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Contracting Essentials for Long-Term Care Pharmacies

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Speaker



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Disclosure Statement

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.



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Pharmacist and Technician Learning Objectives

1. Describe the types and structures of contracts commonly used by an LTC pharmacy.
2. Identify key legal and regulatory considerations that apply to LTC contracts.
3. Evaluate essential elements that define clear, enforceable LTC contracts.
4. Recognize common red flags and risk areas in LTC contracting.



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Introduction

- The term “long term care” (“LTC”) has many components, including:
 - Custodial care facilities – These are facilities that become patients' homes. The patient resides in the facility for the balance of their lives.
 - Skilled Nursing Facility (“SNF”) – A SNF is not limited to elderly patients. However, many SNF patients are elderly patients. If a patient is discharged from a hospital, but if he/she is not well/strong enough to go home, the patient will be admitted to a SNF for a limited number of days. At the SNF, the patient will receive therapy designed to make the patient well/strong enough to go home.



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Introduction

- The term “long term care” (“LTC”) has many components, including:
 - Assisted Living Facilities.
 - Independent Living Facilities.
 - Group Homes.



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Introduction

- Baby Boomers (people born between 1946 and 1964) are retiring at the rate of 10,000 per day.
- On the heels of the Boomers are the aging Generation X and Millennials.
- This means that the demand for LTC services will continue to increase. And this means that demand for LTC pharmacy services will also increase.



The KASASA Exchange, September 3, 2025, "Boomers, Gen X, Gen Y, Gen Z, Gen A and Gen B Explained"
CNBC, February 8, 2024, "As Baby Boomers Hit 'Peak 65' This Year, What the Retirement Age Should Be is Up for Debate"

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Introduction

- LTC pharmacies are subject to federal and state regulations...and such pharmacies "live in a glass house."
- This means that if an LTC pharmacy is doing something it should not be doing, someone knows about it. That "someone" can be a current employee, a former employee, a competitor, or a third-party payor.
- As LTC pharmacies enter into contracts with physicians, hospitals, and others, it is important that the contracts comply with federal and state laws designed to prevent fraud and abuse. This is the focus of this program.



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Legal Guidelines – Federal Statutes

- LTC pharmacies are highly regulated at the federal and state levels. This is largely due to the fact that LTC pharmacies directly or indirectly receive revenue from taxpayer dollars. Five important federal laws affecting LTC pharmacies are:
 - Anti-Kickback Statute (42 U.S.C. § 1320a-7b) ("Federal AKS")
 - Beneficiary Inducement Statute (42 U.S.C. § 1320a-7a (a))
 - Telephone-Solicitation Statute (42 U.S.C. § 1395m(a)(17))
 - False Claims Act (31 U.S.C. § 3729)
 - Physician Self-Referral Statute ("Stark") (42 U.S.C. § 1395nn)

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Safe Harbors to Federal AKS

- Because of the breadth of the Federal AKS, the Office of Inspector General ("OIG") has published a number of safe harbors. If an arrangement meets all of the elements of a safe harbor, the arrangement does not violate the Federal AKS. If an arrangement does not meet all of the elements of a safe harbor, it does not mean that the arrangement violates the Federal AKS. Rather, it means that the parties to the arrangement need to carefully analyze the arrangement in light of the language of the Federal AKS, court decisions, and OIG guidance. Six important safe harbors for LTC pharmacies are:



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Safe Harbors to Federal AKS

- Small Investment Interests
- Space Rental
- Equipment Rental
- Personal Services and Management Contracts
- Employees
- Electronic Health Records



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Legal Guidelines – State Statutes

- Each state has an anti-kickback statute (“State AKS”) that is similar to the Federal AKS.
 - Many State AKSs only apply when the payer is the state Medicaid program.
 - Some State AKSs also apply when the payer is a commercial insurer.
 - Some State AKSs also apply when the payer is a cash-pay patient.
- A number of State AKSs incorporate the federal safe harbors by reference.



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Legal Guidelines – State Statutes

- Many states have a physician self-referral statute similar to Stark.
- All states have statutes specific to physicians.
- All states have statutes specific to pharmacies.



