HOT BUTTON ISSUES FACING PHARMACIES IN THE NEXT 12 MONTHS

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Collaboration with Physicians

INTRODUCTION

There are two overriding reasons for a pharmacy desiring to collaborate with a physician.

Coordination of Care

- ✓ Historically, health care remuneration has been based on the fee-for-service (“FFS”) model.
- ✓ Under the FFS model, providers are paid for the services and products they provide … regardless of patient outcome.
- ✓ Under this model, there is little coordination among the providers treating the same patient.
- ✓ The FFS model has proven to be expensive and inefficient.
- ✓ As such, third party payors (“TPPs”) are pushing providers into the collaborative care (“CC”) model.
- ✓ Under the CC model, providers are expected to coordinate with each other with the goal of healing the patient and keeping the patient healthy.
- ✓ Therefore, pharmacies, physicians and other providers are motivated to work with each other.

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INTRODUCTION

Generate referrals

- ✓ Physicians are important referral sources for pharmacies
- ✓ If a physician knows the pharmacy and is confident in the pharmacy's abilities to service patients, then it is likely that the physician will refer patients to the pharmacy.
- ✓ However, if the collaborative relationship results in remuneration ("anything of value") to the physician, then federal and state anti-fraud laws are implicated.
- ✓ As such, it is important that collaborative relationships fall within exceptions or "safe harbors" to the anti-fraud laws.
- ✓ Note that most of the legal guidelines contained in these slides also apply to Nurse Practitioners and Physician Assistants.

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Collaboration with Physicians: Anti-Fraud Laws

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FEDERAL ANTI-KICKBACK STATUTE

The federal anti-kickback statute ("AKS") prohibits a pharmacy from giving "anything of value" to a physician in exchange for the physician (i) referring federal health care program ("FHP") patients to the pharmacy, (ii) arranging for the referral of FHP patients to the pharmacy, or (iii) recommending the purchase of a service or product from the pharmacy that is covered by an FHP. The term "anything of value" is quite broad and includes (i) payment of money, (ii) payment of expenses, and (iii) providing gifts.

A violation of the AKS is a criminal offense. But there are a number of "safe harbors" to the AKS. If an arrangement falls within a safe harbor, then as a matter of law, the AKS is not violated. If an arrangement does not fall within a safe harbor, that does not necessarily mean the AKS is violated; rather, it means that a thorough examination of the arrangement will need to be made under the wording of the AKS, court decisions, and other published legal guidance.

FEDERAL STARK PHYSICIAN SELF-REFERRAL STATUTE

The federal Stark physician self-referral statute ("Stark") prohibits a physician from referring Medicare and Medicaid patients, for designated health services ("DHS"), to a pharmacy with which the physician (or an immediate family member of the physician) has a financial relationship—unless the financial relationship fits within a Stark exception.

The term "financial relationship" includes (i) an ownership interest by the physician (or an immediate family member of the physician) in the pharmacy and/or (ii) compensation (or anything else of value) from the pharmacy to the physician (or an immediate family member of the physician).

FEDERAL STARK PHYSICIAN SELF-REFERRAL STATUTE

DHS includes prescription drugs.

Violation of Stark results in civil liability.

There are a number of exceptions to Stark, including the Non-Monetary Compensation Exception ("NMC Exception") that allows a pharmacy to spend money each year on gifts, meals and entertainment for a physician—so long as the amount spent does not exceed a set amount. For 2020, that amount is $423.

STATE ANTI-FRAUD LAWS

In addition to federal laws, there are state laws that need to be examined. These include:

- ✓ State anti-kickback statutes - Some statutes apply only when the payor is the state Medicaid program. Other statutes apply even if the payor is a commercial insurer or a cash-paying patient.
- ✓ A number of states have physician self-referral statutes that are similar to Stark.
- ✓ Each state has a set of statutes that are specific to physicians.

Health care attorneys can fairly easily locate these state laws. The non-attorney can obtain a basic understanding by going to Google, typing in the name of the state, and then typing in the following key words: kickback, anti-kickback, referral, fee splitting, patient brokering and/or self-referral.

Examples of Collaborative Arrangements

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CLINICAL STUDY

The pharmacy and physician can participate together in a clinical study.

Ideally, the clinical study will be sponsored by a hospital or medical school and will be overseen by an Institutional Review Board ("IRB"). It is important that the clinical study not be a disguised kickback scheme designed to funnel compensation to referring physicians.

The pharmacy can use the results of the clinical study to show physicians, hospitals and third-party payors (i) that the pharmacy has a sophisticated business model and (ii) that the pharmacy's products and services are successful in treating conditions and keeping patients out of the hospital.

MEDICAL DIRECTOR

A physician (regardless of whether or not he is a referring physician) can be a 1099 independent contractor Medical Director for the pharmacy.

If the physician refers to the pharmacy, then the Medical Director Agreement ("MDA") needs to comply with (i) the Personal Services and Management Contracts safe harbor to the AKS and (ii) the personal services exception to Stark.

- ✓ Among other requirements, (i) the MDA needs to be in writing, (ii) the MDA must have a term of at lease one year, (iii) the compensation must be fixed on year in advance, and (iv) the compensation must be the fair market value ("FMV") equivalent of the physicians' services … and cannot take into account the anticipated number of referrals from the physician to the pharmacy.
- ✓ Further, the services provided by the physician to the pharmacy must be substantive and valuable. They cannot be "made up" 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.

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SPONSORING THE PHYSICIAN AS A SPEAKER

The pharmacy can pay the physician for speaking at educational workshops and dinners.

In order to avoid problems with the AKS and Stark:

- ✓ The topic presented by the physician must be substantive and relevant to the audience.
- ✓ The audience must be made up of individuals who will benefit from what the physician has to say.
- ✓ The compensation to the physician must be FMV.

RENTING SPACE TO/FROM A PHYSICIAN

The pharmacy can rent space from or to a physician.

The arrangement needs to comply with the Space Rental safe harbor to the AKS and the space rental exception to Stark. The safe harbor and exception say the same thing. Among other requirements:

- ✓ The rental agreement must be in writing with a term of at least one year.
- ✓ The rent paid must be fixed one year in advance and be FMV.

EMPLOYEE LIAISON

- The pharmacy can place an employee liaison in the physician's office. The liaison can be present in the physician's office for as many or as few hours as the physician and pharmacy agree on.
- The employee liaison cannot perform any duties that the physician is responsible to perform. Doing so will save the physician money, which constitutes "something of value" to the physician—hence, a violation of the AKS.

EMPLOYEE LIAISON

Examples of what the liaison can and cannot do are:

- ✓ The liaison can educate the physician's employees regarding the products and services provided by the pharmacy. The liaison can do so through formal educational lunches and through informal one-on-one conversations with the physician's employees.
- ✓ The liaison can educate the physician's patients regarding the products and services provided by the pharmacy. The liaison can do so by presenting formal educational workshops and through informal one-on-one conversations with the physician's patients.
- ✓ If a patient of the physician decides that he/she will use the pharmacy, then the liaison can work with the patient to transition him/her to the pharmacy.

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EMPLOYEE LIAISON

Unless the physician pays fair market value compensation to the pharmacy for the liaison's services:

- ✓ The liaison cannot handle preauthorization calls on behalf of the physician.
- ✓ The liaison cannot provide billing services on behalf of the physician.
- ✓ The liaison cannot provide data input services on behalf of the physician.

Sponsoring Physicians at Educational Events

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HYPOTHETICAL SCENARIOS

Scenario #1

Dr. Smith refers federal health care program ("FHCP") patients to ABC Pharmacy. Dr. Smith requests ABC to sponsor his trip to a conference in Palm Springs.

Scenario #2

ABC is holding its annual meeting in Aspen in July for its employees. ABC asks Dr. Jones to speak at the annual meeting. Dr. Jones refers FHCP patients to ABC. In so doing, ABC offers to (i) pay Dr. Jones for his time in preparing for and presenting his program and (ii) reimburse Dr. Jones for his travel expenses.

ANALYSIS OF SCENARIO #1

Dr. Smith refers FHCP patients to ABC. If ABC compensates Dr. Smith, then the transaction creates a financial relationship between Dr. Smith and ABC. As such, the arrangement violates Stark unless an exception is met.

