



RESPONDING TO PBM RE- ENROLLMENT APPLICATIONS, REQUESTS FOR INFORMATION, AND CONTRACT TERMINATIONS

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INTRODUCTION



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- What is a PBM?
 - A Pharmacy Benefit Manager, also known as a PBM, is a third-party administrator contracted by health plans, employers, unions and government entities to manage prescription drug programs.

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- What does a PBM do?
 - PBMs process claims from patients and pharmacies, perform utilization review and formulary management functions, handle customer service issues, develop and manage provider networks, conduct sales and marketing campaigns, and negotiate rates between pharmacies and drug manufacturers. PBMs also facilitate mail order and specialty drug dispensing services.

INTRODUCTION

- Relationship between PBM and Pharmacy
 - A PBM acts as a fiscal intermediary between insurers/payors and pharmacies. The PBM's mission is to help control the cost of drug coverage through the PBM's network of pharmacies, benefit-specific utilization management programs, and formularies (a formulary is a list of drugs able to be prescribed by a physician for use by a plan's participants).

INTRODUCTION

- PBMs are becoming more intrusive - What we are seeing:
 - Request for more information in recredentialing applications
 - Increased audit activity
 - Increased contract termination
- At the end of the day, the PBM is in control of the money.



PBM RE-CREDENTIALING



PBM RE-CREDENTIALING

- PBMs and payors must validate the credentials of pharmacies to ensure they are in good standing with state and federal laws and meet quality performance standards.
- Under the current approach, PBMs collect data from their network pharmacies using batch spreadsheets and questionnaires, as well as confirming they meet requirements through internal checks.
- PBMs will re-credential pharmacies every year or couple of years, depending on the PBM, to ensure each pharmacy meets the PBM's participation requirements.

PBM RE-CREDENTIALING

- Some PBMs have recently adopted new re-credentialing processes specifically for compounding pharmacies.
 - The questionnaire asks new, specific questions of compounding pharmacies, that cover various aspects of the pharmacy's business.
 - The new re-credentialing process also requires the pharmacy to maintain and submit Policies and Procedures relating to various aspects of pharmacy operations and billing practices, such as kickback issues, billing processes, and USP <795> compliance.

PBM RE-CREDENTIALING

- Additionally, the re-credentialing application inquires about
 - (i) the use of pharmacy marketing representatives,
 - (ii) the use of W-2 employees vs. 1099 independent contractors,
 - (iii) central fill relationships, and
 - (iv) pre-printed prescription pads.



RECREREDENTIALING QUESTIONNAIRE: EXAMPLES OF QUESTIONS



QUESTIONS PERTAINING TO MAIL ORDER

- 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?
- 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?

QUESTIONS PERTAINING TO MAIL ORDER

- 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.

QUESTIONS PERTAINING TO MAIL ORDER

- 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.

QUESTIONS PERTAINING TO COMPOUNDING

- Does your pharmacy participate in complex compounding?
- Is your pharmacy registered/affiliated with a compounding supplier?
- Does our 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?

QUESTIONS PERTAINING TO COMPOUNDING

- 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?

QUESTIONS PERTAINING TO 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.).

QUESTIONS PERTAINING TO COMPOUNDING

- 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?

QUESTIONS PERTAINING TO COPAYMENTS

- 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.

QUESTION PERTAINING TO MARKETING

- Does your pharmacy contract with or employ a sales force? If yes, please describe the activities of the sales force.

QUESTIONS PERTAINING TO AFFILIATED PHARMACIES

- 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.

QUESTIONS PERTAINING TO AFFILIATED PHARMACIES

- 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.

QUESTIONS PERTAINING TO DISCIPLINARY ACTIONS

- 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 letter, and any other supporting documents from the State Board of Pharmacy, government entity, or other regulatory authority.
- 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?

QUESTIONS PERTAINING TO DISCIPLINARY ACTIONS

- 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?

QUESTIONS PERTAINING TO LEGAL COMPLIANCE

- 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?

CERTIFICATION

- 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

- 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.



PBM AUDIT



PBM AUDIT

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



REASONS FOR TERMINATION BY THE PBM



REASONS FOR TERMINATION BY PBM

- Pharmacy is engaged in mail-order
 - Many PBMs have their own mail-order pharmacy.
 - PBMs do not like their contract retail pharmacies to compete with the PBMs' mail-order pharmacies.
 - Most re-credentialing questionnaires inquire about the extent of the pharmacy's mail-order business. If the pharmacy discloses information that it is engaged in mail-order beyond a certain threshold, then the PBM may decide to terminate the contract.
 - Or if the PBM finds out (through other means) that the pharmacy is engaged in mail-order beyond a certain threshold, then the PBM may decide to terminate the contract.

REASONS FOR TERMINATION BY PBM

- Pharmacy is engaged in compounding
 - TRICARE and PBMs have been “burned” by some compounding pharmacies.
 - For several years, a number of compounding pharmacies contracted with marketing/lead generation companies (“LGCs”) to generate patients who wanted compounded pain and scar creams.
 - The compounding pharmacies would dispense the pain/scar creams and bill the PBMs an exorbitant amount per month/per patient for the creams.
 - The commercial insurers (that were footing the bills) came down on the PBMs.
 - In turn, PBMs do not want their contract retail pharmacies to be engaged in compounding in a meaningful way.