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60 Day Rule

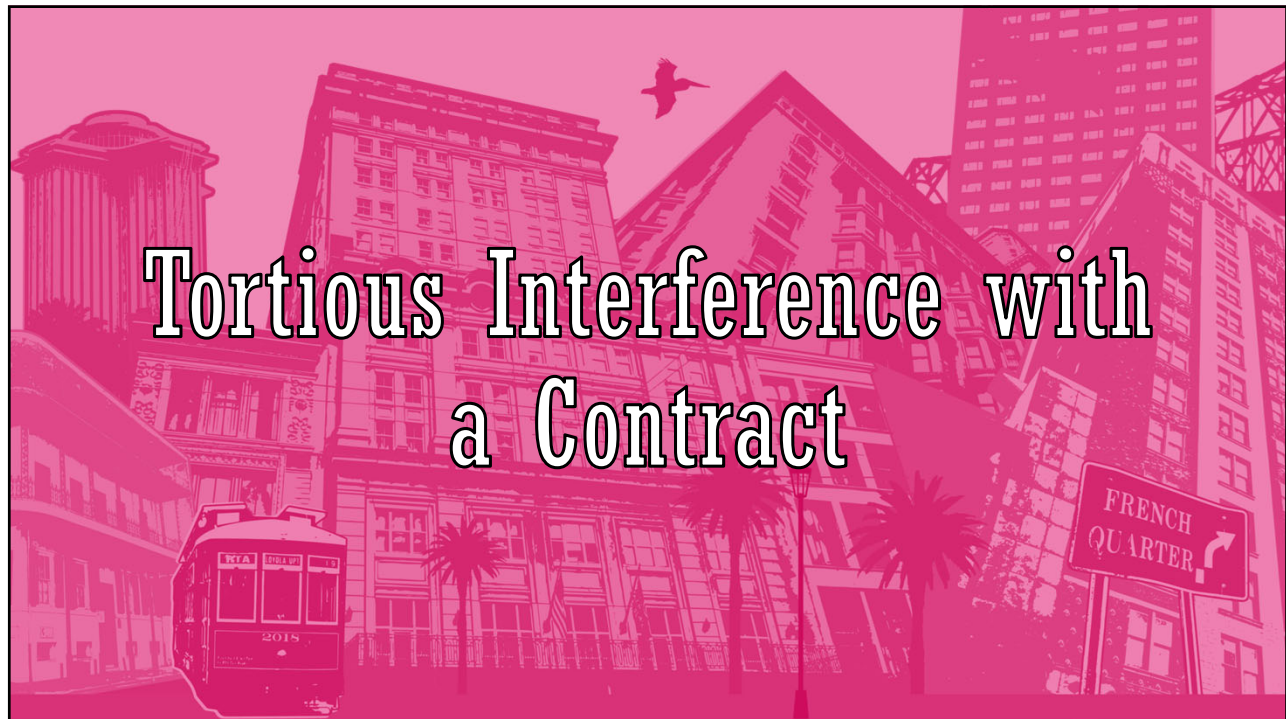
- If a health care provider determines (or with reasonable diligence, should have determined) that it improperly submitted claims to Medicare, the provider has 60 days to (i) report the overpayment to CMS and (ii) refund the claims.
- Failure to comply with the 60 Day Rule may result in the claims becoming false claims in violation of the federal False Claims Act.

OIG Special Fraud Alerts and Special Advisory Bulletins

- The OIG publishes Special Fraud Alerts and Special Advisory Bulletins designed to educate health care providers on how to avoid fraud. Important alerts and bulletins for LTC pharmacies include:
 - 1989 Special Fraud Alert: Joint Venture Arrangements
 - Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B
 - OIG's April 2003 Special Advisory Bulletin: Contractual Joint Ventures
 - Special Fraud Alert: Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer
 - Offering Gifts and Other Inducements to Beneficiaries

OIG Advisory Opinions

- Parties to a proposed arrangement may be concerned that the proposed arrangement will violate the Federal AKS. The parties can choose to ask the OIG to review the proposed arrangement and issue an opinion on whether the proposed arrangement violates the Federal AKS.
- The advisory opinions can be found on the OIG website. The names of the parties are redacted.
- Although an advisory opinion is only binding on the parties to the proposed arrangement, the opinion can nevertheless be helpful to individuals/entities wishing to enter into similar arrangements.



