Why are Physicians Doing Business with Pharmacies?

- Expanding business; increase bottom line
- Make provision of healthcare services more efficient for patients
- Follow more closely patients’ medication management

Risk: Overutilization of prescription drugs

Types of Arrangements

- In-office Dispensing or Pharmacy Wholly Owned by Practice
  - Contract with pharmacy or pharmacy management company to provide management or drug wholesale services
- Practice has ownership interest in pharmacy with others
- Practice investing in pharmacy management company
Road Map for Today's Discussion:

- Each of these 4 types of physician pharmacy ventures will be separately reviewed in light of the federal and state issues that may arise.
- We will additionally discuss the health law issues surrounding management or consulting contracts that may also be present in each of these ventures.
- Compounding issues will be separately addressed because they create a special set of issues.
- Reimbursement issues will also be discussed.

In-Office Dispensing

- AMA Code of Ethics:
  - Opinion 8.06: Physicians should prescribe drugs based solely on medical considerations, patient needs and effectiveness. Physician may dispense drugs within their office so long as the dispensing primarily benefits the patient and fits within self-referral guidelines. Physicians must respect patients' freedom of choice.
  - Opinion 8.0321: Ethical standards to be followed when the physician is making a referral to an entity in which the physician has a financial interest.
    - Patient is informed of the physician's financial interest;
    - Steps have been taken by the practice to address conflicts of interest;
    - Referrals are based upon objective criteria and are medically necessary.

In-Office Dispensing (Stark)

- Stark Law: Prohibits physicians from referring Medicare (and Medicaid) patients for designated health services to any entity with which the referring physician (or immediate family member) has any direct or indirect financial relationship unless an exception applies. 42 U.S.C. § 1395nn
- Most outpatient Prescription drugs are DHS.
  - Outpatient Prescription drugs include those reimbursed by Medicare Parts B and D and Medicaid (42 C.F.R. § 413.351).
  - There is a Stark exception for services, including outpatient prescription drugs, provided through Part C Medicare Advantage plans. (42 U.S.C. § 1395mm(b)(5) Prepaid Plans Exception).
### In-Office Dispensing (Stark)

- Applicable Stark Exception? In-office Ancillary Services (42 U.S.C. § 1395nn(b)(2)).
  - Pharmacy services are provided by [1] a referring physician; [2] a physician who is a member of the group practice or [3] and individual who is supervised by the referring physician or another physician in the group practice (under Medicare's supervision guidelines).
  - Pharmacy services must be provided in a "centralized building" (defined as any part of a building owned or leased on a full time basis for furnishing DHS and not shared with any other party) or in the "same building" in which the referring physician furnishes physician services unrelated to DHS and;
  - Drugs must be billed by the physician performing or supervising the service, the group practice or a an entity wholly-owned by the physician or group practice.
- Note: if it is group practice then it must meet the Stark regulations for what constitutes a group practice under 42 C.F.R. § 411.352. A critical element to the exception is that physicians are not paid based on value or value of pharmacy referrals.

### In-Office Dispensing (Antikickback)

- Antikickback statute: Prohibits anyone from purposefully offering, soliciting, or receiving anything of value to generate referrals for items or services payable by any federal health care program. 42 U.S.C. § 1320a-7b.
- Elements:
  - Remuneration
  - Offered, paid, solicited, or received
  - Knowingly and willfully
  - To induce or in exchange for federal program referrals

### In-Office Dispensing (Antikickback)

**Possible Exceptions:**
- Bona fide employment (42 C.F.R. § 1001.952(i))
  - Amount paid by an employer to a bona fide employee for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare or a state health care program. For purposes of this safe harbor, the term "employee" has the same meaning as it does for purposes of 26 U.S.C. § 3121(d)(2).
  - Personal services and management agreements (applicable to independent contractors)(42 C.F.R. § 1001.952(i))
  - Written agreement for at least a year signed by parties;
  - Covers all the services that are to be provided throughout the term of the agreement; if part-time or sporadic services, then the schedule of those services has to be specifically laid out;
In-Office Dispensing (Antikickback)

Possible Exceptions (Cont’d.):

- Compensation is FMV and not determined in a manner that takes the value or volume of federal business or referrals generated between the parties;
- Aggregate services do not exceed those that are reasonable and necessary to accomplish the "commercially reasonable" business purpose of the services;
- Services performed do not involved promotion of a business or other activities that violate state or federal law;
- If all the elements are not met, then the arrangement is not per se illegal but could carry more risk.

