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ARRANGEMENTS BETWEEN PHARMACIES AND LONG-TERM CARE FACILITIES: LANDMINES TO AVOID

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INTRODUCTION

INTRODUCTION

- Pharmacies have been an integral component of our nation's health care delivery system since the foundation of our country.
- Until the 1930s, pharmacies were subject to very little government oversight.
- Beginning in the first half of the 20th century, particularly with the advent of the Food and Drug Administration and the Drug Enforcement Administration, the federal government began to take an increasing role in regulating pharmacies.

INTRODUCTION

- The same can be said for the states. Beginning in the first half of the 20th century, state boards of pharmacy became more active in regulating pharmacies operating in their states.
- Nevertheless, compared to other health care providers (hospitals, physicians, labs, etc.), regulatory requirements imposed on pharmacies were not particularly stringent.
- This has changed and there are several reasons for the change.

INTRODUCTION

- In the past, with few exceptions pharmacies did not bill Medicare. As a result, there was not a great deal of federal governmental scrutiny of pharmacies. But then there was a "sea change."
- In the first decade of the 21st century, Medicare began paying for prescription drugs for Medicare beneficiaries under Part D. As a result, Medicare now has serious "skin in the game.
- Because Medicare is paying a great deal of money for prescription drugs, Medicare is motivated to scrutinize pharmacy operations to insure that Medicare funds are being wisely spent.

INTRODUCTION

- The same can be said of TRICARE. For the past several years, a number of pharmacies submitted large numbers of claims to TRICARE for compounded drugs … particularly pain and scar creams.
- TRICARE paid these claims until it concluded that the pharmacies were "gaming the system," at which time TRICARE ceased paying for compounded drugs and launched government investigations of compounding pharmacies.
- Because pharmacies are billing Medicare and other government programs, the pharmacies must comply with an array of federal anti-fraud laws such as the Medicare anti-kickback statute and the False Claims Act.

INTRODUCTION

- The primary users of maintenance prescription drugs are the elderly.
- Until recently, the elderly primarily consisted of the 23 million of the "Greatest Generation."
- The Greatest Generation is being replaced by 78 million "Baby Boomers" who are retiring at the rate of 10,000 per day.
- As a result, the demand for health care services, including prescription drugs, is increasing exponentially.

INTRODUCTION

- While most of the aging Boomers will not spend their last years in long term care facilities, because of the sheer number of Boomers, there will be many aging Boomer who will live in facilities.
- This presents an opportunity for pharmacies to develop a niche in serving the elderly.
- Equally as important, this also imposes an obligation on long term care pharmacies to comply with federal and state anti-fraud laws.
- As a result of the large outlays by Medicare and other government programs, there is motivation on the government's part to scrutinize pharmacy operations … particularly long term care pharmacies.

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ANTI-FRAUD LEGAL GUIDELINES

MEDICARE ANTI-KICKBACK STATUTE ("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 a federal health care program (e.g., Medicare, Medicare Advantage, Medicaid, TRICARE), or to induce such person to purchase or lease or recommend the purchase or lease of any item or service reimbursable by a federal health care program.

BENEFICIARY INDUCEMENT STATUTE

- Imposes civil monetary penalties upon a person or entity that offers or gives remuneration to any Medicare/Medicaid beneficiary that the offeror knows or should know is likely to influence the recipient to order an item for which payment may be made under a federal or state health care program.
- This statute does not prohibit the giving of incentives that are of "nominal value" (no more than $15 per item or $75 in the aggregate to any one beneficiary on an annual basis).

ANTI-SOLICITATION STATUTE

- A DME supplier of a covered item may not contact a Medicare beneficiary by telephone regarding the furnishing of a covered item unless:
  - (i) the beneficiary has given written permission for the contact;
  - (ii) a supplier has previously provided the covered item to the beneficiary and the supplier is contacting the beneficiary regarding the covered item; or
  - (iii) if the telephone contact is regarding the furnishing of a covered item other than an item already furnished to the beneficiary, the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months.

STARK PHYSICIAN SELF-REFERRAL STATUTE

- Provides that if a physician has a financial relationship with an entity providing designated health services ("DHS"), then the physician may not refer patients to the entity unless one of the statutory or regulatory exceptions apply.
- DHS includes prescription drugs and DME.

SAFE HARBORS

- Because of the breadth and scope of the AKS, the Office of Inspector General ("OIG") has published a number of "safe harbors." If an arrangement meets the requirements of a safe harbor, then as a matter of law the arrangement does not violate the AKS. If an arrangements does not meet the requirements of a safe harbor, then it does not mean that the arrangement automatically violates the AKS. Rather, the arrangement must be carefully scrutinized under the wording of the AKS, court decisions, and published guidance by the OIG.
- Set out hereafter are five of the most important safe harbors for pharmacies.