Tortious Interference With Contract

- It is acceptable for a pharmacy to compete against other pharmacies for (i) patients and (ii) referral sources. However, there is a line that should not be crossed.
- A classic example is a noncompete/nonsolicitation provision in a contract.
 - Assume that a pharmacist (John Smith) has a written employment contract with ABC Pharmacy.
 - Assume that the employment contract has a noncompete/nonsolicitation provision stating that, following the termination of Smith's employment with ABC, Smith cannot (i) compete against ABC within a specified geographical area for a specified time period and (ii) within a specified time period, solicit ABC patients and referral sources

Tortious Interference With Contract

- A classic example is a noncompete/nonsolicitation provision in a contract (cont.).
 - Assume that immediately after Smith leaves ABC, he goes to work for XYZ Pharmacy. Assume that XYZ is aware of the contract that Smith has with ABC.
 - Upon being hired by XYZ, Smith (i) competes with ABC and (ii) solicits ABC's patients and referral sources.
 - The end result is that XYZ will be "interfering" with Smith's contract with ABC...resulting in XYZ being liable to ABC.

Tortious Interference With Contract

- Another example is a Preferred Provider Agreement ("PPA") that ABC Pharmacy has with a hospital. The PPA states that if ABC provides a laundry list of services for the hospital's patients when they are discharged, the hospital will (subject to patient choice) refer the patients to ABC.
- It is acceptable for XYZ to approach the hospital, educate the hospital on the types of services XYZ can provide, and ask the hospital to also designate XYZ as a preferred provider.
- On the other hand, it is *not* acceptable for XYZ to tell the pharmacy that ABC does not have the personnel and equipment for ABC to fulfill its obligations under its PPA with the hospital.



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Arrangement with LTC Facility



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Arrangement With LTC Facility

- A LTC facility is a referral source for a LTC pharmacy.
- If a LTC pharmacy provides “anything of value” to a LTC facility in exchange for referrals, the Federal AKS is implicated.



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Examples of Prohibited Conduct

- The following are examples of actions by a LTC pharmacy that violate the Federal AKS.
 - The pharmacy conducts monthly drug regimens for the facility at no charge.
 - The pharmacy gifts drug carts and related equipment to the facility.
 - The pharmacy gifts bedding, water bottles, and food to the facility.
 - The pharmacy provides an employee liaison, at no charge to the facility, who provides services that a facility employee would normally have to provide.



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Examples of Acceptable Conduct

- The following are examples of actions by a LTC pharmacy that are legally acceptable.
 - The pharmacy charges fair market value ("FMV") compensation to the facility for conducting monthly drug regimens.
 - The pharmacy allows the facility to use the pharmacy's drug carts for drugs that the pharmacy dispenses. Title to the drug carts remains with the pharmacy...and the pharmacy can regain possession of the drug carts whenever it wishes to do so.
 - The pharmacy provides education seminars/webinars to (i) residents, (ii) family members of residents, and (iii) facility employees.



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Examples of Acceptable Conduct

- The pharmacy provides an employee liaison at no charge to the facility. The liaison (i) works with facility patients who receive drugs from the pharmacy, (ii) educates patients and their caregivers about drug regimens, and (iii) educates the facility regarding services provided by the pharmacy. The liaison does not perform services that a facility employee is normally required to perform.
 - The pharmacy provides services to the facility that a facility employee would normally have to provide. The facility pays FMV compensation to the pharmacy for the services.



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Donation of Electronic Health Records (“EHR”) Software

- To encourage the adoption of EHR technology, the OIG published a safe harbor to the Federal AKS pertaining to the donation of interoperable EHR software.
- To gain the protection of the safe harbor, a number of elements must be met, including the following:
 - The facility must pay at least 15% of the cost of the software.
 - The software must be interoperable.