In-Office Dispensing – State Laws

- State Laws
  - i. State Self referral
    - Some state self referral laws track Stark but others are a little different. i.e. Florida Patient Self Referral Act, Section 456.053, Florida Statutes
    - Supervision requirement: Florida direct supervision; does physician supervision of a pharmacist make sense if it's not legally required?

- ii. State Fraud and Abuse Laws
  - i.e. Florida Patient Brokering Act, 817.505, Florida Statutes

- iii. State Fee Splitting Laws.

- iv. State Pharmacy Laws
  - "Dispensing" is likely defined by state law. In Florida, it is "the transfer of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer or to one who represents that it is his or her intention not to consume the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user." Fla. Stat. § 893.01(7)
In-Office Dispensing – State Laws

- "Administering" is also likely defined by state law. For example, to administer a drug in Florida means "the direct application of a controlled substance, whether by injection, inhalation, or any other means, to the body of a person or animal." Fla. Stat. § 893.02(1). Physicians generally do not need a pharmacy license to administer prescription drugs in their office.
- Special Statutes for in-office dispensing may not require a full pharmacy license.
- Check state law for limitations on physician dispensing for controlled substances.
  - i.e. schedule I and II controlled substances cannot be in office dispensed in Florida but schedule III and IV can.

In-Office Dispensing – State Laws

- State laws
  - Pharmacy Laws: Consider which type of pharmacy. Retail pharmacies may have hour requirements that are inconsistent with the medical office hours.
  - Consider payer issues. Will a payer pay under the same tax payer identification number for medical pharmacy? Will payment to a pharmacy under a tax payer identification number be higher than payment to a dispensing practitioner?
  - Self Referral Laws may prohibit a wholly owned subsidiary. Florida has permitted it under it’s self referral laws if substantially all of the health care services are still provided by the practice.

Contract with Pharmacy to Provide Management or Wholesale Services (Stark)

- Stark: Implicated if physician in the group is also referring patients for DHS to the pharmacy. If no referrals for DHS to the pharmacy (unlikely unless pharmacy is geographically distant) then no Stark implications.
  - "Referral" is broadly defined to include physician orders for tests or services, plans of care, certifications, etc. for the provision of DHS. 42 C.F.R. 411.351.
- Exceptions? Depends on the relationship between the physicians in the practice and the practice that is contracting with the pharmacy.
Contract with Pharmacy to Provide Management or Wholesale Services (Stark)

- If the practice is owned by physicians, then there is a direct financial relationship between the physicians in the practice and the pharmacy that is providing DHS, because of the "stand in the shoes" principle (42 C.F.R. 411.354(c)). Exception for direct compensation required.
- FMV Exception may apply: FMV is defined as the value in arm’s-length transactions, consistent with general market value. General market value is the price that an asset would bring as a result of bona fide bargaining between well-informed parties who are not in a position to generate business for the parties involved and does not take into account the value or volume of referrals (42 C.F.R. 5 411.357(i)).
  - Set forth in writing
  - Compensation set in advance
  - Term of one year
  - Compensation cannot be changed for one year
  - Fair market value
  - Cannot take into account value or volume of referrals

Contract with Pharmacy to Provide Management or Wholesale Services (Stark)

- If the referring physicians in the practice do not have an ownership interest in the Practice (or the Pharmacy), then there may be an indirect compensatory arrangement.
- Indirect compensation exists (42 C.F.R. 411.358(g)(2)).
- Between the referring physician and the entity furnishing DH there is an "affirmative check" of any number (but no fewer than 2) of persons or entities having financial relationships with the physician.
- The referring physician receives aggregate compensation from the person or entity in the chain with which the physician has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DH.
- The entity furnishing DH has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DH.