SMALL INVESTMENT INTEREST

- For investments in small entities, “remuneration” does not include a return on the investment if a number of standards are met, including the following: (i) no more than 40% of the investment can be owned by persons who can generate business for or transact business with the entity, and (ii) no more than 40% of the gross revenue may come from business generated by investors.

SPACE RENTAL

- Remuneration does not include a lessee's payment to a lessor as long as a number of standards are met, including the following:
  - (i) the lease agreement must be in writing and signed by the parties;
  - (ii) the lease must specify the premises covered by the lease;
  - (iii) if the lease gives the lessee periodic access to the premises, then it must specify exactly the schedule, the intervals, the precise length, and the exact rent for each interval;
  - (iv) the term must be for not less than one year; and
  - (v) the aggregate rental charge must be set in advance, be consistent with fair market value, and must not take into account business generated between the lessor and the lessee.

EQUIPMENT RENTAL

- Remuneration does not include any payment by a lessee of equipment to the lessor of equipment as long as a number of standards are met, including the following:
  - (i) the lease agreement must be in writing and signed by the parties;
  - (ii) the lease must specify the equipment;
  - (iii) for equipment to be leased over periods of time, the lease must specify exactly the scheduled intervals, their precise length and exact rent for each interval;
  - (iv) the term of the lease must be for not less than one year; and
  - (v) the rent must be set in advance, be consistent with fair market value, and must not take into account any business generated between the lessor and the lessee.

PERSONAL SERVICES & MANAGEMENT CONTRACTS

- Remuneration does not include any payment made to an independent contractor as long as a number of standards are met, including the following:
  - (i) the agreement must be in writing and signed by the parties;
  - (ii) the agreement must specify the services to be provided;
  - (iii) if the agreement provides for services on a sporadic or part-time basis, then it must specify exactly the scheduled intervals, their precise length and the exact charge for each interval;

PERSONAL SERVICES & MANAGEMENT CONTRACTS

- (iv) the term of the agreement must be for not less than one year;
- (v) the compensation must be set in advance, be consistent with fair market value, and must not take into account any business generated between the parties; and
- (vi) the services performed must not involve a business arrangement that violates any state or federal law.

EMPLOYEES

- Remuneration does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made, in whole or in part, under Medicare or under a state health care program.

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 anti-kickback statute.

SPECIAL FRAUD ALERTS & 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 state anti-kickback statutes only apply when the payor is a government health care program.
- Other state anti-kickback statutes apply regardless of the identity of the payor.
- In addition, each state has laws that are specific to pharmacies. These laws normally include provisions addressing kickbacks.

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PAYING FOR A FACILITY'S EHR

PAYING FOR A FACILITY'S EHR

- Many pharmacies work with skilled nursing facilities ("SNFs") and custodial care facilities (collectively referred to as "Facilities").
- A Facility is a "referral source" to the pharmacy. Even though the Facility may give "patient choice," if the pharmacy dispenses a drug to a Facility patient, the law considers the patient to be a "referral" from the Facility.
- If the pharmacy gives "anything of value" to the Facility, then the pharmacy is at risk of being construed to be "paying for a referral" … hence, a "kickback."

PAYING FOR A FACILITY'S EHR

- The federal anti-kickback statute ("AKS") applies to any patient covered by a federally funded health care program.
- The AKS prohibits the pharmacy from giving anything of value to a referral source in exchange for (i) referring, or arranging for the referral of, a federally funded health care program patient to the pharmacy or (ii) recommending the purchase of a product that is paid for by a federally funded health care program.
- Under the AKS, the party providing something of value (the pharmacy) and the party receiving something of value (the Facility) are *both* liable.

PAYING FOR A FACILITY'S EHR

- Separate and apart from the AKS, each state has its own anti-kickback statute.
- Some state anti-kickback statutes apply only when the payer is the state Medicaid program.
- Other state anti-kickback statutes apply even if the payer is commercial insurance or a cash-paying patient.

PAYING FOR A FACILITY'S EHR

- In order for a Facility to serve Medicare and Medicaid patients, federal law imposes a number of requirements on the Facility.
- These requirements cost the Facility money in order to comply.
- One such requirement is for the Facility to have a pharmacy perform a monthly drug regimen review ("DRR") on each patient.