ABC would like to reimburse Dr. Smith for his expenses in attending the Palm Springs conference. The Nonmonetary Compensation exception only applies to compensation paid to a physician in the form of items or services, not cash or cash equivalents. Further, Dr. Smith reached out to ABC to request the compensation. The exception does not apply if the physician solicits an entity for the compensation. Accordingly, the arrangement does not fall within the Nonmonetary Compensation exception.

ANALYSIS OF SCENARIO #1

This scenario also would likely not meet the PSA exception or the FMV exception. Both exceptions require the physician to provide a service to the entity. Dr. Smith's attendance at the Palm Springs conference does not constitute a "service" for ABC.

Dr. Smith refers FHCP patients to ABC, and if ABC agrees to cover some of Dr. Smith's expenses to attend the Palm Springs conference, then Dr. Smith is receiving renumeration … thereby implicating the AKS. To avoid problems under the AKS, the arrangement would need to meet an AKS safe harbor. Because Dr. Smith is not providing a service to ABC, the PSMC safe harbor is not met.

ANALYSIS OF SCENARIO #2

Like the first arrangement, Dr. Jones refers FHCP patients to ABC and a financial relationship will form if ABC compensates Dr. Jones. As such, the arrangement implicates Stark unless an exception is met.

Unlike the first arrangement, Dr. Jones is providing ABC a service by speaking at an ABC sponsored meeting attended by ABC's employees. The purpose of his presentation is to educate and train the ABC employees on clinical and related issues.

Since Dr. Jones is providing ABC a service, the arrangement can be structured to fall under the PSA exception. The written agreement must include: (i) a detailed description of Dr. Jones's presentation, how it will be given, and the intended audience; (ii) a set compensation amount that is fair market value; and (iii) an agreement term for not less than one year. The PSA exception also requires that the service be reasonable and necessary for the legitimate business purposes of the arrangement.

ANALYSIS OF SCENARIO #2

ABC's arrangement may also fall within the FMV exception. It is reasonable to assume that Dr. Jones's presentation will be commercially reasonable and furthers a legitimate business purpose. Note that the FMV exception also requires compliance with the AKS. The arrangement can be structured to comply with (or substantially comply with) the PSMC safe harbor. This is so long as the arrangement is put in writing and the agreement includes the safe harbor's requirements.

To reduce the risk of an enforcement action, ABC should include significant detail on the amount of time Dr. Jones will be paid to prepare and give his presentation. For example, the agreement can require Dr. Jones to submit his presentation for approval by ABC prior to the Aspen meeting. The agreement should also limit Dr. Jones's expenses to reasonable amounts and require Dr. Jones to submit an invoice of his time and expenses to ABC. This will allow ABC to review Dr. Jones's expenses and ensure that his costs are reasonable and within the compensation amount set forth in the agreement. Only after ABC's review and approval of the invoice should ABC compensate Dr. Jones.

ANNUAL WELLNESS VISITS (AWVS)/REMOTE PATIENT MONITORING (RPM)/CHRONIC CARE MANAGEMENT (CCM)

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.

Preparing for a PBM Audit

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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

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 by alerting the PBM in advance of the change in the pharmacy’s billing pattern.

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.

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.

Mindset in Responding to a PBM Audit

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MINDSET

The pharmacy's approach should be "Let's solve the problem" as opposed to being defensive and attempting to "win an argument." This approach is necessitated by the following:

There is an old saying: "Possession is 9/10ths of the law." At the end of the day, the PBM possesses the pharmacy's money. Regardless of whether the PBM is right or wrong, if it refuses to pay the pharmacy for new claims or recoups money previously paid to the pharmacy, then the pharmacy will financially suffer.

- ✓ Possessing the pharmacy's money places the PBM in a superior negotiating possession.
- ✓ The PBM has more money than the pharmacy and, as such, is better able to afford to "lawyer up."
- ✓ The PBM can terminate the pharmacy contract without cause. Thus, if the pharmacy engages in an overly-aggressive approach with the PBM, then there is a risk that the PBM will exercise its termination right.

THE DEADLINE

The letter from the PBM will give a deadline by which the pharmacy is to respond.

- ✓ The letter may give a specific date (e.g., February 24, 2020).
- ✓ The deadline may be something like “30 days from the date of this letter”
- ✓ The deadline may be something like “30 days from the date of your receipt of this letter.”

If the deadline is “30 days from date of this letter,” then the pharmacy needs to carefully note the date of the letter. It is not uncommon for the pharmacy to receive the letter 10-14 days from the date that the PBM mails the letter.

- ✓ Thus if the date of the letter is February 5, and if the pharmacy must respond within the 30 days from the date of the letter, but if the pharmacy does not actually receive the letter until February 20, then the pharmacy has less than 15 days to respond.

DETERMINING THE DEADLINE AND ASKING FOR AN EXTENSION

If the deadline is “30 days from date of your receipt of this letter,” then the pharmacy needs to determine the date that it received the PBM letter. Because the PBM does not know the exact date that the pharmacy receives the letter, then there is a risk that if the pharmacy submits its response within 30 days from the date that the pharmacy received the letter, the PBM will take the position that the pharmacy’s response was not timely. Therefore, to be safe, and assuming that the pharmacy received the PBM letter just a couple of days from the date of the letter, then the pharmacy should respond to the audit within 30 days from the date of the letter, not from the date of receipt of the letter.

It is reasonable for the pharmacy to ask for a on-time extension…usually, a 10 - 14 extension. It is not unusual for a PBM to grant such an extension. If the PBM does grant an extension, it is important that the pharmacy obtain confirmation of such extension in writing from the PBM (usually in the form of an email).

PBM Audit:
Hire a Health Care Attorney

ROLE OF THE ATTORNEY

It is important that at the outset, the pharmacy hire a health care attorney who has experience in responding to PBM audits. It will do the pharmacy no good…and will probably cause harm…if the pharmacy hires an attorney with no experience in dealing with PBMs. The health care attorney can (i) assist the pharmacy in organizing an effective response to the audit and (ii) work with the pharmacy to avoid costly mistakes.

ROLE OF THE ATTORNEY

Working together, the pharmacy and its health care attorney have three goals:

- ✓ Work with the pharmacy to ensure that it submits an effective audit response.
- ✓ Avoid the scenario in which the PBM concludes that the pharmacy has committed fraud and, therefore, the PBM turns its documents over to the U.S. Department of Justice and/or the state's Attorney General's Office.
- ✓ Avoid an extrapolated audit. An extrapolation occurs when the PBM reviews what it believes is a statistically valid sample of patient files and determines that x% of the reviewed files are deficient. At that point, the PBM will "extrapolate" by applying that percentage to all of the pharmacy's files pertaining to the product made the subject of the PBM audit. This can result in a relatively small dollar-for-dollar overpayment becoming a very large overpayment.

Determining What the PBM is Focusing on

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WHAT THE PBM IS FOCUSING ON

Hopefully, the pharmacy can determine from the PBM letter what it is that the PBM is focusing on.

If from the way the letter is worded, the pharmacy cannot determine what the PBM is focusing on, then the pharmacy should contact the PBM with the goal of making this determination. There will be occasions where the PBM will be forthcoming. But there will be occasions when the PBM simply says: "We don't have to tell you that. You just need to send us the documents we have asked for." In this instance, all the pharmacy can do is make an educated guess.

In the past, the PBM's primary focus was on whether the pharmacy (i) received a valid prescription, (ii) dispensed the drug in accordance with the prescription, and (iii) submitted the claim for exactly what was dispensed.

- ✓ This type of inquiry was in line with what most providers believe an audit should be (i.e., whether the pharmacy's documents are correct).

WHAT THE PBM IS FOCUSING ON

However, recently PBM audits resemble investigations more than they resemble documentation audits.

- ✓ The audit may request the pharmacy's documentation to determine if the pharmacy received a valid prescription, dispensed the drug in accordance with the prescription, and billed for exactly what was dispensed.
- ✓ But most audits will go beyond basic documentation questions and ask for documentation/information designed to allow the PBM to determine if the pharmacy (i) is in compliance with the terms of the PBM contract and collateral documents (e.g., PBM policies and procedures) incorporated by reference in the PBM contract and (ii) is engaged in fraudulent activities.

