



EDUCATIONAL RESOURCES

Hot Button Legal Issues Facing Pharmacies in the Next 12 Months

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 PHARMACY



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Telehealth



Introduction

- In the years leading up to the pandemic, health care delivery had been shifting towards telehealth.
- This made sense because many health care encounters did not need to be face-to-face.
- A number of ailments can be diagnosed via a live video conference with the physician.
- A number of treatments can be ordered via a live video conference with the physician. A patient's vital signs can be monitored with remote technology.
- All providers can utilize technology to assist the patient in setting up his equipment and educate the patient on how to use the equipment.

Introduction

- In short, there are many scenarios in which a patient should not have to leave the confines of his home to receive health care.
- Pre-pandemic, the shift towards telehealth had been led by commercial insurers, not by Medicare. Commercial insurers were more open to telehealth than the Medicare program. Insurers recognized the cost-saving benefits of telehealth; Medicare was slow to follow the private sector's lead.
- But then COVID changed everything. Beginning in March 2020, the health care delivery system went into triage mode. The focus was to keep as many patients as possible out of the hospitals to free up hospital beds for the sickest.

Medicare Policy Changes

- Policy Changes
- Since early March 2020, CMS has issued a number of waivers, regulations, and rules pertaining to telehealth.
- In doing so, CMS
 - expanded the health care workforce by removing barriers to providing care;
 - removed regulatory barriers with the goal of ensuring that hospitals can handle a surge of COVID patients; and
 - removed regulatory barriers with the goal of ensuring that patients have access to care while remaining at home.

Medicare Policy Changes

- Coronavirus Preparedness and Response Supplemental Appropriations Act (March 6, 2020)
- Coronavirus Preparedness and Response Supplemental Appropriations Act (March 27, 2020)
- New CMS Rules
 - CMS issued rules (CMS-1744-IFC, CMS-5531-IFC) and FAQs addressing telehealth expansion during the PHE. Medicare now pays for telehealth services at the same rate as in-office visits for all diagnoses, not just services related to COVID. Physicians can reduce or waive Medicare beneficiary cost-sharing for telehealth visits, virtual visits, e-visits, and remote monitoring services.

Medicare Policy Changes

- Medicare Telehealth Changes
 - Patients can receive telehealth and other technology-based services wherever the patients are located.
- CMS has expanded the types of practitioners who may provide telehealth services.
- Telehealth can now be billed by all provider types who are eligible to bill Medicare for their professional services.
- Clinicians can provide remote patient monitoring services to both new and established patients and these services can be provided to patients with only one disease.

Telehealth

- Beneficiary consent can be obtained remotely. Physician supervision of other health care professionals can be performed remotely for services that require it.
- There is a temporary waiver of the requirement that a practitioner be licensed in the state where he is providing services (note that state requirements still apply).
- The CARES Act permanently allows mid-level providers including nurse practitioners and physician assistants to prescribe DME for patients. In many instances, these changes apply to Medicaid.
- Commercial payors have adopted many of these changes and have expanded access to telehealth in significant ways.

Telehealth

- Office for Civil Rights (“OCR”) Relaxation of Technology Requirements
 - Historically, telehealth requirements limited access to telehealth to those with access to advanced technologies. OCR relaxed HIPAA requirements for the use of technology to facilitate the relaxed CMS guidelines for telehealth including standards of good faith for the HIPAA requirements when using alternate technology.
- Future of Telehealth
 - Most experts anticipate that the expansion of telehealth is here to stay. The best analogy may be that we are experiencing 10 or more years of progress towards telehealth in a matter of months. It is unlikely that all of this progress will be reversed.



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Offering Value-Added Services to Customers While Avoiding Prohibited Inducements

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Beneficiary Inducement Statute + Federal Anti-Kickback Statute

- Key elements of the Beneficiary Inducement Statute
 - This statute prohibits a provider from offering or giving anything of value to a federal health care program (“FHCP”) patient that the provider knows, or should know, is likely to persuade the person to purchase a product or service covered by an FHCP.
 - In the preamble to the regulations implementing this statute, the OIG stated that the inducement statute does not prohibit the giving of incentives that are of nominal value.
 - The OIG defines “nominal value” as no more than \$15 per item or \$75 in the aggregate to any one FHCP patient on an annual basis.
 - Nominal value is based on the retail purchase price of the item.

