be focusing on today

Physician

- A physician is a referral source to a pharmacy.
- The physician refers patients who are covered by a government health care program, who are covered by commercial insurance, or desire to pay cash.
- If a pharmacy provides meals, gifts and entertainment to a physician, then both the pharmacy and the physician need to comply with the federal and state laws that govern these arrangements.



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Expenditures for Physicians

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What a Pharmacy Can Spend on a Physician

- While the Stark non-monetary compensation exception allows a pharmacy to spend up to a set amount per year (e.g., \$429 in 2021) for non-cash/non-cash equivalent items for a physician, the AKS does not include a similar exception.
- Nevertheless, if the Stark exception is met, it is unlikely that the government will take the position that the non-cash/non-cash equivalent items provided by the pharmacy to the physician violate the AKS.

What a Pharmacy Can Spend on a Physician

- In addition to complying with Stark and the AKS, the pharmacy and the physician also need to comply with applicable state law.
- Even though the pharmacy and the physician will need to confirm this, it is likely that compliance with the non-monetary compensation exception will avoid liability under state law.
- Bottom line is that a pharmacy can provide gifts, entertainment, meals, and similar items to a physician so long as the combined value of all of these items do not exceed the annual amount set by CMS (\$429 in 2021).

What a Pharmacy Can Spend on a Physician

- While the Stark non-monetary compensation exception applies to expenditures on behalf of a physician, the exception does not apply to expenditures on behalf of the physician's staff.
- In fact, Stark does not apply to the physician's staff. Expenditures on behalf of the physician's staff must be examined in light of the AKS.

What a Pharmacy Can Spend on a Physician

- Separate from furnishing gifts and entertainment, and subsidizing trips, the pharmacy can pay the physician for legitimate services.
- For example, if the pharmacy has a legitimate need for a Medical Director, then the pharmacy and physician can enter into a Medical Director Agreement that complies with both the PSMC safe harbor to the AKS and the Personal Services exception to Stark.

What a Pharmacy Can Spend on a Physician

It is permissible for a pharmacy to pay a physician to present an education program if the following requirements are met:

- The program is substantive and valuable to the audience.
- The compensation paid to the physician is the fair market value equivalent of the time and effort the physician expended to (i) prepare for the program and (ii) present the program.

Medical Director Agreement

- A pharmacy can enter into an independent contractor Medical Director Agreement with a physician.
- The MDA must comply with the (i) PSMC safe harbor to the AKS and (ii) the Personal Services exception to Stark.

Renting Space

- A pharmacy can rent space to/from a physician so long as the rental agreement complies with the (i) Space Rental safe harbor to the AKS and (ii) space rental exception to Stark.
- A pharmacy can rent space to/from a non-physician referral source so long as the rental agreement complies with the Space Rental safe harbor to the AKS.

Joint Venture with Physician

When forming a joint venture with a physician, then not only must the arrangement comply with (i) the Small Investment Interest safe harbor or (ii) the 1989 Special Fraud Alert/April 2003 Special Advisory Bulletin, but the arrangement must comply with Stark.

- If the JV Pharmacy is located in a rural area, then the physician can refer Medicare/Medicaid patients to the JV Pharmacy.
- If the JV Pharmacy is not located in a rural area, then the physician cannot refer Medicare/Medicaid patients to the JV Pharmacy.

Pharmacy Owned/Managed Physician Clinic

- In some states, a pharmacy can own a physician clinic ... and employ the physician.
- Other states will not allow a physician to be employed by a pharmacy. In those states:
 - The medical practice will be owned by a legal entity (e.g., Professional Association or “P.A.”) owned by a physician.
 - The physician will be employed by his/her P.A.
 - The pharmacy will (i) rent the space to the P.A., (ii) rent furniture, fixtures and equipment to the P.A., and (iii) provide services to the P.A.

Stark Rural Provider Exception

- In entering into an arrangement with a physician in a rural area, the pharmacy needs to focus on the rural provider exception.
- The rural provider exception states that an ownership interest by a physician in a rural provider is not considered a “financial relationship” under Stark.