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Avoidance of Kickback

- Assume that ABC owns/leases a building that provides both skilled nursing care and custodial care. In other words, the building is both a SNF and a traditional nursing home.
- Assume that a pharmacy dispenses drugs to SNF and custodial care patients.
- The pharmacy may be tempted to provide drugs to a skilled nursing patient for below fair market value ("FMV") compensation in order to motivate ABC to refer custodial care patients to the pharmacy.



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Avoidance of Kickback

- Doing so will result in "something of value" flowing from the pharmacy to ABC in exchange for the referral of pharmacy dispenses patients. This, in turn, will violate the AKS.
- And so it is important that ABC pay FMV compensation to the pharmacy for the drugs that it dispenses to SNF patients.



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Avoidance of a Kickback

- A pharmacy may be tempted to donate products and services to a SNF, or to engage in activities that will save the SNF money.
- The pharmacy needs to avoid doing this because such actions will likely violate the AKS.



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Failure of SNF to Pay

- It is not uncommon for a pharmacy to provide products/services to a SNF patient and then discover that the SNF refuses to pay for the products/services.
- The facility's reasoning may be that because it is granting the pharmacy access to the facility's custodial care patients, the pharmacy should not expect payment from the facility for the products and services to the facility's Part A patients.



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Failure of SNF to Pay

- This scenario violates the AKS because free products/services to Part A patients (i.e., SNF patients) constitute “something of value” provided by the pharmacy to the facility...in exchange for referrals of custodial care patients by the facility to the pharmacy.
- Both the facility and the pharmacy are liable under the AKS.



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Permitted Gifts to SNF Patients

- The pharmacy can provide a gift to a SNF patient if the gift has a retail value of \$15 or less.
- The gift cannot be cash or cash equivalent such as a gift card or pre-paid credit card.
- The pharmacy can provide multiple gifts to a SNF patient so long as the retail value of all the gifts, combined, during any given 12 month period does not exceed \$75.



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Examples of Acceptable Gifts to SNF Patients

- Books
- Electronic products
- Food
- Flowers
- Vitamins
- Skin care products



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Impermissible Gifts to SNF Patients

- Cash, gift cards, pre-paid credit cards
- Individual gift that has a retail value in excess of \$15
- Multiple gifts during the course of 12 months that, combined, have a retail value in excess of \$75



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Providing Products to SNFs

- As a general rule, the AKS prohibits the pharmacy from donating products to a SNF.
 - However, the pharmacy can deliver possession of iPads and drug carts to a SNF so long as (i) title to the iPads and drug carts remains with the pharmacy and (ii) the SNF uses the iPads and drug carts only in conjunction with its relationship with the pharmacy.
 - On the other hand, the pharmacy cannot donate drug carts and/or bedding to the SNF because such items cannot be limited to the SNF's relationship with the pharmacy. Rather, donation of these items is simply relieving the SNF of its costs to purchase bedding.



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Consulting Pharmacy Services



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Consulting Pharmacy Services

- 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.



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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.



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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.



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Introduction

- Assume that a LTC facility ("facility") is amenable to entering into a "preferred provider" arrangement with a pharmacy in order to have the pharmacy on standby to timely dispense drugs to the facility's patients.
- How should the facility and pharmacy consummate their preferred provider arrangement? An important first step is for the hospital and DME supplier to execute a Preferred Provider Agreement ("PPA") that contains a number of provisions, including the following:

Introduction

- The facility provides (or arranges for the provision of) many services to its residents. The facility desires to appoint a qualified Preferred Provider to pharmacy services to patients who elect to utilize the Preferred Provider and the pharmacy desires to serve in the capacity of the Preferred Provider for the facility.
- The facility has confidence in the quality of the pharmacy's services, the pharmacy has a good reputation, and the pharmacy is willing to support the mission of the facility.

Appointment of Preferred Provider

- The facility appoints the pharmacy as its Preferred Provider for furnishing pharmacy services to residents who elect to receive such services from the pharmacy, and the pharmacy accepts the appointment.

Duties of the Pharmacy

- As requested by the facility pursuant to a physician's prescriptions, the pharmacy will furnish pharmacy services to patients.
- The pharmacy services furnished by the pharmacy will be provided in the same manner and be of the same quality as the pharmacy services that the pharmacy customarily provides to its other patients.

