



EDUCATIONAL RESOURCES

# PREPARING FOR AND RESPONDING TO A PBM AUDIT

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# MINDSET IN RESPONDING TO A PBM AUDIT

# 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 suffer financially.
  - 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 has the ability to 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 rights.



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# MEETING THE DEADLINE

# 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 26, 2020).
  - The deadline may be something like “30 days from date of this letter.”
  - The deadline may be something like “30 days from 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 to 14 days from the date that the PBM mails the letter.
  - Thus, if the date of the letter is February 10 and if the pharmacy has to respond within 30 days from the date of the letter, but if the pharmacy does not actually receive the letter until February 25, then the pharmacy has less than 15 days to respond.

# DETERMINING THE DEADLINE

- 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.

# ASKING FOR AN EXTENSION

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- It is reasonable for the pharmacy to ask for a one-time extension, usually a 10 to 14-day extension. And, 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).



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# HIRE A HEALTHCARE ATTORNEY



# ROLE OF THE ATTORNEY

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- 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 3 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.



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# DETERMINING WHAT THE PBM IS FOCUSING ON

# 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.

# COMPLIANCE WITH CONTRACT – COLLATERAL DOCUMENTS

- The pharmacy's contract with the PBM contains a number of 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.

# COMPLIANCE WITH CONTRACT – 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.



# COMPLIANCE WITH CONTRACT – MAIL ORDER

- 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?

# COMPLIANCE WITH CONTRACT – MAIL ORDER

- 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 (cont'd):
  - 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?

# COMPLIANCE WITH CONTRACT – MAIL ORDER

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- 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 (cont'd):
  - Is your pharmacy accessible by public transportation that charges set fares, runs on fixed routes, and is available to the public?
  - Does your pharmacy offer patient consultation?

# COMPLIANCE WITH CONTRACT – MAIL ORDER

- 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 (cont'd):
  - 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.

# COMPLIANCE WITH CONTRACT – MAIL ORDER

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- 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 (cont'd):
  - 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.

# COMPLIANCE WITH CONTRACT – 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?

# COMPLIANCE WITH CONTRACT – 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 (cont'd):
  - 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?
  - 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.).



# COMPLIANCE WITH CONTRACT – 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 (cont'd):
  - 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.

# LEGAL COMPLIANCE – COLLECTION OF COPAYMENTS

- An example pertains to collection of copayments (cont'd):
  - 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.”

# 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 1099 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.

# LEGAL COMPLIANCE – AFFILIATED PHARMACIES

- With the goal of uncovering this type of scheme, in an audit the PBM may ask the following questions (cont'd):
  - 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 – TELEHEALTH

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- Telehealth is a good thing. Health care delivery is rapidly adopting myriad telehealth models. Telehealth is cost-effective and grants health care services to patients who might otherwise not have such services.
- But, there is an underbelly to telehealth. A number of pharmacies are securing prescriptions from physicians who never have a face-to-face encounter with patients. Rather, the physicians only review the patient's chart or have a short telephone conference with the patient.

# LEGAL COMPLIANCE – TELEHEALTH

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- These types of telehealth encounters may not comply with (i) telehealth requirements of the state in which the patient resides and/or (ii) coverage requirements of third-party payors (“TPPs”).
- And so in audits PBMs are beginning to request information designed to educate the PBM on whether the pharmacy is dispensing drugs in reliance on prescriptions resulting from telehealth encounters and, if so, whether such telehealth encounters are legally compliant.

# LEGAL COMPLIANCE – DISCIPLINARY ACTIONS

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- 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.

# LEGAL COMPLIANCE – DISCIPLINARY ACTIONS

- 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

- With the goal of discovering disciplinary actions, in an audit, the PBM may ask the following questions (cont'd):
  - 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, or waged or salaried employment relationship.

# 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 (cont'd):
  - 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.

# 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 (cont'd):
  - 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.

# CERTIFICATION

- And finally, in an audit, the PBM may ask the pharmacy to provide a certification that looks something like the following (cont'd):
  - 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.