Stark Rural Provider Exception

- Rural providers are defined as those that furnish at least 75% of the designated health services (“DHS”) they provide to residents of a “rural area.”
- Thus, whether this exception applies depends on whether at least 75% of the patients that the pharmacy’s services are located within a “rural area.”
- “Rural area” is defined as “an area that is not an urban area as defined in 42 CFR 412.62(f)(1)(ii) which states that “the term urban area means a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget”

Annual Wellness Visits/Remote Patient Monitoring/Chronic Care Management

- Assume that the physician (i) has AWVs with patients, (ii) provides RPM to patients and/or (iii) provides CCM to patients.
- Assume that the pharmacy assists the physician in (i) conducting AWVs and (ii) providing RPM and CCM.
- It is the physician that is paid for AWVs, RPM and CCM. If the pharmacy assists with AWVs, RPM and CCM for free, then such assistance constitutes “something of value” to a referral source, thereby implicating the AKS and Stark.
- In order to avoid AKS and Stark problems, the physician must pay fair market value compensation to the pharmacy for the pharmacy’s services.

Education Workshops

- The physician can set up times for the pharmacy to send representatives to the physician's office to educate the physician's employees regarding (i) products and services offered by the pharmacy and (ii) how the pharmacy's products/services can treat specific conditions.
- The physician can set up times for the pharmacy to send representatives to the physician's office to present workshops to the physician's patients who have conditions that can be treated by the pharmacy's products and services.

How can regulatory issues lead to an investigation?

Possible Investigation Causes

- Referrals
- Whistleblowers
- Anonymous complaints
- Caught in the “net” of another investigation
- Data Analytics

Audits Tips and Tricks to Better Avoid Investigations



PBM Audits

PBM Audit

PBMs typically audit pharmacies in order to detect any improper payment by the PBM on behalf of the plan or consumer and to verify that the patient received the correct medication in the appropriate dose. PBMs will also conduct an audit on a pharmacy to verify that contracts are being adhered to.

PBM Audit

A challenge to pharmacies is the incorporation of the PBM's policy manuals into its contracts. The manuals can end up having the same importance as the contracts. To ensure policies are being followed, contracts usually give the PBM the authority to conduct an audit.

PBM Audit

An audit usually starts by the pharmacy receiving a letter from the PBM indicating that an audit is scheduled. PBMs can conduct field/on-site audits performed at the pharmacy that involve physical observations, prescription reviews, and checks for compliance with Medicare Part D regulations. Audits by telephone are usually used to correct claim billing for a small number of claims. Desk/mail audits use automated means to review pharmacy claims and encounter data received by the PBM.

Preparing for an Audit

Preparing for an Audit

- The pharmacy should understand what its contract with the PBM says.
- If the PBM contract incorporates outside documents (e.g., policy manuals), then the pharmacy should understand what the outside documents say.
- The pharmacy should determine if its operations comply with the contract and outside documents.
- The pharmacy should review its previously submitted questionnaires to the PBM so that the pharmacy will know what it has represented to the PBM.

Preparing for an Audit

The pharmacy should understand what the “hot button” issues are for the PBM. Examples include:

- Extent of pharmacy’s mail-order business
- Extent of pharmacy’s compounding
- Whether the pharmacy has out-of-state pharmacy licenses
- Pharmacy’s policy towards reducing or waiving copayments
- Whether the pharmacy markets through W2 employees or 1099 independent contractors

Preparing for an Audit

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Preparing for an Audit

Assume that the pharmacy determines that its billing pattern will noticeably change. This may result, for example, from the pharmacy landing a large contract that will result in the pharmacy dispensing a large volume of a particular drug. A sudden change in the pharmacy's billing pattern may trigger an edit in the PBM's software ... triggering an audit. The pharmacy can attempt to head off such an audit by alerting the PBM in advance of the change in the pharmacy's billing pattern.