Duties of the Pharmacy

- **Drug Cart and Related Equipment** – The Supplier will maintain a drug cart and related equipment at the suitable to allow the pharmacy to provide pharmacy services to patients.
- **Availability** – The pharmacy will use its best efforts to provide pharmacy services to patients within the time frame specified by the facility.
- **Initial Contact** – The pharmacy will contact a patient within ___ hours of receipt of the referral from the facility to schedule delivery of the drug.
- **Delivery** – The pharmacy will deliver drugs to the patient, as mutually agreed to by the facility and the pharmacy.



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Duties of the Pharmacy

- **Billing** – The pharmacy will bill and collect for its own account all charges to patients and third-party payors. The facility will cooperate as reasonably requested by the pharmacy in obtaining and providing documentation required to support claims for payment for the prescribed drug.
- **24 Hour Availability** – The pharmacy will provide 24 hour service, seven days per week telephone availability to the facility and patients.
- **Complaints** – The pharmacy will promptly address any patient or caregiver complaints or concerns and coordinate its response with the facility as appropriate.
- **Facility Staff Education** – The pharmacy will (i) educate the facility staff regarding the pharmacy services, (ii) be available to answer questions posed by facility staff, and (iii) resolve concerns expressed by the hospital staff.



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Duties of the Pharmacy

- **Regulatory Compliance** - The pharmacy will maintain a written Compliance Plan and an active internal compliance program under the direction of a designated Compliance Officer to ensure that the pharmacy does not knowingly fail to comply with the service and billing requirements established by Medicare, Medicaid, and other third party payors.
- **Resources** – At its own cost and expense, the pharmacy will provide all drugs, staff, vehicles, office space, and other resources necessary or appropriate to perform its duties.



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Duties of the Facility

- **Notice of Selection** – In the event the patient selects pharmacy to provide pharmacy services, the facility will so notify the pharmacy and provide the pharmacy with complete and accurate information as may be necessary for the pharmacy to perform its duties.
- **Preferred Provider Status** – The facility will accord the pharmacy “Preferred Provider” status to serve patients requiring pharmacy services. Nevertheless, the “Preferred Provider” status will not be construed as compromising any patient's right to select his or pharmacy of choice.



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Duties of the Facility

- **Patient Choice** – The facility will inform patients of their right to select their pharmacy of choice. In the event that a patient does not express a preference for a particular pharmacy, the facility will inform the patient of the preferred provider arrangement and recommend pharmacy. The facility will be responsible for ensuring that patients are given free choice of pharmacies and will document such choice in accordance with applicable law.
- **Information** – For each patient served pursuant to this PPA, the facility will provide the pharmacy with information, including the patient's identifying and clinical information, the pharmacy services, the name of the ordering physician, the expected delivery date, and insurance and other third party billing information.



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Duties of the Facility

- **Coordination** – If required for a patient, the facility will coordinate the provision of pharmacy services with nurses, aides, therapists, or other caregivers involved with the patient's care.
- **Advanced Notice** – To promote continuity of care, patient convenience and cost efficiencies, the facility will use commercially reasonable efforts to provide the pharmacy with advance notice of a patient's pharmacy services needs.
- **Complaints** – The facility will promptly inform the pharmacy of any pharmacy services-related patient complaints or concerns of which the facility becomes aware and, if appropriate, will coordinate and cooperate with the pharmacy in fashioning an appropriate response.



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No Referrals Required/No Remuneration

- There is no requirement that any patients be referred from one party to the other party. Neither party will directly or indirectly pay remuneration to the other party.

Term and Termination

- The term will be for one year.
- At the end of one year, and at the end of each year thereafter, this PPA will automatically renew.
- Either party may terminate this PPA, with or without cause, by giving the other party at least ____ days prior written notice.

Indemnification

- Each party ("Indemnifying Party") will indemnify and hold harmless the other party ("Indemnified Party") from and against any liability on account of damaged property or bodily injury arising out of intentional acts, reckless acts, or negligent acts of the Indemnifying Party.