PBM Audit:
Compliance with Contract

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COLLATERAL DOCUMENTS

The pharmacy's contract with the PBM contains several obligations that the pharmacy must meet. Such obligations are found in the contact itself. But in addition, the contract will likely contain a clause that says something like the following: "Pharmacy agrees to abide by the provisions of PBM's policies and procedures, including PBM's coverage policies."

- ✓ These "collateral documents" are as much a part of the contract as the wording contained in the contract itself.

MAIL ORDER

Most, if not all, PBMs have their own mail-order pharmacies. They do not like pharmacies, that are in network, to compete with the PBMs' mail-order pharmacies. As such, most in-network pharmacies are in the PBM's retail network, not in the PBM's mail-order network.

The contract between a PBM and a retail pharmacy will likely contain one of the following provisions:

- ✓ Pharmacy will not ship drugs via mail-order.
- ✓ Not more than __% of pharmacy's dispensed drugs will be via mail-order.
- ✓ Not more than __% of pharmacy's gross annual revenue will be derived from mail-order.

COMPOUNDING

Several years ago, PBMs “got burned” by a number of compounding pharmacies.

- ✓ The compounding pharmacies aggressively marketed compounded pain and scar creams.
- ✓ When the compounding pharmacy received a prescription for compounded pain or scar cream, then the pharmacy would create a 30-day tube of the cream and ship the tube to the patient.
- ✓ The compounding pharmacy would then submit a claim (for a ridiculous amount of money) to the PBM. And the PBM would pay the amount of the claim submitted by the pharmacy.
- ✓ PBMs eventually put a stop to this business practice. Now, most PBM contracts either do not allow compounding at all or allow compounding only in a limited capacity.

COLLECTION OF COPAYMENTS

In addition to inquiring if the pharmacy is meeting the terms of the PBM contract, audits today ask questions that normally would be asked by a government agency conducting an investigation.

An example pertains to collection of copayments.

- ✓ As it pertains to federal health care program ("FHCP") patients, federal law requires a pharmacy to make a reasonable attempt to collect copayments…and to reduce/waive a copayment on a patient-by-patient basis only if the patient establishes an inability to pay all or or a portion of the copayment. If a pharmacy routinely reduces or waives copayments for FHCP patients, then the pharmacy will likely violate the federal anti-kickback statute ("AKS") and the federal beneficiary inducement statute.

COLLECTION OF COPAYMENTS

Most states have similar laws that apply to commercial insurance patients.

And a number of PBM contracts have a provision that requires a pharmacy to make a reasonable attempt to collect copayments…and to reduce/waive a copayment on a patient-by-patient basis only if the patient establishes an inability to pay all or a portion of the copayment.

In order to determine if the pharmacy is meeting its obligation to attempt to collect copayments, in the audit the PBM may ask the following question: “Does your pharmacy ever waive or offer a reduction of member copayments? If yes, please provide a copy of your written policy relating to the waiver/reduction of copayments.”

COLLECTION OF COPAYMENTS

The AKS makes it a felony to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce a person or entity to refer an individual for the furnishing or arranging for the furnishing of any item or service reimbursable by an FHCP, or to induce such person to purchase or lease or recommend the purchase or lease of any item or service reimbursable by an FHCP.

If a pharmacy pays commissions to 1009 independent contractor marketing reps in exchange for the generation of FHCP patients, then the pharmacy likely violates the AKS.

On the other hand, if a W2 employee marketing rep generates FHCP patients for the pharmacy, and if the pharmacy pays discretionary bonuses to the employee that are based, in part, on the generation of FHCP patients, then the risk of violating the AKS is low. This is because of the employee exception and safe harbor to the AKS.

MARKETING

The AKS makes it a felony to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce a person or entity to refer an individual for the furnishing or arranging for the furnishing of any item or service reimbursable by an FHCP, or to induce such person to purchase or lease or recommend the purchase or lease of any item or service reimbursable by an FHCP.

If a pharmacy pays commissions to 1009 independent contractor marketing reps in exchange for the generation of FHCP patients, then the pharmacy likely violates the AKS.

On the other hand, if a W2 employee marketing rep generates FHCP patients for the pharmacy, and if the pharmacy pays discretionary bonuses to the employee that are based, in part, on the generation of FHCP patients, then the risk of violating the AKS is low. This is because of the employee exception and safe harbor to the AKS.

AFFILIATED PHARMACIES

There is a saying in Western Lore: “That cowboy is trying to stay one step ahead of the posse.”

Some pharmacies have taken that saying and have applied it to how they conduct business. For example:

- ✓ John Smith owns ABC Pharmacy.
- ✓ Smith is aware that a PBM will likely terminate ABC’s contract.
- ✓ And so Smith will open up XYZ Pharmacy, XYZ will secure a contract with the same PBM, and ABC will transfer its patients to XYZ.

AFFILIATED PHARMACIES

With the goal of uncovering this type of scheme, in an audit the PBM may ask the following questions:

- ✓ Is your pharmacy directly or indirectly affiliated with any other pharmacies?
- ✓ List the identity of any person who has a direct or indirect ownership interest in your pharmacy.
- ✓ Do any of the pharmacy owners have a direct or indirect ownership interest in any other pharmacy?

AFFILIATED PHARMACIES

Have any of the owners, members, principals, officers or directors of your pharmacy owned any other pharmacies? If yes, please attach a list of the pharmacies, their NCPDP numbers, and the names of the owners, entity members, principals, officers and directors.

Has your pharmacy ever changed names? If yes, please attach a list of the previous names, NCPDP numbers, if different, and the dates of the name changes.

Has your pharmacy ever undergone a change in ownership? If yes, please provide a list of the previous owners' names, ownership dates, and NCPDP numbers, if different.

DISCIPLINARY ACTIONS

With many audits, PBMs want to determine if the pharmacy has had problems with government regulatory agencies. If the PBM determines that such problems do exist, then the PBM may not want the pharmacy in its network.

With the goal of discovering disciplinary actions, in an audit the PBM may ask the following questions:

- ✓ Has your pharmacy (or another pharmacy affiliated with your pharmacy) been disciplined by a State Board of Pharmacy, government entity or any other regulatory authority (i.e., State or Federal DEA or State Medicaid Program)? If yes, please attach explanation of action taken, Board order or letter, and any other supporting documents from the State Board of Pharmacy, government entity, or other regulatory authority.

DISCIPLINARY ACTIONS

- ✓ Have any of your pharmacists, pharmacy technicians, owners or employees been disciplined by the State Board of Pharmacy, a government entity, or any other regulatory authority (i.e., State or Federal DEA or State Medicaid Program) in the last 10 years?
- ✓ Presently, or at any time in the last 10 years, has your pharmacy, its owners, principals, or any of your pharmacists been the subject of a civil lawsuit or criminal prosecution involving fraud, receipt, deception, or a similar offense involving moral turpitude?

PGM Audit:
Review, Organize, and Rehabilitate

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REVIEW THE FILES TO BE SUBMITTED

The pharmacy needs to carefully review each document to be submitted. In doing so, the pharmacy needs to determine if the document complies with PBM coverage guidelines. These guidelines can be found in the pharmacy's contract with the PBM and in collateral documents that are incorporated by reference in the contract.

It is human nature for the pharmacy not to be objective as it reviews its patient files. As such, it is wise for the pharmacy to have a health care attorney or a consultant review the patient files.

REVIEW THE FILES TO BE SUBMITTED

If the pharmacy desires to hire a consultant to review patient files, but the pharmacy is concerned that the consultant will find serious problems with the files, and if the pharmacy is further concerned that the consultant's work and findings are not protected by the attorney-client privilege, then the pharmacy may want to take the following steps:

- ✓ The pharmacy will hire an attorney to review the documents and assist the pharmacy in responding to the audit.
- ✓ The attorney will, in turn, hire the consultant. The consultant will work for the attorney, not for the pharmacy. Assuming that the attorney and pharmacy take the proper steps to protect the attorney-client privilege, then the consultant's findings do not have to be disclosed…unless the pharmacy decides to disclose such findings.
- ✓ Normally, the pharmacy will not have a problem with the consultant's findings being disclosed to the PBM. However, in the event that the consultant finds evidence of fraud, then the pharmacy may want to protect such evidence with the attorney-client privilege.