Preparing for an Audit

- The pharmacy should review its previously submitted questionnaires to the PBM so that the pharmacy will know what it has represented to the PBM.
- The pharmacy should understand what the “hot button” issues are for the PBM. Examples include:
 - Extent of pharmacy’s mail-order business
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 - Whether the pharmacy markets through W2 employees or 1099 independent contractors

Preparing for an Audit

- The pharmacy should conduct limited self-audits throughout the year. Each audit will be “limited” in the sense that it will focus on a specific aspect of the pharmacy’s operation.
- Once a year, the pharmacy should hire an outside consultant to conduct a full audit of the pharmacy’s operations to determine if they are in compliance with the law in general and with the PBM contracts in particular.

Preparing for an Audit

The pharmacy should have a system in place to receive, catalogue and respond to (i) phone calls, (ii) emails, (iii) hard copy mail, and (iv) other types of outside communications. In doing so, the pharmacy wants to avoid the scenario in which the pharmacy receives communication from a PBM, but the pharmacy does not respond because the communication does not find its way to the pharmacy owner/manager ... it has “fallen through the cracks.”

Preparing for an Audit

The pharmacy should organize and train an Audit Response Team (“ART”). The team members will be employees of the pharmacy.

- A person will be designated as the ART Leader.
- If a PBM representative, without an appointment, “walks through the front door” of the pharmacy, then the ART Leader will be immediately informed and he/she will coordinate the pharmacy’s response.
- Likewise, if a written or telephonic communication is received from a PBM, then the communication will be forwarded to the ART Leader.

Preparing for an Audit

- The pharmacy may want to periodically conduct mock drills.
 - A person posing as PBM representative, will come onsite unannounced and request patient files. The mock PBM representative will be introduced to the ART Leader.
 - A mock PBM letter can be mailed to the pharmacy ... or a mock PBM email can be sent to the pharmacy ... or a mock PBM phone call can be made to the pharmacy. The communication will be forwarded to the ART Leader.

Audit Response Protocol

Audit Response Protocol

- The pharmacy should adopt a formal protocol to respond to an audit. Specifically:
 - Employees who open mail should be alerted to look for any envelope from a PBM.
 - Employees who answer the phone should be alerted to look for phone calls from PBMs.
 - When an employee is alerted to the possible existence of a PBM audit, he/she should immediately notify pharmacy management.

Responding to an Audit

Responding to an Audit

- The pharmacy should consult with a health care attorney who has experience with PBMs. The attorney should (i) guide the pharmacy in responding to the audit and (ii) approve any documents that the pharmacy submits to the PBM.
- The pharmacy's approach should be "let's resolve the problem" as opposed to "let's win the argument."
 - It is highly unlikely that the PBM will back down and concede to the pharmacy.
 - On the other hand, unless the facts are egregious, there is a reasonable possibility that the PBM will agree to an amicable resolution.

Responding to an Audit

- It is important that the pharmacy meet the deadlines imposed by the PBM. The PBM will likely agree to a reasonable request for a deadline extension.
- It is equally important that the information submitted by the pharmacy be complete and accurate.



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Inventory Audits are Problematic

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An Inventory Audit May Require Coordination with Wholesalers

Inventory Audit

- PBM may request a detailed purchase history related to the specific audited claim(s) in the form of vendor invoice(s) in order to facilitate verification of drug purchases for the NDC and quantity corresponding to the specific audited claim(s)
- Vendor invoices must be submitted by the vendor via fax directly to the PBM
 - Coordinate with your wholesaler account manager and manufacturer account manager
 - Ensure timely submission by the indicated due date
 - Ensure the requested reference numbers listed
 - Identify and ensure submission to the provided channel (fax, email)



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Failure to Collect Co-Pays

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Failure to Collect Full Co-Pay

- Instead of collecting the full co-pays, some pharmacies only collect a flat rate.
- By discounting the copayment owed by the patient, the pharmacy is essentially waiving the remainder of the copayment.
- A waiver of copayment (whole or partial) should only be made when financial hardship is documented.

Failure to Collect Full Co-Pay

- Furthermore, up-front discounting of the copayment could be viewed as a reduction of the pharmacy's actual charge for the medication and will likely affect the pharmacy's usual and customary charge for the medication.
- The pharmacy needs to have a Financial Hardship Policy in place

How PBM Audits Can Lead to Investigations?



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