Beneficiary Inducement Statute + Federal Anti-Kickback Statute

- Key elements of the federal Anti-Kickback Statute
 - AKS - It is a felony for a health care provider to knowingly and willfully offer or pay any remuneration to induce a person/entity to refer an individual for the furnishing or arranging for the furnishing of any item for which payment may be made under an FHCP, or the purchase or lease or the recommendation of the purchase or lease of any item for which payment may be made under an FHCP.
 - Stark - This statute provides that if a physician has a financial relationship with an entity providing “designated health services,” the physician may not refer Medicare/Medicaid patients to the entity unless a Stark exception applies.

Safe Harbors

- Because of the breadth of the AKS, the OIG has published a number of safe harbors.
- A safe harbor is a hypothetical fact situation such that if an arrangement falls within it, the AKS is not violated.
- If an arrangement does not fall within a safe harbor, it does not mean that the arrangement violates the AKS. Rather it means that the arrangement needs to be carefully scrutinized under the language of the AKS, applicable case law, and other published guidance.

Advisory Opinions, Special Fraud Alerts, and Special Advisory Bulletins

■ Advisory Opinions

- A health care provider may submit to the OIG a request for an advisory opinion concerning a business arrangement that the provider has entered into or wishes to enter into in the future.
- In submitting the advisory opinion request, the provider must give to the OIG specific facts.
- In response, the OIG will issue an advisory opinion concerning whether or not there is a likelihood that the arrangement will implicate the AKS.

Advisory Opinions, Special Fraud Alerts, and Special Advisory Bulletins

- Special Fraud Alerts and Special Advisory Bulletins
 - From time to time, the OIG publishes Special Fraud Alerts and Special Advisory Bulletins that discuss business arrangements that the OIG believes may be abusive and educate health care providers concerning fraudulent and/or abusive practices that the OIG has observed and is observing in the industry.

States

- All states have enacted statutes prohibiting kickbacks, fee splitting, patient brokering, or self-referrals.
- Some statutes only apply when the payer is a government health care program.
- Other statutes that apply regardless of the identity of the payer.

Collaboration with Hospital to Prevent Readmissions

- Hospital Readmissions Reduction Program:
 - if a patient is readmitted after discharge within a certain period of time, for a particular disease, the hospital can be subjected to future payment reductions for Medicare.
- A hospital can contract with a provider to monitor/work with discharged patients so that they are not readmitted soon after being discharged.
- If the hospital asks the provider to furnish post-discharge services to the patient that the provider would normally not be expected to furnish, the hospital should pay fair market value compensation to the provider for the services.

Loan/Consignment Closets

- Assume that the provider furnishes DME. A provider may place inventory in a hospital or physician office. The DME must be for the convenience only of the hospital's/physician's patients and the hospital/physician cannot financially benefit, directly or indirectly, from the products.
- If a provider pays rent for a space in which the consigned inventory is placed, the arrangement should comply with the Space Rental safe harbor. If rent is being paid to a physician, the arrangement should also comply with the Space Rental Exception to Stark.

Failure to Collect Full Copayment

- Instead of collecting the full copayment, some providers only collect a flat rate.
- By discounting the copayment owed by the patient, the provider is essentially waiving the remainder of the copayment.
- A waiver of copayment (whole or partial) should only be made when financial hardship is documented.
- Furthermore, up-front discounting of the copayment will likely be viewed as a reduction of the provider's actual charge for the product/service and will likely affect the provider's usual and customary charge for the product/service.

Failure to Collect Full Copayment

- The provider needs to avoid entering into a sham copayment subsidy arrangement.
- Such an arrangement can take many forms. However, the end result is that the patient ends up paying none of the copayment, or only a small portion of the copayment.