ORGANIZE THE FILES TO BE SUBMITTED

When the pharmacy submits the requested files to the PBM, the files need to be organized in such a way that they tell a clear, concise story.

The pharmacy cannot assume that the PBM employee (who reviews the files) will be as sophisticated as the pharmacy employee who submitted the files. If the PBM employee cannot understand a file, then he/she will likely fill in the blanks with his/her imagination. In order to avoid this, the files should be organized in such a way that they will be easy for the PBM employee to understand.

PBM Audit:
Submission of Documents

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TELL A STORY

When they are submitted, the patient files should be organized in such a way that they "tell a story." The story that the pharmacy wants the files to tell is that (i) each product delivered to a patient was in response to a valid prescription, (ii) the pharmacy dispensed the exact product that was prescribed, and (iii) the pharmacy billed only for the product that was dispensed. These are the "basics."

- ✓ If the basics are present, then if there is a deficiency with some aspect of the patient file, hopefully the PBM will overlook the deficiency and approve the claim.

REHABILITATE THE FILES TO BE SUBMITTED

In reviewing the files requested by the PBM, the pharmacy may conclude that some of them may be deficient. These are the files that the pharmacy concludes may trigger a recoupment.

If possible, the pharmacy should take steps to rehabilitate the deficient files. “Rehabilitation” entails securing contemporaneous documentation that fills in the gaps.

- ✓ For example, the pharmacy may determine that a physician’s prescription (that was issued a year ago) lacks important information. The pharmacy can approach the physician and ask him/her to sign a document that corrects the prescription. Such a document will need to be dated today (not the date of the original prescription) and should say that this current information “relates back” to the original prescription. Such a rehabilitation attempt may or may not work, but it is better than doing nothing.
- ✓ In rehabilitating documents, it is important that the pharmacy be honest and transparent (e.g., no back dating).

COPIES AND EXPLANATORY LETTER

When the pharmacy submits the requested documents to the PBM, the pharmacy needs to retain two sets of copies: one set for the pharmacy and one set for the pharmacy's attorney.

In some (but not all) instances, it is wise for the pharmacy to include an explanatory letter with the submitted documents. Such a letter will explain some of the points that are not clear on the face of the documents.

An explanatory letter needs to be from the pharmacy, not from the pharmacy's attorney. As a rule, PBMs do not want to deal with attorneys…unless they have no choice.

FOLLOW UP WITH THE PBM

After it submits its documents to the PBM, the pharmacy should follow up with the PBM to confirm that the PBM has timely received the documents.

In its follow-up phone call or email exchange with the PBM, the pharmacy should (i) represent to the PBM that the pharmacy can supplement the submitted documents as requested by the PBM and (ii) explain to the PBM that the pharmacy will be available any time that the PBM has questions.

Resolving conflict with PBMs: Key Takeaways

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TAKEAWAY #1

Corrective Action Plan

As is often the case, in a dispute with a PBM, "**the truth is in the middle.**"

The PBM normally has at least some credible evidence that the pharmacy has committed some mis-steps. On the other hand, the pharmacy normally has credible evidence that whatever mis-steps it has taken are not as egregious as the PBM thinks they are.

With the above in mind, the pharmacy should consider offering a robust Corrective Action Plan.

TAKEAWAY #2

Reconsideration

Sometimes the PBM contract and/or the PBM policies and procedures specifically allow the pharmacy to submit a reconsideration.

Even if the contract/policies do not discuss reconsiderations, the pharmacy should nevertheless request permission to file a reconsideration.

In submitting a reconsideration, the pharmacy should submit evidence and arguments designed to persuade the PBM to adopt a more conciliatory approach to resolving the issue with the pharmacy.

TAKEAWAY #3

Negotiated Settlement

As previously discussed, the PBM has more money than the pharmacy and it is easy for the PBM to "lawyer up."

Recognizing this disparate bargaining position, the pharmacy should consider entering a settlement with the PBM in which:

1. The PBM gains a victory
2. The pharmacy can "live to fight another day."

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TAKEAWAY #4

Try to Avoid Takeaways 1-3

The pharmacy's audit response should be thorough and persuasive enough to allow the pharmacy to not have to consider Takeaways 1-3.

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Defrauding PBMs: Criminal Liability

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INTRODUCTION

Pharmacies understand that if a pharmacy commits fraud pertaining to patients covered by a federal health care program ("FHCP"), then the pharmacy is potentially criminally liable under federal anti-fraud laws such as the federal anti-kickback statute ("AKS"), federal False Claims Act ("FCA"), mail and wire fraud, and related federal laws (e.g., conspiracy and money laundering). Many pharmacies understandably (but mistakenly) also believe that if a pharmacy commits fraud against a third-party payor not connected to an FHCP ("Private Payor"), then there is no federal criminal liability. This is an illusory belief. As will be discussed below, a federal criminal statute extends to health care fraud involving Private Payors.

Recently, a criminal "Information" was filed in federal district court against an individual ("John Smith") and others. An Information sets out the criminal charges that the U.S. Department of Justice ("DOJ") asserts against individuals and companies. An Information is similar, but not the same as, an Indictment.

INTRODUCTION

The Information focuses on (i) Smith, owner and manager of a company ("ABC"), and (ii) ABC's relationship with a pharmacy ("XYZ"). The Information also focuses on two other unidentified pharmacies.

The alleged criminal arrangement was complex as there were various steps for each process and alleged multiple attempts to "hide and/or fix the paper trail" that the arrangement was leaving. Allegedly, ABC and XYZ created a sham manufacturer "coupon" system that was intended to remove beneficiary copayment obligations. Most, if not all, PBMs require participating pharmacies within their network to make a reasonable attempt to collect copayments from patients. PBMs prohibit pharmacies from waiving or reducing the patient copayment requirement unless the patient can establish a financial inability to pay. This prohibition is contained in the agreements that pharmacies enter into with PBMs. If a pharmacy routinely waives/reduces copayments, then it is at risk for (i) a PBM audit and (ii) possible termination of the pharmacy's contract with the PBM. In addition, as shown by the Information, implementing an arrangement designed to avoid collecting copayments can lead to criminal liability.

INTRODUCTION

The ABC/XYZ arrangement departs from most known copayment arrangements because ABC and XYZ were implementing the arrangement allegedly to defraud Private Payors such as Aetna and Blue Cross Blue Shield. Contrary to common belief, arrangements within the private, third-party payor sphere are not immune from federal government scrutiny or enforcement. This can be seen in the Information as the DOJ is focusing on broad definitions of health care programs and health care fraud under 18 U.S.C. 1347.

SPECIFIC CHARGES

The specific charge against Smith reads as follows: “[T]he defendant, [Smith], did knowingly and willfully, that is, with the intent to further the object of the conspiracy, combine, conspire, confederate, and agree with [the owner of XYZ] and other persons known and unknown to the United States Attorney, to knowingly and willfully execute a scheme and artifice to defraud a health care benefit program affecting commerce, that is, as defined in Title 18, United States Code, Section 24(b), and to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of such health care benefit programs, in connection with the delivery of and payment of health care benefits, items and services, in violation of Title 18, United States Code, Section 1347.”

SPECIFIC CHARGES

The DOJ is alleging that Smith created a platform where pharmacies could apply a manufacturer's coupon towards the beneficiary's copayment. ABC served as the prescription benefit administrator to adjudicate the copayment portion of the cost of a prescription. This arrangement took place from June 2014 through January 2016, and the DOJ is alleging that the purpose of the arrangement was to submit or cause to submit false and fraudulent claims to health care benefit programs (i.e., Private Payors).

