



EDUCATIONAL RESOURCES

HOT BUTTON ISSUES FACING PHARMACIES IN THE NEXT 12 MONTHS

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EDUCATIONAL RESOURCES

PBM ISSUES

PBM AUDITS

- The approach
 - 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 position.
 - 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.

DETERMINING 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

- Asking for an extension
 - 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).

BEST INTERNAL PHARMACY PRACTICES

- Assign and train dedicated pharmacy staff to respond to all desktop and onsite audits and reviews. Beneficial to include a pharmacist or pharmacy technician in the audit team.
- Create a distinct audit team email and a dedicated fax and phone number (audits@senderrarx.com)
- Document all audits and record audit date, reference number, due date, supporting documents submission date, submission source (fax, email, mail), audit reason code (document request, prescription verification, etc), audit findings, recoupment amounts, audit status (open, closed)
- Develop diligent follow up processes

BEST INTERNAL PHARMACY PRACTICES

- Develop extensive audit findings appeal processes
 - Engage pharmacy clinical teams
 - Engage prescribers (prescriber clarification letters, etc.)
 - Engage patients (patient attestation letters, etc.)
- Observe audit patterns and trends and develop internal self-audits

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.

WHAT THE PBM IS FOCUSING ON

- 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.

COLLATERAL DOCUMENTS

- The pharmacy's contract with the PBM contains several obligations that the pharmacy must meet. Such obligations are found in the contract 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/SPECIALTY

- Most, if not all, PBMs have their own mail-order and specialty pharmacies. They do not like pharmacies, that are in network, to compete with the PBMs' mail-order and specialty pharmacies. As such, most in-network pharmacies are in the PBM's retail network, not in the PBM's mail-order/specialty network.
- The contract between a PBM and a retail pharmacy will likely contain one or more of the following provisions pertaining to mail-order (the contract will also likely contain similar provisions pertaining to specialty).
 - 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.

MAIL-ORDER/SPECIALTY

- In order to determine if the pharmacy is engaged in prohibited mail-order, the questions posed by the PBM in the audit may include one or more of the following:
 - Does your pharmacy fill prescription claims under multiple NCPDPs?
 - Does your pharmacy hold a license in more than one state?
 - Is your pharmacy a retail walk-in pharmacy that services the general public?
 - Is your pharmacy a closed-door pharmacy?
 - Is 25% or more of your pharmacy business mail order?
 - Is your pharmacy licensed to fill prescriptions for Medicare Part D long term care providers in multiple states?

MAIL-ORDER/SPECIALTY

- Is your pharmacy licensed to fill prescriptions for Medicare Part D home infusion providers in multiple states?
- Is your pharmacy open for walk-in service 24 hours a day?
- Does your pharmacy offer emergency prescription services after hours?
- Does your pharmacy have a drive-through?
- Does your pharmacy offer a delivery service?
- Is your pharmacy less than or equal to ¼ mile walking distance from public transportation?
- Is your pharmacy accessible by public transportation that charges set fares, runs on fixed routes, and is available to the public?

MAIL-ORDER/SPECIALTY

- Does your pharmacy offer patient consultation?
- Indicate the percentage of Rx volume in each of the following settings: Open Door/Retail/Community __%; Closed Door/Clinic Facility __%; Mail Order __%; Nursing Home/LTC __%; Internet Pharmacy __%; Other __%
- Does the owner/pharmacist-in-charge currently hold any non-resident state licenses? If so, please submit a copy.
- Indicate the percentage of Rx volume in each of the following settings: Open Door/Retail/Community __%; Closed Door/Clinic Facility __%; Mail Order __%; Nursing Home/LTC __%; Internet Pharmacy __%; Other __%
- Does the owner/pharmacist-in-charge currently hold any non-resident state licenses? If so, please submit a copy.
- Does your pharmacy deliver prescriptions to out-of-state customers? If yes, identify states where your pharmacy serves customers and provide out-of-state pharmacy licenses.

COMPLIANCE WITH CONTRACT - 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.

COMPOUNDING

- In order to determine if the pharmacy is engaged in prohibited compounding, the questions posed by the PBM in the audit may include one or more of the following:
 - Does your pharmacy participate in complex compounding?
 - Is your pharmacy registered/affiliated with a compounding supplier?
 - Does your pharmacy have a dedicated lab/area for compounding?
 - Does your pharmacy have dedicated technicians for compounding only?
 - Does your pharmacy have any of the following compound equipment: unguator, hot plate, homogenizer, ointment mill, tube sealer, capsule filling system?
 - Does your pharmacy anticipate filling more than 10% of retail claims as non-sterile compounds?
 - What types of compounds does your pharmacy make or anticipate making: topical analgesics, hormone replacement therapy, sterile compounds, scar cream, other?