Contract with Pharmacy to Provide Management or Wholesale Services (Antikickback)

- May be violated in at least three ways:
  - If the contractual terms offered to the physician practice take into account potential referrals for federal business from the practice to the pharmacy and the management fee charged to the practice is below FMV to induce those referrals;
  - If the wholesale price of drugs sold to the physician practice is lower than FMV in order to induce the practice to refer patients to the pharmacy for items or services reimbursed by federal payors;
  - If the management arrangement has a marketing component and the management fee varies depending on the number of referrals the management company generates for the practice.
Contract with Pharmacy to Provide Management or Wholesale Services (Antikickback)

Antikickback Safe Harbors

- Personal Services and Management Contracts
- Discount Safe Harbor potentially applicable for the wholesale drug arrangement (42 C.F.R. § 1001.952(h))
  - Applies to goods or services received by a buyer "which submits a claim or request for payment for the good or service for which payment may be made in whole or in part under Medicare or a State health care program," provided certain other conditions described in the regulations are satisfied.

Contract with Pharmacy to Provide Management or Wholesale Services (Antikickback)

  - Health care provider in one line of business expanding into a related line of business;
  - New business predominately or exclusively serves the physician-owner’s existing patient base;
  - Physician-owner’s primary contribution to the venture is referrals and the physician-owner makes little or no investment but retains profits;
  - Practical effect of the management arrangement is to provide the physician-owner to bill for services provided by the manager;
  - Manager provides turnkey services.

Practice Contracts with Pharmacy Management Company (Stark)

- Stark: Assuming that the pharmacy management company is not owned by a pharmacy, there are no Stark implications because management company is not providing any DHS services.
- If owned by pharmacy, a possible circumvention scheme exists that carries civil money penalty exposure (42 U.S.C. 1395(g)(4)). "Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than $100,000 for each such arrangement or scheme."
Practice Contracts with Pharmacy Management Company (Antikickback)

- Antikickback: implicated in this arrangement if the contract with the management company has a marketing component where payments to the management company are related (directly or indirectly) to the amount of business the marketing activities generate for the pharmacy.

- Percentage-based payments to management company with a marketing component is a problem. (See OIG Advisory Ops. 11-17, 98-4).

Practice Contracts with Pharmacy Management Company (Antikickback)

- Exception: Personal Services and Management Contracts (42 C.F.R. § 1001.952(d))
  - If the management relationship with the pharmacy includes only administrative tasks such as billing, collections, payroll, etc., then risk of antikickback scrutiny is greatly reduced.

Practice (or individual physician) has ownership interest in Pharmacy with others (Stark)

- Stark: Physician would not be able to refer Medicare (Parts B and D)/Medicaid patients to this entity because the physician practice has a direct investment interest in this entity.
  - No exception for DHS (for drugs covered by Part B, D, or Medicaid)
  - If drugs are not covered by Medicare Parts B and D or Medicaid, then Stark would not prohibit referrals.
Practice (or individual physician) has ownership interest in Pharmacy with others (Antikickback)

Antikickback: Implicated if the physician is also a referral source for the pharmacy.
- Exception? Maybe, Small Entity Investment Exception (42 C.F.R. § 1001.952(a)(2))
- A physician-pharmacy joint venture has to satisfy the 60/40 Investor Test and 60/40 Revenue Test. These tests require that no more than 40 percent of the value of the investment interests of each class of investment interests be held in the previous fiscal year or previous 12-month lookback period by investors who are in a position to generate business for the venture. In addition, no more than 40 percent of the venture’s gross revenue related to the furnishing of health care services in the look-back period may come from business generated from investors.
- This exception also has a requirement that the terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