PAYING FOR A FACILITY'S EHR

- Electronic medication administrative records ("eMARs") are not required for DRR; hard copy records are acceptable. Nevertheless, a Facility may desire to utilize eMAR software ("Software") for DRR and for other purposes.
- The Facility and a pharmacy (that receives referrals from the Facility) may wish to enter into an arrangement in which the pharmacy pays for the Software. It is at this juncture that the Facility and pharmacy find themselves on the proverbial "slippery slope."
- Assume that the pharmacy receives referrals from the Facility and desires to pay for the Software. By virtue of paying for the Software, the pharmacy is providing "something of value" to the Facility … hence, the AKS is implicated.

PAYING FOR A FACILITY'S EHR

- The Office of Inspector General ("OIG") has published a number of "safe harbors" to the AKS.
- If an arrangement complies with all of the elements of a safe harbor, then as a matter of law the AKS is not violated. If an arrangement does not comply with all of the elements of a safe harbor, then it does not mean that the AKS is violated.
- Rather, it means that the arrangement must be carefully scrutinized in light of the language of the AKS, court decisions, and other published guidance.

PAYING FOR A FACILITY'S EHR

- The applicable safe harbor is the Electronic Health Records safe harbor ("EHR Safe Harbor").
- It states than an entity may donate software and training services "necessary and used predominantly to create, maintain, transmit, or receive electronic health records" if the following 12 requirements are satisfied:
  - The donation must be made to an entity engaged in delivery of health care by an entity (except for a laboratory company) that provides and submits claims for services to a federal health care program. A pharmacy is an acceptable donor and a Facility is an acceptable recipient.

PAYING FOR A FACILITY'S EHR

- The Software must be interoperable at the time it is provided to the recipient. Software is deemed to be interoperable if it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology. Interoperable means that the Software is able to (i) "communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings," and (ii) "exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered." The Software can be used for tasks like patient administration, scheduling functions, and billing and clinical support, but electronic health records purposes must be predominant.

PAYING FOR A FACILITY'S EHR

- The donor cannot place a restriction on the use, compatibility, or interoperability of the item or service with other EHR systems.
- Receipt of items or services is not conditioned on doing business with the donor.
- Eligibility for, and the amount or nature of, the items or services provided is not based on the volume or value of referrals or other business generated between the parties.
- There must be a written, signed, agreement specifying: (i) the items and services; (ii) the donor's cost of providing the items and services; and (iii) the amount of the recipient's contribution.
- The recipient cannot already possess or have obtained items or services with similar capabilities as those provided by the donor.

PAYING FOR A FACILITY'S EHR

- For items or services that can be used for any patient regardless of payer status, the donor does not restrict the recipient's ability to use the items or services for any patient.
- The items and services do not include office staffing and are not used to conduct personal business or business unrelated to the recipient's health care practice.
- The recipient must pay 15% of the donor's cost for the items and services prior to receipt, and the donor cannot finance or loan funds for this payment.
- The donor's cost for the items or services cannot be shifted to a federal health care program.
- Transfer of the items or service must occur on or before December 31, 2021.

PAYING FOR A FACILITY'S EHR

- As noted above, the Software can be used for services beyond the pharmacy's DRR as long as (i) the Software is not used primarily for personal business or business unrelated to the Facility's clinical operations, and (ii) the pharmacy does not restrict the Facility from otherwise using the Software or from interfacing with other electronic prescribing or electronic health records systems.
- If the arrangement does not comply with all of the elements of the EHR Safe Harbor, then the arrangement will need to be examined in light of the language of the AKS, court decisions, and other published guidance.

PAYING FOR A FACILITY'S EHR

- An important guidance is the OIG's December 7, 2012 Advisory Opinion No. 12-19, which addressed four proposed arrangements involving a pharmacy's provision of items and services to Community Homes in which the pharmacy's customers reside.
- The OIG opined that it would not impose administrative sanctions in connection with Proposals A – C, but would likely impose such sanctions against Proposal D. Under Proposal D, the pharmacy would provide to Community Homes a free sublicense for "Software Z" for use in connection with the pharmacy's customers.

PAYING FOR A FACILITY'S EHR

- In determining that Proposal D would likely result in administrative sanctions, the OIG pointed out the following:
  - "Software Z is not interoperable.
  - Data that a Community Home would create and store in Software Z, including MAR documentation, would not be readily transferable to other systems, resulting in Community Home data lock-in and, thereby, referral lock-in … [I]f a Community Home resident began receiving medications from the [donor pharmacy] and later decided to receive medications from another pharmacy, then the Community Home could face having to either transition that resident's data to another system or assume the full payment for a Software Z sublicense.
  - This situation could give rise to a significant incentive for the Community Homes to steer patients to the [donor pharmacy] rather than one of its competitor[s]."