# EXAMPLE OF INVESTIGATIVE REVIEW LETTER FROM PBM

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[Name of Pharmacy]

[Address of Pharmacy]

ATTN: Pharmacy Owner

NCPDP: \_\_\_\_\_

Re: Pharmacy Provider Number # / NPI # \_\_\_\_\_ ("Provider")

# EXAMPLE OF INVESTIGATIVE REVIEW LETTER FROM PBM

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Dear Pharmacy Owner,

In accordance with the Provider Agreement, including the Provider Manual, [PBM] has identified [Pharmacy], NCPDP \_\_\_\_\_ (“Provider”) for investigative review. Data trends and information from other sources suggest that Provider has been engaging in improper contact with our sponsor’s members in violation of Section \_\_ of the Provider Agreement and may be billing invalid prescriptions.

# EXAMPLE OF INVESTIGATIVE REVIEW LETTER FROM PBM

Specifically, data analysis shows:

\_\_ Doctors, located in the states of \_\_\_\_, \_\_\_\_ and \_\_\_\_, have prescribed drugs resulting in \_\_ claims Provider billed to patients in [state where Pharmacy is located].

Based on these trends, Provider must submit documentation and responses to the attached questions no later than the close of business \_\_\_\_, 20\_\_.

# EXAMPLE OF INVESTIGATIVE REVIEW LETTER FROM PBM

Please be advised that [PBM] is prepared to pursue any and all available remedies, including legal action and termination of Provider's Agreement, if Provider fails to cooperate with this request. Disclosure information must be submitted in writing, via email, fax, or letter carrier service by the specified due date. Should Provider not be truthful or [PBM] obtains knowledge that Provider or any third-party contractor is engaged in improper member contact without disclosure, it will be grounds for immediate termination.

# QUESTIONS POSED BY PBM IN CONJUNCTION WITH INVESTIGATIVE REVIEW LETTER

- Describe the Provider's process and procedure to validate the prescription, including that a patient/prescriber relationship existed.
- Did/does Provider have any direct or indirect contractual or ownership relationship(s) with any individual with prescriptive authority, including the prescriber(s) for the identified claim?

# QUESTIONS POSED BY PBM IN CONJUNCTION WITH INVESTIGATIVE REVIEW LETTER

- Was the prescription obtained as part of marketing activities, either directly or indirectly, carried out by Provider? These would include, but not be limited to:
  - Internal or external sales force representatives
  - Third-party marketing firm(s)
  - Call center or other outreach to members
- If contact was made with the patient, what was the method used (call center, online survey, etc.)?



# QUESTIONS POSED BY PBM IN CONJUNCTION WITH INVESTIGATIVE REVIEW LETTER

- Does Provider have any business arrangement with any person or entity responsible for generating pharmacy business through marketing directly to members or to doctors?
- This includes any relationships with vendors that provide telemedicine services, solicit patients, engage in telemarketing, or solicit physicians. If yes, identify all such relationships and for each identified relationship, Provider must include:
  - Name of the entity providing services
  - Length of Provider's relationship with vendor
  - Description of the services or goods provided

# QUESTIONS POSED BY PBM IN CONJUNCTION WITH INVESTIGATIVE REVIEW LETTER

- Does Provider disclose claim level detail to any third party or vendor including, but not limited to, data about PBM reimbursement rate(s), prescription claim coverage, member claims, or otherwise? If yes, please identify the vendor/third party and describe the information being provided.
- Is Provider enrolled in a service or compound network (i.e. a parent company that manages other pharmacies or a third-party management company) that may have generated the identified claim or other pharmacy claims? If yes, please describe.



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# ADEQUATE INVENTORY AUDITS MAY REQUIRE COORDINATION WITH WHOLESALERS



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# DETERMINING HOW TO SUBMIT THE REQUESTED DOCUMENTATION

# DETERMINING HOW TO SUBMIT THE REQUESTED DOCUMENTATION

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- Does the PBM want the documentation in a hard copy or electronic format?



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# REVIEW, ORGANIZE, AND REHABILITATE

# 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.



# 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 (cont'd):
  - 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.

# 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.

# REHABILITATE THE FILES TO BE SUBMITTED

- 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).



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# SUBMISSION OF DOCUMENTS

# 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.

# MAINTAIN TWO SETS OF COPIES

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- When the pharmacy submits the requested documents to the PBM, the pharmacy needs to retain 2 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 general rule, PBMs do not want to deal with attorneys unless they have no choice.



# FOLLOW UP WITH THE PBM

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- 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

# KNOW YOUR APPEAL RIGHTS BEFORE YOU RESPOND TO THE AUDIT



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# “WIN” YOUR AUDITS BY RESPONDING, NOT REACTING



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# QUESTIONS?



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# THANK YOU

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