LESSON FOR PHARMACIES

The Information shows that the federal government can reach beyond federal health care programs to police the entirety of the health care industry. Section 18 of the United States Code is aptly named “Crimes and Criminal Procedure,” and the government use of the specific health care provision Section 1347 demonstrates the government’s willingness to proceed against providers that defraud commercial insurers. By definition, a health care benefit program includes private insurance plans (e.g., Blue Cross Blue Shield) affecting commerce and supplying health care items or services. Section 1347 makes it illegal to defraud such a program. Violations of this particular section can result in fines or imprisonment (up to 20 years) or both. It is also important to note that a person does not need “actual knowledge” or intent to commit a violation of this section to be prosecuted under it.

LESSON FOR PHARMACIES

For many reasons, it is important that the pharmacy be legally compliant in everything it does. It is important that the pharmacy understand that if it "proceeds down the slippery slope" and engages in actions that, if a FHCP was involved, would clearly violate a federal anti-fraud statute, such actions can nevertheless result in criminal liability even if no FHCP is in the picture. In the Information, ABC and XYZ allegedly implemented an arrangement (a "scheme" in the eyes of the DOJ) that defrauded commercial insurance companies. In working with Private Payors, pharmacies should not engage in acts that, if a FHCP was involved, would violate a federal anti-fraud statute.

Entering the CBD Arena

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THE KEY TERMS

Cannabis – Cannabis is a genus of flowering plants, which contain compounds called cannabinoids. There are numerous cannabinoids in cannabis plants, but the most studied cannabinoids are (1) THC and (2) CBD.

THC (delta-9-tetrahydrocannabinol) – This is the psychoactive component of cannabis that is the primary cause of the “high” associated with cannabis in recreational users. THC has long been thought to have some medical benefits.

THE KEY TERMS

CBD (Cannabidiol) – This is a cannabinoid that some think has more potential medical benefits than THC but with minimal psychoactive effects. CBD does not cause a “high.”

CBD Oil – CBD Oil is derived from the cannabis plan through a distilling process.

Marijuana – In the most basic form, marijuana is made of the dried flower buds of cannabis plants, which contain the highest concentrations of THC.

Hemp – Hemp is a cannabis plant, particularly used for the soft fiber derived from the stalk of the plant. THC is present in hemp in trace amounts. In the United States, to be classified as “hemp,” the government requires that it contain no more than 0.3% THC.

WHAT DISTINGUISHES CBD PRODUCTS?

CBD

Does not create a “high”

Under federal law, legal CBD products in the U.S. are derived from hemp; state laws may also allow marijuana-derived CBD

Typically said to treat seizures, depression, migraines, other mental disorders, and joint pain or swelling; both CBD and THC can be used to treat pain, anxiety, and nausea

Few known side effects. It may raise the level in the blood of certain medications.

Some research suggests that CBD is an inhibitor of CYP450 enzymes, common in drug metabolism, which creates more potential drug-to-drug interaction issues and safety concerns.

The World Health Organization (“WHO”) reports that CBD shows no effects to indicate abuse or dependence potential

THC and Marijuana

Does create a “high,” due to its psychoactive component

Marijuana has a higher THC than hemp

Potential medical uses include glaucoma, muscle spasticity, and insomnia. Both CBD and THC can be used to treat pain, anxiety, and nausea.

Potential side effects may include: slower than average response time, memory loss, feeling of being “high,” coordination issues, increased heart rate, dry mouth, and red eyes

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HOW CAN CBD BE TAKEN?

Inhalation (vaping or smoking) – This may expose the user to carcinogens from smoking and unknown potential long-term side effects of vaping

Sublingual Products – Sprays, oils, or lozenges that allow the CBD to be ingested without being subjected to the digestive track.

Edibles – These include gummies, truffles, mints, baked goods, drinks, etc.

Topicals – There are numerous CBD-infused lotions, balms, salves, and transdermal patches.

WHAT DOES CBD TREAT?

Childhood Epilepsy Syndromes – The strongest scientific support for CBD use is for childhood epilepsy syndromes, such as Dravet syndrome and Lennox-Gastaut syndrome, which do not respond to antiseizure medications. The FDA approved Epidiolex, which contains CBD, to aid patients with these conditions.

Anxiety, insomnia, other mental health issues – CBD is commonly used in association with these issues. There is, however, little scientific support.

Chronic Pain – A European animal study showed CBD applied to skin could lower pain and inflammation due to arthritis.

*There is still very little scientific research on the effectiveness of CBD and even fewer human studies. As the ability to access CBD and hemp increases, more studies will be conducted.

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FEDERAL LAW: THE 2018 FARM BILL

The Agriculture Improvement Act of 2018 (Farm Bill) was passed in December 2018.

It established a new category of cannabis: Hemp, defined as cannabis containing 0.3% or less of THC. The Act also noted that marijuana (a Schedule 1 illegal substance), as defined in the Controlled Substance Act (CSA), does not include “hemp.”

This does ***not*** make all CBD products legal under federal law.

The Farm Bill provides that state governments may create regulatory frameworks for industrial production of hemp.

WHAT CAN AND CANNOT BE DONE UNDER FEDERAL LAW?

The Farm Bill only legalized products derived from hemp that are produced in accordance with the Farm Bill, which requires hemp be grown by licensed producers pursuant to state or federal regulations.

The FDA Commissioner stated that the Farm Bill "explicitly preserved the FDA's current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug and Cosmetic Act and Section 351 of the Public Health Service Act."

So, what does this mean? If the CBD is derived from hemp produced in accordance with the Farm Bill, it *may* be legal under federal law, depending on the purpose for which it is grown.

To date, with the exception of Epidiolex, no product containing cannabis or cannabis-derived compounds has been approved as safe and effective for use in any patient population.

FEDERAL PITFALLS

CBD cannot be sold as a dietary supplement or food additive, according to the FDA, because CBD is the active ingredient in an FDA-approved drug, Epidiolex.

Until the FDA approves CBD as a supplement or food additive, there are legal risks, including licensure and DEA action, involved with selling these types of CBD products.

Unless dictated otherwise by state law, the CBD products currently on the market are not regulated. Unregulated CBD products are often the subject of poor quality control.

FEDERAL PITFALLS, CONT.

Some CBD sellers and manufacturers have made egregious, unproven claims about CBD products.

The FDA has issued numerous warning letters.

Some lessons can be derived from these warning letters:

- ✓Avoid CBD products with over-the-top therapeutic claims, such as that a CBD product may cure cancer, arthritis, Alzheimer's, bipolar disorder, or opioid addiction.
- ✓Avoid CBD products that make "drug-like" claims that they prevent, treat, or cure pain, anxiety, inflammation, etc.
- ✓Be aware that claims on social media are also being monitored and referenced in warning letters.

THE BOTTOM LINE UNDER FEDERAL LAW

At first glance, the Farm Bill appears to throw open the CBD door. Proceed with caution, however, because it becomes quickly apparent that the wide open door is largely an illusion.

Consider all the carve outs:

- ✓No products with THC over 0.3%
- ✓No unapproved health products, dietary supplements, or food (which means literally almost everything but the one drug approved by the FDA and possibly some topical items)

The FDA can pursue these violations, but it has limited staff for enforcement and only warning letters have been issued to date.

What are left are very few “legal” products under federal law.

WHAT ABOUT STATE LAW?

While federal law does not give clear guidance, state laws add another layer of complexity that pharmacies must wade through in evaluating whether or not to enter the CBD arena.

The answer to almost every question under state law is, “It depends.”

There are scenarios in which activities are legal under federal law but prohibited under state law … and vice versa.

To further complicate matters, a number of states have statutes that legalize CBD products derived from marijuana, with varying degrees of carve outs and regulations.

Even the “pitfalls” now have “pitfalls.”

STATE LAW LIMITATIONS

Does the state's law apply to all entities?

- ✓Each state's law is different. A state's law will normally specify who can grow, manufacture, or sell a CBD or THC product. A state's law may designate a process for licensure. In Kentucky, for example, there is not a limitation on who can have a CBD product derived from industrial hemp. However, CBD derived from marijuana is only excepted when "transferred, dispensed, or administered" pursuant to the order of a physician practicing at a hospital or clinic associated with a Kentucky public university or medical school.

Many state laws dictate when CBD can be dispensed by limiting its use to certain medical conditions or modifying the amount of THC a product can contain to be excepted from prosecution.