Movement to Integrated Care Model

- Third-party payors are pushing providers away from the traditional fee-for-service model into the integrated care model. Under this model, providers are expected to coordinate with each other so that they work as a team to heal the patient and then keep the patient healthy.
- Further, reimbursement is tied to patient outcome. While commercial insurers are on the forefront in pushing the integrated care model, government health care programs are also going down this path.

Movement to Integrated Care Model

- As providers engage in the integrated care model, they will desire to furnish products and services to patients, free of charge, intended to promote access to care. Over the past several years, there has been an easing of restrictions against providing free products and services designed to promote access to care. Such easing of restrictions can be found in the Affordable Care Act, OIG regulations, and in two recent OIG Advisory Opinions.

Relaxation of Stark Law and Kickback Statute

- On November 20, 2020,
 - the OIG published modifications to the safe harbors to the AKS and
 - CMS published modifications to Stark.
- The goals of the modifications are to promote coordination of care and break down socio-economic barriers to health care.
- The message for providers is that CMS and the OIG are acknowledging the importance of providers coordinating with each other even if such coordination would have historically implicated the AKS, Stark, and the beneficiary inducement statute.



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Collaboration with Physicians

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Introduction

- There are 2 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.

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.

Federal Statutes

- 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
 - an ownership interest by the physician (or an immediate family member of the physician) in the pharmacy and/or
 - compensation (or anything else of value) from the pharmacy to the physician (or an immediate family member of the physician).

Federal Statutes

- 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 2021, that amount is \$429.

Example – 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. 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
 - that the pharmacy has a sophisticated business model and
 - that the pharmacy's products and services are successful in treating conditions and keeping patients out of the hospital.

Example – 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, the Medical Director Agreement (“MDA”) needs to comply with
 - the Personal Services and Management Contracts safe harbor to the AKS and
 - the personal services exception to Stark.

Example – Medical Director

- Among other requirements,
 - the MDA needs to be in writing,
 - the MDA must have a term of at least one year,
 - the compensation must be fixed on year in advance, and
 - the compensation must be the fair market value 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.

Example – 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
 - products and services offered by the pharmacy and
 - 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.

Example – 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 fair market value.

Example – 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 fair market value.

Example – 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.

Example – 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.

Example – 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.

The 60-Day Rule



Introduction

- Prior to enactment of the Affordable Care Act, when a pharmacy determined that Medicare should not have paid certain past claims, then it was common for the pharmacy
 - not to voluntarily refund the claims, but
 - to correct the problem from a go-forward standpoint.
- This type of “go and sin no more” response, while questionable before enactment of the Affordable Care Act, is clearly not adequate since passage of the Affordable Care Act.

The 60-Day Rule

- Key elements of the 60-Day Rule
 - Section 6402 of the Affordable Care Act states that any provider or supplier that receives an overpayment must
 - report to CMS and
 - provide written notice of the reason for the overpayment.
 - The overpayment must be reported and returned no later than 60 days after it is identified. Failure to do so may result in civil monetary penalties under the Federal False Claims Act.
 - In its final rule, CMS provided guidance regarding the obligations of providers and suppliers to report and repay overpayments.

The 60-Day Rule

- Key elements of the 60-Day Rule
 - The final rule addressed the lookback period. This is the time period for which a pharmacy must examine its patient files for overpayment obligations. CMS originally proposed a 10-year lookback period. However, the final rule shortened the lookback period to 6 years.
 - The final rule stated that, as a general rule, a pharmacy will have 6 months to investigate possible overpayments before the 60-day clock starts running. Compare this to the proposed rule which said that the investigation should be conducted with all deliberate speed.

The 60-Day Rule

- Key elements of the 60-Day Rule
 - The final rule addressed what it means to identify an overpayment. According to the final rule, identification occurs when a pharmacy “has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment.”
 - Under the final rule, a pharmacy will have identified an overpayment
 - if the pharmacy conclusively knows about it or
 - if the pharmacy would have known about it by acting with reasonable diligence. Although the term “reasonable diligence” gives flexibility to CMS, CMS is unlikely to punish a good faith compliance effort.



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Working With, Not Against, PBMs

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Mindset

- 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.