In-Office Dispensing – State Laws

- State law issues:
  - State Self Referral Laws; In Florida, the Board of Medicine approved a physician investment in a separate pharmacy that provides cash only fertility drugs. The physicians fit their pharmacy investment under the investment exception to the Florida Patient Self Referral Act. This exception requires, among other things, that no more than 50% of the investors be in a position to refer.
  - If other hurdles are overcome, and such investment is possible, note that States such as Florida, Pennsylvania and Arizona require that physicians make certain disclosures to patients before a patient is referred to an entity in which the physician is an investor. See PA code § 23.10; Fla. Stat. § 456.052; Ariz. Rev. Stat. § 32.

In-Office Dispensing – State Laws

- For example, in Florida, the disclosure of the investment interest must be made in writing and notify the patient of their right to receive the services from the provider of their choice, as well as a list of the names and addresses of at least two alternative sources. Fla. Stat. § 456.052.
- An additional law under the Florida Medical Practice Act makes it criminal to fail to make certain investment disclosures.
- Accordingly, physicians must consider whether: (1) it is permissible under state laws to refer one of their patients to a pharmacy or dispensing practice where they are an owner or an investor; and (2) if so, whether appropriate investment disclosure compliance must be implemented in connection with the in-house pharmacy venture.
Physician Investing in Pharmacy Management Company (Stark)

- **Stark**: Assuming that the pharmacy management company is not owned by a pharmacy, there are no Stark implications because management company is not providing any DHS services.
- If pharmacy management company is owned by a pharmacy to which the practice refers business, then potential Stark implications.
- See circumvention scheme above.

Physician Investing in Pharmacy Management Company (Antikickback)

- **Antikickback**: If management company is not owned by a pharmacy – no kickback issue. However, if there is pharmacy ownership, antikickback might be implicated if the physician is getting returns on his investment in the pharmacy management company that are based, directly or indirectly, on money that the pharmacy management company comes from the physician's referrals for federal health care business.
- Percentage based payments to the management company that vary with business generated by the physician are a problem because the physician's distribution from investment would vary with volume of referrals.
- Exceptions: May be Personal Services and Management Contracts (42 C.F.R. § 1001.952(d)).

Physician Investing in Pharmacy Management Company (State Laws)

- **State Law**
  - Also consider state fraud and abuse law
  - Be aware of percentage fees. They may be considered illegal fee splitting.
  - Make sure unlicensed management company is not doing activities which would constitute the unlicensed practice of the pharmacy.
Main Takeaways

• If any of the arrangements don’t fit squarely within the antikickback safe harbors, they are not per se illegal – just greater risk.

• BUT if any of the arrangement do not fit squarely under the Stark exceptions, then exposure to strict liability.

• Failure to comply with Stark or antikickback statutes can form a basis for potential False Claims Act actions.

Reimbursement Issues

• Coverage of drugs often varies between different payors so the types of drugs that are reimbursed and the payment policies vary accordingly.

• Coverage for outpatient prescription drugs offered by public payors:
  • Medicare Part B (does not generally pay for drugs that can be self-administered; see 42 C.F.R. 410.29(a)).
  • Medicare Advantage (specific coverage of drugs offered under the plan benefit);
  • Medicare Part D (drugs typically tiered on formularies);
  • Medicaid (each state's program typically has a formulary of covered drugs);
  • Tricare (also uses formulary and offers some coverage for compounded drugs).