In light of the Farm Bill, many states are expanding the allowed use of hemp-based CBD.

WHAT DOES THE BOARD OF PHARMACY SAY?

Each pharmacy must check the Board of Pharmacy's rules for the state(s) in which the pharmacy operates.

For example:

- ✓The North Carolina Board of Pharmacy answered a question in its FAQ page stating pharmacies cannot legally sell CBD "supplements."
- ✓The West Virginia Board of Pharmacy initially voted to prohibit the sale of non-FDA approved CBD products in the pharmacy setting, but then withdrew that prohibition. It cautioned pharmacies to carefully consider the impact state and federal laws might have on sales and noted that over a third of the samples of CBD oil tested contained THC, a Schedule 1 controlled substance.

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FDA Inspections and Responses

FDA INSPECTION: OVERVIEW

Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 374(a)(1).

It allows FDA investigators to enter, at reasonable times, facilities in which drugs are manufactured, processed, packed, or held for introduction into interstate commerce.

In addition, Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act allows the FDA to request, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, any records or other information that may be inspected under Section 704(a).

FDA INSPECTION: OVERVIEW

There are three basic categories of inspections:

- ✓A COMPREHENSIVE INSPECTION is requested by FDA headquarters or the district office and can cover everything in the pharmacy subject to FDA jurisdiction. These inspections can take less than a day, or they may last for weeks.
- ✓An ABBREVIATED INSPECTION is an inspection that covers only critical factors that are identified in the Inspectional Guidelines, the FDA Investigations Operations Manual (IOM), or under an inspectional program from FDA headquarters.
- ✓A DIRECTED INSPECTION is triggered by an identifiable event, such as a recall, consumer complaint follow-up, competitor complaint, or other specific incident.

FDA INSPECTION: OVERVIEW

Regardless of the type of inspection, the key issue will be whether the pharmacy is in compliance with 503A guidelines. If the inspector believes that the pharmacy is not in compliance, he or she will issue an FDA-483 Inspectional Observations.

The final decision as to whether a pharmacy is in compliance with 503A guidelines will be made by FDA headquarters in Silver Spring, Maryland.

FDA INSPECTION: OVERVIEW

Key personnel should be familiar with their roles in dealing with the investigator. (Although pharmacy inspections ordinarily involve only one FDA investigator, the agency can send two or more investigators.)

Once the inspection begins, it is crucial that the key personnel in all operations promptly be made aware of the presence of the FDA. If a corporate Inspection Leader is not available to respond to the FDA, other personnel need to understand the pharmacy's policies when answering the investigator's inquiries.

FDA INSPECTION: OVERVIEW

FDA inspections are usually unannounced. Thus, the pharmacy must be prepared for an inspection at any time.

Contacts with FDA investigators require the utmost professionalism. Investigators have a job to perform. The FDA's Investigations Operations Manual says that investigations "must always be conducted with tact, honesty, diplomacy, and persuasiveness." § 5.2.5.4.

FDA INSPECTION: OVERVIEW

Do not create an adversarial environment; it is counterproductive. On the other hand, the pharmacy must recognize that the investigator is not there to befriend it. No matter what the investigator says, the investigator is not there for the pharmacy's benefit.

The investigator should be courteously received during the course of his or her visits. Usually, this attitude will achieve the best results for the pharmacy and establish a better long-term relationship with the FDA. Conversely, a series of confrontations with the investigator can cause an otherwise manageable situation to deteriorate rapidly.

FDA INSPECTION: OVERVIEW

The degree of corporate cooperation will be reflected in the investigator's Establishment Inspectional Report ("EIR").

- ✓The EIR is an internal FDA document that comprehensively describes the inspection.
- ✓The EIR describes all aspects of the investigation, e.g., the history of the pharmacy, pharmacy management, inspectional findings, the lay-out of the facility, discussions with management about problems, etc.
- ✓The pharmacy's attitude will be reflected in the EIR, which will then go into the FDA's permanent file on the pharmacy.
- ✓It is often helpful to obtain a copy of the EIR through a Freedom of Information Act request once the inspection has been concluded.

FDA INSPECTION: OVERVIEW

An Inspection Leader must be assigned to deal with the FDA. This designated individual may also be appointed to handle the telephone communications. This leader should be aware of all aspects of the pharmacy's policies, operations, and record-keeping systems.

Alternatively, an Inspection Group can be set up. This group would then assign a Leader who would be responsible for the group's actions. The group would be made up of persons familiar with the pharmacy's policies for dealing with the FDA and with the pharmacy's operations.

FDA INSPECTION: OVERVIEW

The Leader and/or the group should accompany the investigator throughout the inspection.

The FDA may follow-up the inspection with a telephone call. All telephone calls from the FDA should be handled by the pharmacy's Inspection Leader.

FDA INSPECTION: OVERVIEW

The investigator should be made aware at the outset that there is a pharmacy policy for dealing with the FDA. This will help when questions arise on how to answer the inquiries made by the investigator.

An FDA investigator will more readily accept a denial based on established policy than a refusal based on an “instant policy” created on the spot. In responding to issues such as the taking of photographs, access to corporate records, and signing affidavits, as well as other problem areas, politely explain that the investigator’s request cannot be granted because of an existing pharmacy policy.

Inspection Authority

INSPECTION AUTHORITY

Section 501(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 351(j), deems a drug to be adulterated if “it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.”

INSPECTION AUTHORITY

If the pharmacy refuses inspection, the FDA's recourse would be to obtain a search warrant allowing it entry onto the premises.

There is no legal basis for completely refusing an inspection, except if the FDA wishes to inspect at an unreasonable time.

Refusal can lead to an FDA enforcement action. It also injures the relationship with the agency. Thus, refusal is almost never a viable option. However, the inspection must be at a reasonable time.

INSPECTION AUTHORITY

Sometimes a pharmacy will allow the FDA to inspect the facility but refuse to show certain records.

The investigator may say that this "partial refusal" violates § 331(f). However, although the investigator may cite § 331(f), this provision applies only if the FDA does actually have inspectional authority over those documents. In the event of a partial refusal, investigators generally will telephone their supervisor for instructions.

A pharmacy is not subject to the FDA's full inspectional powers.

However, if the pharmacy is not in compliance with 503A guidelines, then it will be subject to full inspection.

INSPECTION AUTHORITY

The inspector will attempt to determine if the pharmacy is in compliance with 503A guidelines. If the inspector concludes that the pharmacy is not in compliance, then the inspector will attempt to determine if the pharmacy is in compliance with current good manufacturing practices (“cGMPs”) for drugs.

Be sure that prior to any inspection the investigator issues a “Notice of Inspection” Form FDA-482 and that his or her credentials are up to date.

INSPECTION AUTHORITY

Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act also allows the FDA to request, in advance of or in lieu of an inspection, any records or other information that may be inspected under Section 704(a). 21 U.S.C. § 374(a)(4). The failure to produce the records requested by the FDA pursuant to Section 704(a)(4) in a timely manner may cause drugs to be adulterated.

Consequently, refusing to respond to such a request is usually not a viable option. However, the request must be within a reasonable timeframe, within reasonable limits, and in a reasonable manner.

Proprietary Information

PROPRIETARY INFORMATION

Special attention should be paid to records that contain proprietary information. These documents should be marked **"CONFIDENTIAL - TRADE SECRET,"** and this fact should specifically be called to the attention of the investigator. Make sure that the investigator notes that the material is considered trade secret information. This notation minimizes the risk that the information will be disclosed to third parties under the Freedom of Information Act ("FOIA").

However, the pharmacy should not "overplay its hand" and mark documents as "CONFIDENTIAL-TRADE SECRET" when, in fact, they do not constitute a "trade secret." Too many claims of confidentiality may cause the FDA to view all claims of confidentiality skeptically. The pharmacy should adopt written guidelines as to when a document qualifies as a "trade secret."

PROPRIETARY INFORMATION

Generally, FDA personnel are barred from disclosing any trade secret information to anyone outside the agency. 21 U.S.C. § 331(j); 18 U.S.C. § 1905.

However, the FDA may release these documents to Congress. Congress is not bound by the same obligations to preserve confidentiality.