Mindset

- 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, there is a risk that the PBM will exercise its termination right.

Recredentialing

- Key Elements of Recredentialing
 - PBMs will recredential pharmacies every year or couple of years to ensure that they meet the PBMs' participation requirements.
 - As part of the recredentialing process, the PBM will require the pharmacy to complete and submit a questionnaire.
 - The questionnaire will be lengthy and will require the pharmacy to provide detailed information. It is important that the pharmacy truthfully answer the questions contained in the questionnaire. If certain answers are not truthful, the PBM will likely find out. This can result in
 - the PBM terminating the contract and
 - recouping payments previously made.

Recredentialing

- Key Elements of Recredentialing
 - The recredentialing application will likely inquire about all or most of the following:
 - extent of the pharmacy's compounding;
 - use of marketing reps;
 - use of W-2 employees vs. 1099 independent contractors;
 - central fill arrangements;
 - pre-printed prescription pads;
 - collection of copayments;
 - out-of-state licensure; and
 - extent of mail-order business.

Preparing for an Audit

- Key Elements of Preparing for an Audit
 - The pharmacy should understand what its contract with the PBM says.
 - If the contract incorporates outside documents (e.g., policy manuals), 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 the 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 W-2 employees or 1099 independent contractors.
 - 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.

Preparing for an Audit

- Key Elements of Preparing for an Audit
 - Once a year, the pharmacy may want to 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 PBM contracts in particular.
 - The pharmacy should have a system in place to receive, catalogue, and respond to:
 - phone calls,
 - emails,
 - hard copy mail, and
 - other types of outside communications.
 - 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.

Responding to Audit: 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, 2022).
 - 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.”

Responding to Audit: Determining the Deadline

- If the deadline is “30 days from date of this letter,” 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, the pharmacy has less than 15 days to respond.

Responding to Audit: Determining the Deadline

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

Responding to Audit: 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.

Responding to Audit: Determining What the PBM is Focusing on

- Key Elements of Preparing for an Audit
 - 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.

Responding to Audit: Determining What the PBM is Focusing on

- Key Elements of Preparing for an Audit
 - In the past, the PBM's primary focus was on whether the pharmacy
 - received a valid prescription,
 - dispensed the drug in accordance with the prescription, and
 - submitted the claim for exactly what was dispensed.

Responding to Audit: Determining What the PBM is Focusing on

- Key Elements of Preparing for an Audit
 - 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
 - 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
 - is engaged in fraudulent activities.

Responding to Audit: Determining What the PBM is Focusing on

- Responding to Audit: Compliance with Contract
 - 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.

Responding to Audit: Determining What the PBM is Focusing on

- Mail-Order
 - 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.

Legal Compliance - Copayments and Marketing

- 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.

Legal Compliance - Copayments and Marketing

- 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 - Copayments and Marketing

- 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, the risk of violating the AKS is low.

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.

Legal Compliance Affiliated Pharmacies

- For example:
 - John Smith owns ABC Pharmacy.
 - Smith is aware that a PBM will likely terminate ABC's contract.
 - So, Smith will open up XYZ Pharmacy, XYZ will secure a contract with the same PBM, and ABC will transfer its patients to XYZ.
- In an audit, the PBM will likely ask questions designed to uncover this type of scheme.

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, 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?

Review the 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 the Documentation to be Submitted

- 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, 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.

Review the Documentation to be Submitted

- Rehabilitate the 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.

Tell a Story

- When the pharmacy submits documents in response to an audit, the documents should be organized in such a way that they tell a story. The story that the pharmacy wants the documents to tell is that
 - each product delivered to a patient was in response to a valid prescription,
 - the pharmacy dispensed the exact product that was prescribed, and
 - 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 2 sets of copies
 - 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 rule, PBMs do not want to deal with attorneys unless they have no choice. Having said this, it is advisable for the pharmacy's health care attorney to "ghost write" the letter for the pharmacy's signature.

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
 - represent to the PBM that the pharmacy can supplement the submitted documents as requested by the PBM and
 - explain to the PBM that the pharmacy will be available any time that the PBM has questions.

Questions?





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Thank you

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