• Coverage for outpatient prescription drugs offered by private payors:
  • Pharmacy benefit managers (PBMs) – negotiated prices for drugs on formularies
  • Commercial payors – limitations on the types of drugs covered (often use formularies)

Special Issues for Compounding Pharmacies

• Coverage of compounded drugs:
  • Certain federal payors (i.e. TRICARE) may cover these drugs. Medicare Part D only provides coverage for compounded drugs that are prescribed for a "medically accepted indication". Reimbursement is limited to FDA approved component(s) of the compounded medication. Most compounded drugs are made from bulk powders, which are not FDA approved, and are not covered under Part D. Coverage of compounds under Part C is not clearly defined – seems to be up to the individual insurer to set the payment policy.
  • Kickback: Implicated if physicians have ownership interest in the compounding pharmacies and they refer to those pharmacies.
  • Potential False Claims actions based on medical necessity for compounding laws – are the drugs actually efficacious?
Special Issues for Compounding Pharmacies

Compounding pharmacies have been subject to recent scrutiny:

- FCA settlement of $3.8 million with a compounding pharmacy in Florida (Medi Mix, LLC) the top biller for compounded pain medication (to TRICARE) for submission of claims to TRICARE for compounded drugs referred from a physician whose wife was an officer of the pharmacy and the drugs prescribed were not “individually prescribed or dispensed by a bona fide treating physician for a specific medical condition. . . .” The Department of Defense Special Agent in Charge stated that “fraud and abuse by pharmacies and medical providers for compounded pain prescriptions [are] a significant threat. . . .”
- In October, 2014, government agents raided OK Compounding Pharmacy located near Tulsa pursuant to a search warrant. The search was based on a multi-agency health care fraud investigation of the compounding pharmacy. No arrests were made at the time this article was published.
- In December, 2014, the DEA registration of Westchase Compounding Pharmacy was deactivated following a raid of the Tampa based pharmacy. During the DEA raid, agents seized eleven boxes of controlled substances. Following their DEA registration deactivation, the pharmacy’s attorneys obtained a temporary restraining order against the DEA and initiated a suit for the DEA’s failure to follow proper raid procedures. However, following a settlement between the parties, the suit was ultimately dropped. The DEA agreed to reinstate the pharmacy’s registration under the condition that the pharmacy follow the law. According to the article, there were no criminal charges filed against the pharmacy.
- In February, 2016, four northeast Florida physicians who ran a compounding pharmacy settled with the Department of Justice for $10,000,000. The government alleged fraudulent claims submitted to TRICARE for compounded medications. Many patients claimed creams not used. Cost of the creams 4-5% of amount billed. Shared up to 40% of revenue with referring physicians. Physicians claimed conducting a research study but no results published and no patients informed.
GAO Report on Payment Practices of Compounded Drugs - October 2014

Why did GAO conduct this report?
- Compounded drugs may have one or more of their ingredients may not be approved by the FDA, which affects potential safety and effectiveness.
- Members of Congress are concerned about variables in prices and payment practices.

What did GAO examine?
- Medicare, Medicaid, private health insurance, and state and local payment practices for compounded drugs dispensed in pharmacies.

What did GAO find?
- Payment practices vary across Medicare, Medicaid, and private health insurance.
- Compounded drugs dispensed in pharmacies:
  - Claims for these compounded drugs have sufficient information to identify the compounded drug and its ingredients.
  - As a result, payors can readily determine whether or not the compounded drug and its ingredients are covered.

Compounded drugs dispensed in outpatient settings:
- Claims for these compounded drugs do not have billing codes and therefore do not have sufficient information to identify the compounded drugs and their ingredients.
- As a result, most payors do not pay for these compounded drugs and its ingredients.
- It is unknown how many compounded drugs are dispensed in the outpatient setting.

GAO Report on Payment Practices of Compounded Drugs - October 2014 (Findings and Recommendation)

Medicare Part B payment policy
- Medicare Part B payment policy for compounded drugs does not specify whether payment is available for non-FDA-approved bulk drug substances.
- Medicare Part B claims contractors do not collect information on FDA approval status of ingredients.
- Because Medicare Part B payment policy is unclear on whether payment is available for non-FDA-approved ingredients and contractors do not collect FDA approval information, CMS may have paid for compounded drugs inconsistently with its payment policy.

GAO’s recommendation
- CMS should clarify its Medicare Part B payment policy to clearly allow or restrict payment for non-FDA-approved bulk drug substances.
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