COMPOUNDING

- Indicate the percentage income derived from: Medicaid _%; Medicare _%; Workers Comp _%; 340B _%; Compounds _%; Dispensing Physician _%
- Does your pharmacy provide sterile compounding medications? If yes, please provide the most current certification document (e.g., PCAB, air flow hood/HEPA filtration, etc.).
- Does your pharmacy provide compound product samples to physicians?
- Does your pharmacy provide compounding services for or through any other entities (i.e., providing compounding services through other pharmacies or directly to physicians for dispensing)?
- Does your pharmacy compound investigational/non-FDA approved compounds?

LEGAL COMPLIANCE – 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 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.
- Most states have similar laws that apply to commercial insurance patients.

LEGAL COMPLIANCE – COLLECTION OF COPAYMENTS

- And several 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.”

LEGAL COMPLIANCE – 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 W-2 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.

LEGAL COMPLIANCE – MARKETING

- In order to determine if the pharmacy is engaged in prohibited marketing practices, in an audit the PBM may ask the following questions:
 - Does your pharmacy use individual marketing reps to market your pharmacy's products and services?
 - If the answer to the preceding question is "yes," are the marketing reps W-2 employees or 1099 independent contractors?
 - If your pharmacy uses individual 1099 independent contractor marketing reps, how are the reps compensated?
 - Does your pharmacy contract with marketing companies? If so, list their names and explain how the marketing companies are compensated.

LEGAL COMPLIANCE – 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.

LEGAL COMPLIANCE – 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?
 - 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.

LEGAL COMPLIANCE – 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.

LEGAL COMPLIANCE – 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?

LEGAL COMPLIANCE – IN GENERAL

- With the goal of determining if the pharmacy is legally compliant in multiple areas, in an audit the PBM may ask the following questions:
 - Does your pharmacy use or provide pre-printed prescription forms for any of your compound preparations?
 - Does any person with prescriptive authority have a direct or indirect financial interest in your pharmacy? A "financial interest" includes, but is not limited to, any direct ownership, ownership by an immediate family member (spouse, child, etc.), paid consulting relationship, waged or salaried employment relationship.
 - Identify the names of all primary and secondary wholesalers/suppliers that service your pharmacy. Provide a copy of the most recent invoices from each wholesaler/supplier.
 - Do you have a policy in place for setting your usual and customary price?
 - Does your pharmacy have a central fill or shared services arrangement with any other pharmacy or facility? If yes, provide the corresponding licenses and identify all pharmacies/facilities with which your pharmacy has such a relationship.
 - Does the sum of your Average Wholesale Price (AWP) for specialty claims exceed 50% of the sum of your AWP for all prescriptions?

CERTIFICATION

- And finally, in an audit the PBM may ask the pharmacy to provide a certification that looks something like the following:
 - I certify that each answer on this Questionnaire is true and correct.
 - I agree to notify [Name of PBM] immediately in writing in the event of a change in the information provided which would make any part of the Questionnaire untrue or inaccurate. I understand that failure to do so will be considered a breach of my Provider Agreement and could result in disciplinary action including, but not limited to, immediate termination of my Provider Agreement.
 - I give [Name of PBM], and its designers, permission to contact any individual, company, organization, etc., including state and federal licensing agencies, as may be necessary to verify the information submitted herein and to ask questions about disciplinary actions, the pharmacy's license, or any pharmacist licensed, employed by or dispensing prescriptions at the pharmacy.
 - I certify that training, which meets the CMS requirement for fraud, waste and compliance training, has been conducted within 90 days of hire and annually thereafter for all employees and other persons who administer or deliver the Medicare Part D benefit.

REVIEW DOCUMENTATION 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 DOCUMENTATION 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 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.

REHABILITATE DOCUMENTATION 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).

VENDOR INVOICES

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

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.

COPIES AND EXPLANATORY LETTER

- Maintain two sets of copies
 - 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.
- Explanatory letter
 - 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 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.



EDUCATIONAL RESOURCES

REGULATORY GUIDELINES

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.



EDUCATIONAL RESOURCES

EXAMPLES OF COLLABORATIVE ARRANGEMENTS

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.

MEDICAL DIRECTOR

- Among other requirements:
 - (i) the MDA needs to be in writing
 - (ii) the MDA must have a term of at least 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.

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.

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.