PROPRIETARY INFORMATION

All documents in the FDA's files are potentially subject to release under FOIA. Probably the best solution is to stamp "Confidential - Trade Secret" on each copy of any proprietary documents provided to the investigator. This will alert the FDA employee responsible for handling the FOIA request to the confidentiality claim.

The pharmacy may have internal audit files on hand. These files would contain the findings of inside auditors or outside consultants. Audits do not have to be shown to the FDA. The FDA has said that it will not typically request these audits.

PROPRIETARY INFORMATION

The pharmacy will have patient records. The pharmacy can reasonably ask that the investigator not seek to copy records that contain patient identifiers.

Alternatively, the pharmacy may tell the investigator that the pharmacy wishes to delete patient identities from copied documents.

Information to Which the FDA is not Entitled

INFORMATION TO WHICH THE FDA IS NOT ENTITLED

Because financial data may bear upon the pharmacy/manufacturer dichotomy, it is possible that the investigator will request sales information.

The FDA does not have authority to obtain financial information. The pharmacy should decide in advance whether it wants to give this information.

The FDA is also not authorized to inspect sales data, pricing data, research data, and personnel data (other than technical qualifications).

The pharmacy does not have to release marketing plans or similar information.

INFORMATION TO WHICH THE FDA IS NOT ENTITLED

It is the pharmacy's responsibility to understand these limits.

The FDA investigator is not obliged to advise the pharmacy that a request is outside the scope of the FDA's authority.

If the FDA investigator asks for the documents, and the pharmacy voluntarily provides them, the documents can be used against the pharmacy.

The FDA's investigators generally know these limits and will respect a denial.

They ask for the information because they know that many pharmacies will provide these documents even though they do not need to do so.

Copying of Documents

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COPYING OF DOCUMENTS

The FDA may request records in advance of or in lieu of an inspection under Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act.

Upon receipt of such a request, the pharmacy is required to provide the requested records and information in a timely manner, in either electronic or physical form, at the expense of the pharmacy. Absent a request for records under Section 704(a)(4), however, the pharmacy is not required to supply the FDA investigator with a photocopy of its records.

So what should you do if the FDA inspector asks to copy records?

COPYING OF DOCUMENTS

The longer the investigator is present, the more likely a problem could arise.

It is sensible (and customary) to make the copies for the investigator.

- ✓Always make a duplicate set of copies for the pharmacy's own records.
- ✓These copies should go in the pharmacy's "Inspections File."
- ✓If the copying is extensive, the pharmacy can charge the agency for the service, although this is not normally done.
- ✓The investigator should be asked to initial and date the back of the original record to identify the record that the copy came from.

COPYING OF DOCUMENTS

Do not let the investigator have free access to the photocopying machine. Someone should be present with the investigator at all times. Have someone do the copying for the investigator. Nor should the pharmacy let the investigator have unrestricted access to the files -- provide only those documents that are specifically requested.

Copies of proprietary records, if supplied to the agency, should be stamped “Confidential - Trade Secret.” Do not let copies of these records out of the pharmacy without imprinting that statement.

Samples

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SAMPLES

The FDA may collect samples of product, e.g., compounded drug and the accompanying label.

Use the following procedures:

- ✓Always take a duplicate sample from the same batch for your review and testing.
- ✓Ask the agency what tests are going to be performed so that duplicate tests can be done by the pharmacy's laboratory. For example, the FDA may want to conduct sterility tests.
- ✓The pharmacy can charge the agency for samples, but this is not usually done for samples of nominal value. If the samples are expensive, the pharmacy may legitimately request reimbursement.

SAMPLES

The pharmacy should get a Receipt for Sampling Form FDA-484 from the investigator. The investigator should provide the pharmacy with the original FDA-484. The investigator may ask the pharmacy to sign the FDA-484. There is no harm in doing so, but there is no benefit either. The easiest policy to implement is an absolute prohibition against employees signing any FDA document.

In some circumstances, the pharmacy may want to consider refusing sampling by the agency. Ordinarily, though, the FDA can obtain a sample through some other means. Moreover, declining to allow FDA to collect samples may cause drugs to be deemed adulterated. Thus, this type of refusal is usually futile and probably counterproductive.

Photographs

PHOTOGRAPHS

"Pictures are worth a thousand words." Or, as the FDA Investigations Operations Manual says, "photographs are one of the most effective and useful forms of evidence." § 5.3.4. This is surely true when used as direct evidence in litigation.

The best corporate policy is **"NO CAMERAS ARE ALLOWED IN THE FACILITY."** This is to protect trade secrets, patient privacy, and compounding procedures. A sign stating this policy should be posted at the reception desk. By giving this type of notice, the pharmacy may prevent a direct confrontation with the FDA investigator on the subject of photography.

PHOTOGRAPHS

The FDA's draft guidance on circumstances that constitute delaying, denying, limiting, or refusing an inspection states that "[p]hotographs are an integral part of an FDA inspection because they present an accurate picture of facility conditions.

Not allowing photography by an FDA inspector may be considered a limitation if such photographs are determined by the investigator(s) to be necessary to effectively conduct that particular inspection."

The pharmacy should also be aware that the investigator may say that the FDA has the right to photograph as a result of a Supreme Court decision.

PHOTOGRAPHS

Citing that case, a June 13, 1986, FDA field memorandum says that “photographs are an integral part of an inspection and should be taken.”

The case relied on by the FDA involved the Environmental Protection Agency’s right to photograph a facility from a plane. No trade secret information was photographed.

Regardless of what the investigator says, the FDA has no clear statutory or legal authority to support taking pictures.

PHOTOGRAPHS

More often than not, an FDA investigator will not insist upon photographs if it is demonstrably forbidden by pharmacy policy.

Occasionally, however, the investigator will feel very strongly about this issue. This is most likely to occur when the investigator has observed particularly deplorable conditions, e.g., rodent infestation in food warehouses.

The FDA has gone to court from time to time to obtain a warrant authorizing the use of a camera.

Signing Official Documents

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SIGNING OFFICIAL DOCUMENTS

An official of the pharmacy may be asked to supply copies of shipping records or invoices, and then to sign documents identifying the source, verifying shipment, or confirming other information on the status of any sample the FDA collects.

Or the pharmacy may be asked to confirm in writing its compounding and dispensing practices. This is usually in a form of an “affidavit” prepared by the FDA. The FDA has no authority to compel the pharmacy to sign anything.

SIGNING OFFICIAL DOCUMENTS

The policy for signing such forms or statements should be established in advance. Signing the document does not benefit the pharmacy in any way.

The better approach is to have pharmacy officials refuse to sign or to even give an oral “OK” that the statement is correct. (The FDA investigator would note a verbal affirmation and use it against the pharmacy).

SIGNING OFFICIAL DOCUMENTS

Look at the scenario in which the FDA inspector prepares the affidavit in the pharmacy's name, makes a mistake, and asks the pharmacy to initial the error. By doing this, and not correcting elsewhere, the pharmacy might be impliedly indicating that it had read the affidavit and did not disagree with it.

Similarly, if the pharmacy does read the affidavit and feels it is incorrect in a specific statement, it may be tempted to point out the error. The FDA might then argue that identifying only a single error implies that the pharmacy agrees with all other statements.

SIGNING OFFICIAL DOCUMENTS

Assume that the FDA inspector states on the affidavit that “the pharmacy refused to sign the affidavit” and asks the pharmacy to sign that statement. The pharmacy should not sign or initial the affidavit if it has already decided not to sign the affidavit or other official forms.

Signing or orally acknowledging a statement could be used against the pharmacy in a future enforcement action. Declining to sign would not protect the pharmacy from further actions but does make the agency’s job harder in documenting its case. The most prudent policy is not to sign any document prepared by the FDA.

Inspection File

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ESTABLISH AN INSPECTION FILE

After each inspection, the pharmacy should create a separate file. This file will include the notes taken during the inspection by pharmacy employees, the forms filled out regarding the inspection, duplicates of the records copied by the investigator, the FDA-482 Notice of Inspection, the FDA-483 Notice of Observations, the FDA-484 Receipt of Samples, the pharmacy's analytical results for samples tested, and any subsequent correspondence with the agency.