REASONS FOR TERMINATION BY PBM

- Pharmacy is routinely waiving copayments
 - Federal law, most state laws, and most PBM contracts require the pharmacy to “take reasonable steps” to collect copayments.
 - Pharmacies are prohibited from routinely waiving copayments.
 - A pharmacy can waive copayments, on a patient-by-patient basis, if the patient submits financial information justifying the waiver.

REASONS FOR TERMINATION BY PBM

- Pharmacy markets through 1099 independent contractors
 - The federal anti-kickback statute (“AKS”) states that a pharmacy cannot “give anything of value” to a person/entity in exchange for the person/entity referring (or arranging for the referral of) patients to the pharmacy who are covered by a federal government health care program.
 - Each state has an anti-kickback statute that essentially says the same thing as the AKS. Some state anti-kickback statutes apply only when the payor is the state Medicaid program. Other state anti-kickback statutes apply even if the payor is a commercial insurer or a cash-paying patient.

REASONS FOR TERMINATION BY PBM

- If a pharmacy pays percentage compensation to a 1099 independent contractor (individual sales rep or LGC) that arranges for the referral of government health care program patients to the pharmacy, then the AKS is implicated...and an applicable state anti-kickback statute may be implicated.
- As part of the re-credentialing process, the PBM may ask the pharmacy to provide information and documents pertaining to the use by the pharmacy of 1099 independent contractors for marketing. If the information/documents provided by the pharmacy indicate that the pharmacy is paying commissions to 1099 independent contractors, then the PBM may decide to terminate the contract.



RESPONSE TO PBM TERMINATION LETTER



RESPONSE TO PBM TERMINATION LETTER

- The first thing that the pharmacy needs to realize is that it and the PBM have unequal bargaining positions.
- Specifically, the PBM (i) “possesses the pharmacy’s money” and (ii) has an unlimited capacity to litigate with the pharmacy.
- If the pharmacy sues the PBM, or threatens to sue, then the PBM will not be fazed.
- The approach that has the best chance of being successful is for the pharmacy to contact the PBM in order to “work the problem.”
- The termination letter will likely give a reason for the termination. The pharmacy should attempt to work with the PBM to address - and resolve - that “reason.”

RESPONSE TO PBM TERMINATION LETTER

- If a PBM determines the pharmacy is providing mail order that is excluded from the agreement, the PBM may offer the pharmacy the opportunity to abstain from further mail order.
 - Attestation
- If the pharmacy is unsuccessful at resolving the termination “at the lower level,” then the pharmacy’s attorney should reach out to one of the PBM’s in-house attorneys.



ATTESTATION REQUESTED BY PBM (MAIL ORDER)



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- Sample Language

- "The pharmacy reiterates its agreement that it will not ship any prescription drugs, durable medical equipment or prescribed diabetic supplies by U.S. Mail, Federal Express, DHL, UPS or similar national, regional or local carrier."
- "The pharmacy understands that the Pharmacy Provider Agreement permits it to provide same day home delivery to [Name of PBM] members residing in [Name of State]."
- "If the pharmacy violates any of the representations in this attestation, the pharmacy agrees that any such violation constitutes grounds for immediate termination pursuant to Section ___ of the [Provider] Agreement."



RESCISSION OF TERMINATION LETTER (MAIL ORDER)



RESCISSION OF TERMINATION LETTER (MAIL ORDER)

- “[Name of PBM] has completed its review of the information provided as part of the [Date] appeal hearing regarding the decision to terminate [Name of Pharmacy] for cause from participation in all of [Name of PBM]’s, provider networks.”

RESCISSION OF TERMINATION LETTER (MAIL ORDER)

- “Please be advised that after discussion and deliberation, [Name of PBM] hereby rescinds its original decision to terminate [Name of Pharmacy] for cause from all [Name of PBM] provider networks conditioned on [Name of Pharmacy]’s acceptance of the following probationary conditions and Corrective Action Requirements:
 - [Name of Pharmacy] is required to re-evaluate [its] internal procedures to ensure compliance with the [Name of PBM] mailing prohibition restrictions and update all applicable policies and procedures [that include] proof of the remediation effort.

RESCISSION OF TERMINATION LETTER (MAIL ORDER)

- [Name of Pharmacy] agrees to comply with the terms and conditions of the Agreement and Provider Manual.
- [Name of Pharmacy] will need to respond in writing with an understanding of the mailing prohibition and the compliance with state laws”
- “If [Name of Pharmacy] fails to agree or comply or is found in violation at a later time, [Name of Pharmacy] will be subject to termination from all [Name of PBM] provider networks for no less than five (5) years.”



BEST PRACTICES



BEST PRACTICES

- Like it or not PBMs are in the driver's seat
- Understand your Provider Agreement
- Be familiar with the PBM's provider manuals
- Ensure process are in place for promptly responding to request for information.
- Perform regular self-audits to ensure compliance



QUESTIONS?





THANK YOU

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