EDUCATIONAL RESOURCES

CONSULTING PHARMACY SERVICES

CONSULTING PHARMACY SERVICES

- As noted above, in order for a Facility to serve Medicare and Medicaid patients, federal law imposes a number of requirements on the Facility.
- One such requirement is for the Facility to have a pharmacy perform a monthly drug regimen review (“DRR”) on each patient.
- In order to meet the DRR requirement, the Facility will need to enter into a Pharmacy Consulting Agreement (“PCA”) with a pharmacy.

CONSULTING PHARMACY SERVICES

- Assume that the pharmacy dispenses drugs to the Facility's patients. Regardless of how much "patient choice" the Facility gives the patients, under the AKS the Facility will be considered to be a "referral source" to the pharmacy.
- Under the AKS, the pharmacy cannot "give anything of value" to a referral source (i.e., the Facility). "Anything of value" includes subsidizing the Facility's expenses. Therefore, violation of the AKS can occur if the pharmacy provides consulting services for free or for compensation that is below fair market value.

CONSULTING PHARMACY SERVICES

- The safest form of compensation by the Facility to the pharmacy is for the Facility to pay fixed annual compensation (e.g., \$12,000 over the next 12 months) to the pharmacy that is the fair market value equivalent of the pharmacy's services. Fixed annual (fair market value) compensation is an important element of the Personal Services and Management Contracts safe harbor to the AKS.
- A less conservative method of compensation (but one that is low risk from a kickback standpoint) is for the Facility to pay the pharmacy by the hour. Such per hour compensation needs to be fair market value.
- The guidance set out above is not limited to DRR services. Rather, the guidance applies to any type of services rendered by a pharmacy to a Facility.



EDUCATIONAL RESOURCES

SHAM TELEHEALTH ARRANGEMENTS

SHAM TELEHEALTH ARRANGEMENTS

- Pharmacies are aggressively engaged in marketing and it is not uncommon for a pharmacy to dispense drugs to patients residing in multiple states.
- When a pharmacy is marketing to patients in multiple states, the pharmacy may run into a “bottleneck.”
- This involves the patient’s local physician. A patient may desire to purchase a prescription drug from the out-of-state pharmacy, but it is too inconvenient for the patient to drive to his physician’s office.
- Or if the patient is seen by his local physician, the physician may decide that the patient does not need the drug and so the physician refuses to sign a prescription.
- Or even if the physician does sign a prescription, he may be hesitant to send the order to an out-of-state pharmacy.

SHAM TELEHEALTH ARRANGEMENTS

- In order to address this challenge, some pharmacies are entering into arrangements that will get them into trouble.
- This has to do with “telehealth” companies.
- A typical telehealth company has contracts with many physicians who practice in multiple states.
- The telehealth company contracts with and is paid by:
 - (i) self-funded employers that pay a membership fee for their employees,
 - (ii) health plans, and
 - (iii) patients who pay a per visit fee.
- Where a pharmacy will find itself in trouble is when it aligns itself with a telehealth company that is not paid by employers, health plans and patients but, rather, is directly or indirectly paid by the pharmacy.

SHAM TELEHEALTH ARRANGEMENTS

- Here is an example:
 - Pharmacy purchases leads from a marketing company
 - The marketing company sends the leads to the telehealth company
 - The telehealth company contacts the leads and schedules audio or audio/visual encounters with physicians contracted with the telehealth company
 - The physicians issue prescriptions for drugs
 - The telehealth company sends the prescriptions to the pharmacy
 - The marketing company pays compensation to the telehealth company for its services in contacting the leads and setting up the physician appointments
 - The telehealth company pays the physicians for their patient encounters
 - The pharmacy mails the drug to the patient
 - The pharmacy bills (and gets paid by) a government program.

SHAM TELEHEALTH ARRANGEMENTS

- There can be a number of permutations to this example, but you get the picture.
- Stripping everything away, the pharmacy is paying the ordering physician.
- To the extent that a pharmacy directly or indirectly pays money to a telehealth physician, who in turn writes a prescription for drugs that will be dispensed by the pharmacy, the arrangement will likely be viewed as remuneration for a referral (or remuneration for “arranging for” a referral).
- If the payer is a federal health care program, then the arrangement will likely violate the AKS.
- If the payer is the state Medicaid program, then the arrangement will likely violate both the AKS and the state anti-kickback statute.
- If the payer is a commercial insurer, then the arrangement may violate a state statute.



EDUCATIONAL RESOURCES

QUESTIONS?

Email us at customerservice@achcu.com



EDUCATIONAL RESOURCES

THANK YOU

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