Maintaining all information in a single file will make it easier to reconstruct the circumstances of the inspection years later, if necessary. Never show this file to the FDA, or to anyone outside the pharmacy who is not bound by confidentiality.

Gifts

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GIFTS

Without question, gifts should never be offered to any investigator.

It is a federal offense to give a gift to a federal agent.

Meals

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MEALS

The pharmacy should not offer to take the investigator to lunch. FDA employees are prohibited from accepting meals from regulated industry. It is not inappropriate to offer coffee, tea or a soft drink if that is the customary practice for all visitors.

If the pharmacy wants to have lunch with the investigator, let him pick up his own bill. It is much better, though, to recommend a restaurant where the investigator can eat without being accompanied by a pharmacy employee.

FDA-483

FDA-483 (LIST OF OBSERVATIONS) RESPONSE

At the inspection's end, the investigator will have an exit interview with management to detail the findings of the inspection and to obtain the pharmacy's comments.

If no FDA-483 is issued, the investigator may still have some recommendations for how to improve the pharmacy's operations. Sometimes, an investigator will suggest some way in which a pharmacy can strengthen its claim to be a pharmacy, not a manufacturer. Or the investigator may make a suggestion about shelf-life testing.

FDA-483 (LIST OF OBSERVATIONS) RESPONSE

In such a case, listen and take all suggestions under review but do not promise implementation. No further follow-up is necessary for this type of exit interview.

If an FDA-483 is issued, the investigator is going to request a direct and immediate response. It would be advisable to review each point for clarification with the investigator but make no comments regarding follow-up action unless the pharmacy is certain that a specific action can and will be taken. Explain that the list will be reviewed by management, and a written response soon will be mailed to the district office.

FDA-483 (LIST OF OBSERVATIONS) RESPONSE

One section of the establishment inspection report ("EIR") specifically addresses the exit interview.

- ✓Statements made during the exit interview will be reported in detail in the EIR.
- ✓Do not reject observations out-of-hand, become defensive, or be unwilling to listen; on the other hand, make commitments sparingly.
- ✓Any commitments will be recorded.
- ✓The safest response is of the "We have no comment on that at this time" variety.

FDA-483 (LIST OF OBSERVATIONS) RESPONSE

In preparing a written response to the FDA-483, make sure it is timely and accurate. If there are significant or numerous observations, the pharmacy should consult with regulatory counsel before responding.

The FDA's current policy is to try to issue Warning Letters within a few weeks of the completion of the inspection. A Warning Letter would state that the pharmacy has violated the law in some respect; this letter is made publicly available.

The response should be received by the FDA within ten days or so. If necessary, a supplemental response can be submitted later.

FDA-483 (LIST OF OBSERVATIONS) RESPONSE

Each observation in the FDA-483 will be separately numbered.

The response letter should address each point individually.

- ✓Give a detailed reason for any disagreement with the findings.
- ✓When responding to a valid point, concisely explain how the pharmacy will modify its conduct or what changes will be made.
- ✓Do not admit that there was an error or flaw; rather, just describe the new procedures.

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FDA-483 (LIST OF OBSERVATIONS) RESPONSE

Give a target date for corrective actions to be implemented. This date should be realistic.

All responses should be made in a positive tone and in a spirit of cooperation. The response to the FDA-483 is part of the FDA's permanent record and is made available to third parties through the Freedom of Information Act.

If trade secret information is enclosed, identify the portions that are confidential and ask the FDA not to release those sections of the letter.

State Opioid Taxes

STATE OPIOID TAXES

Three states – Delaware, Minnesota and New York – specifically impose taxes and fees on opioid manufacturers and distributors. Other states are considering imposing such taxes.

The following summary discusses the general compliance requirements of opioid laws now in effect.

STATE OPIOID TAXES

Delaware

Delaware imposes an impact fee on opioid manufacturers. Delaware defines manufacturer very broadly to include anyone “engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription opioid drug.” The law imposes a $0.01 per “morphine milligram equivalent” (MME) for a prescription opioid dispensed and reported in the state Prescription Monitoring Program

(PMP) or $0.0025 per MME for a prescription opioid that is a generic substitution. The manufacturer must pay the fee if it dispenses more than 100,000 MMEs of prescription opioids in Delaware in a single quarter. The Delaware Secretary of State calculates the fee for each qualifying manufacturer based on the PMP reports and issues a quarterly invoice. See Del. Code Ann. Tit. 16, section 4802B.

Under the PMP, Delaware pharmacies and practitioners, and out of state pharmacies that deliver into Delaware, must electronically report data pertaining to the sale of all controlled substances. The report must include the name and national drug code (NDC) for each prescription.

The Delaware impact fee became effective June 12, 2019. The law establishing the fee expires on Jan. 1, 2025.

STATE OPIOID TAXES

Minnesota

Minnesota imposes several different license fees on opioid manufacturers and wholesalers. As of July 1, 2019, Minnesota imposes an opioid product registration fee. The registration fee is $250,000 a year for any manufacturer that sells, delivers, or distributes 2 million or more units of an opiate into the state. For purposes of the law, one unit equals “one tablet, capsule, patch, syringe, milliliter, or gram.” This fee is paid by manufacturers whose opioid products are sold in Minnesota.

As of March 1, 2020, all manufacturers and wholesalers must report to the state Board of Pharmacy all sales, deliveries, and distributions of opiates into Minnesota. The report is due each March 1 and must include data for the prior calendar year. All pharmacies must report any intercompany deliveries or distributions of opioids into the state to the extent those deliveries and distributions are not reported by a wholesaler. By April 1 of each year, the Board of Pharmacy will notify all manufacturers that meet the threshold that the fee is due.

In addition to the product registration fee, Minnesota imposes an annual license fee on all manufacturers of opiate containing products of $55,000. The state also imposes an annual license fee on all wholesalers of opiate products of $5,000.

STATE OPIOID TAXES

New York

New York imposes an excise tax levied on the first opioid sales into the state. The tax is imposed on "opioid registrants" which includes anyone who holds and transfers title to an opioid unit and is required to register with the state as a manufacturer or distributor of a controlled substance. The law essentially applies to anyone who manufactures or distributes controlled substances in New York.

The tax is imposed on the first sale into New York. Thus, any transfer of title of an opioid unit for consideration by a registrant in New York for the first time is subject to tax. First time sales do not include transfers by prescription to the ultimate user of an opioid unit. Sales of opioid units from a New York manufacturer to a purchaser outside the state are excluded from the tax.

STATE OPIOID TAXES

The tax is $0.0025 on each MME with a wholesale acquisition cost of less than $0.50 per unit or $0.0150 on each MME with a wholesale acquisition cost of $0.050 or more per unit. All persons subject to the tax must file an excise tax return with the New York Commissioner of Taxation and Finance. The return must include the total MMEs subject to tax and the total tax due.

The first returns are due to be filed on Jan. 21, 2020. Thereafter, returns are due quarterly on the 20th of the month following the end of the calendar quarter. The New York law allows registrants to claim refunds for tax paid on cancelled purchases or for taxes paid on sales of MMEs that were not subject to tax. In addition, New York requires registrants to file registrants to file an annual report with the New York Department of Health detailing customer names, sales dates, and gross receipts for all controlled substance transactions.

STATE OPIOID TAXES

Compliance and recordkeeping

All companies manufacturing or selling opioid products should be aware of the relevant tax and fee laws in Delaware, Minnesota, and New York discussed above. Taxpayers should also be aware that more states are likely to propose and enact similar laws. Compliance with opioid fees and taxes should be a high priority. Each of the states has substantial penalties associated with failures to file or to remit fees and taxes. Therefore, companies should know what types of opioids (usually legislatively determined) are subject to tax. They should also know the threshold sales amounts that will be subject to tax. Further, knowing the types of transactions that trigger taxation and fees is critical as well as tracking new and amended opioid tax legislation and regulation.

As importantly, all companies should keep detailed records of the type, the amount (in both dollars and by unit), and destination/origin of all opioid sales and purchases. Finally, companies subject to state taxes and fees should be cognizant of all filing and reporting requirements.

Questions?

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