Insurance

- Each party will maintain insurance of such kinds and in such amounts as are usual in the party's business or operations.
- Evidence of the insurance coverage will be provided by each party to the other upon request.



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Introduction

- Assume that a pharmacy enters into an agreement with a subcontractor located in e.g., Mumbai (India) or Manila (Philippines).
- Many U.S. businesses (health care related and non-health care related) contract with offshore subcontractors for BPO (business, process, outsource) services. BPO services are sometimes referred to as “back office” services. The motivation for doing so is to reduce costs.
- As will be discussed, below, it is generally permissible for pharmacies to utilize offshore subcontractors...but as is often the case, the “devil is in the details.”

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Federal Guidelines

- There are no federal laws that prohibit the use of offshore subcontractors. During enrollment and revalidation, or when there is a change in such an arrangement, the pharmacy may have to disclose the existence of offshore subcontractors.
- In 2007 and 2008, CMS issued several memoranda to Part C sponsors concerning the use of offshore subcontractors. According to the memoranda:
 - Sponsors are to report specific offshore subcontractor information and complete attestations regarding protection of protected health information ("PHI").
 - Sponsors may, in turn, pass these requirements onto network providers.

State Guidelines

- On December 30, 2010, CMS issued a memorandum to State Medicaid Directors that prohibits State health plans from providing payments (for items and services) to a financial entity located offshore.
- This does not prohibit payment to outsourcing facilities located offshore that provide plan administration or call centers for enrollment or claims adjudication.
- On the other hand, this **does** prohibit a State plan from making payments to a provider's bank that is located offshore.
- This also prohibits the State plan from paying offshore telemedicine companies and pharmacies.

State Guidelines

- On April 11, 2014, the OIG issued a Memorandum Report to CMS regarding the use of offshore subcontractors.
- The OIG issued a questionnaire to all State Medicaid programs regarding the use of offshore subcontractors.
- The questionnaire focused on protections the State Medicaid programs had in place for protection of PHI when using offshore subcontractors.
- Based on the Memorandum, several State Medicaid programs prohibit the use of offshore subcontractors.

Third Party Payors (“TPPs”)

- It is important for the pharmacy to review (i) its contracts with TPPs, (ii) the provider manuals of the TPPs the pharmacy works with, and (iii) the payor policies of the TPPs the pharmacy works with.
- TPPs may (i) require the pharmacy to give advanced notice before contracting with an offshore subcontractor, (ii) require the pharmacy to obtain the permission of the TPP to contract with an offshore subcontractor, (iii) prohibit the use of offshore subcontractors, or (iv) have no policy at all regarding offshore subcontractors.

Privacy Laws of Other Countries

- In addition to understanding the requirements of the federal government, State Medicaid programs, and TPPs, it is important that the pharmacy expect its offshore subcontractor to comply with its own country's privacy laws.
- A number of countries have privacy laws that are similar to HIPAA.



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Medical Director Agreement



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Medical Director Agreement

- A pharmacy can enter into an independent contractor Medical Director Agreement ("MDA") with a physician who is a referral source for the pharmacy.
- The MDA must comply with the (i) Personal Services and Management Contracts safe harbor to the AKS and (ii) the Personal Services exception to Stark.



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Medical Director Agreement

- Among other requirements:
 - The MDA must be in writing and have a term of at least one year.
 - The physician must provide substantive services.
 - The methodology for calculating compensation to the physician must be fixed one year in advance and be the FMV equivalent of the physician's services.



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Employee Liaison

- A pharmacy may designate an employee to be on a facility's premises for a certain number of hours each week.
- The employee may educate the facility staff regarding services the pharmacy can offer.
- The employee liaison may not assume responsibilities that the facility is required to fulfill.
- Doing so will save the facility money, which will likely constitute a violation of the AKS.

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Paying Physician to Provide Education Program

- It is permissible for a pharmacy to pay a physician to present an education program if the following requirements are met:
 - The program is substantive and valuable to the audience.
 - The compensation paid to the physician is the FMV equivalent of the time and effort the physician expended to (i) prepare for the program and (ii) present the program.

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