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MEDICAL DIRECTOR AGREEMENT

MEDICAL DIRECTOR AGREEMENT

- A pharmacy can enter into an independent contractor Medical Director Agreement with a physician.
- The MDA must comply with the
  - (i) Personal Services and Management Contracts safe harbor and
  - (ii) the Personal Services exception to the Stark physician self-referral statute.
- 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 compensation to the physician must be fixed one year in advance and be the fair market value equivalent of the physician's services.

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SHAM CLINICAL STUDIES

SHAM CLINICAL STUDIES

- "You can put lipstick on a pig, but it is still a pig."
- Under the typical sham clinical study program, the physician refers patients to the pharmacy. The pharmacy dispenses a compounded medication (e.g., pain cream) to the patient.
- The physician "collects data" from the patient (e.g., "After applying the pain cream, from a scale of one to ten, what is your pain level?").
- The physician shares the information with the pharmacy. The information is rudimentary, the pharmacy does not need it, and it is the same information that the pharmacy can secure itself.

SHAM CLINICAL STUDIES

- The pharmacy pays the physician $___ per patient per month.
- In some clinical studies physicians have been known to make about $80,000 over a six month period.
- These “sham” studies violate the AKS.
- The pharmacy may argue that it is not paying for referrals, but is paying for legitimate services.
- Remember the statement about “putting lipstick on a pig.” A number of courts have enumerated the “one purpose” test. This test states that if one purpose behind a payment is to induce referrals, then the AKS is violated even if the principal purpose is to pay for legitimate services.

SHAM CLINICAL STUDIES

- In a sham clinical study, there is no question that "one purpose" behind the payments is to induce referrals. In fact, the primary purpose of the payments is to induce referrals.
- Assume that the physician refers no patients to the pharmacy who are covered by a government health care program.
- The pharmacy will need to look at its state anti-kickback statutes.

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SHAM INSURANCE POLICIES TO WAIVE COPAYMENTS

SHAM INSURANCE POLICIES

- Depending on the drug, the third party reimbursement to the pharmacy may be high.
- If the copayment is 20%, then this will result in a high copayment.
- Most patients cannot afford a high copayment.
- In an attempt to “solve” the copayment problem, the pharmacy may be tempted to enter into a “sham” insurance arrangement.
- This arrangement will normally take one of two forms.

SCENARIO ONE

- In one scenario, the patient will pay a minimal “premium” (e.g., $10) to the pharmacy. In exchange, the pharmacy represents to the patient that he/she has purchased an “insurance policy” to cover the copayment.

SCENARIO TWO

- In the second scenario, the pharmacy will pay an upfront fee to the "insurance company" ("ABC"). ABC will, in turn, issue an "insurance policy" to the pharmacy.
- The pharmacy will collect little to no copayments from its patients.
- If the pharmacy is subjected to a PBM audit and if the PBM asks to see if the pharmacy is collecting copayments from a list of named patients, then ABC will pay money to the pharmacy that constitutes the copayments the named patients should have paid.
- Even then, the amount paid by ABC is less than what the patients should have paid.

SHAM INSURANCE POLICIES

- Both of these arrangements are subterfuges—or ruses—in an attempt not to impose a large copayment obligation on the patient.
- These arrangements are “shams” on their face.
- One of the reasons these are not true insurance products is because an insurance policy must be issued by a licensed insurance company.
- To be licensed as an insurance company, the pharmacy or ABC must meet many requirements imposed on insurance companies.
- One important requirement is that the insurance company must show the state that it has a minimum level of capital reserves.

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GIFTS TO PHYSICIANS

INTRODUCTION

- A physician is a referral source to the pharmacy.
- The physician refers patients who are covered by a government health care program, who are covered by commercial insurance, or desire to pay cash.
- If a pharmacy pays money to a physician for services, or provides meals, gifts and entertainment to a physician, or subsidizes a trip that the physician will take, then both the pharmacy and the physician need to comply with the federal and state laws that govern these arrangements.

WHAT A PHARMACY CAN SPEND ON(OR PAY TO) A PHYSICIAN

- While Stark allows a pharmacy to spend up to $398 per year for non-cash/non-cash equivalent items for a physician, the AKS does not include a similar exception.
- Nevertheless, if the Stark exception is met, it is unlikely that the government will take the position that the non-cash/non-cash equivalent items provided by the pharmacy to the physician violate the AKS.
- In addition to complying with Stark and the AKS, the pharmacy and the physician also need to comply with applicable state law.

WHAT A PHARMACY CAN SPEND ON(OR PAY TO) A PHYSICIAN

- Even though the pharmacy and the physician will need to confirm this, it is likely that compliance with the $398 Stark exception will avoid liability under state law.
- And so the bottom line is that a pharmacy can provide gifts, entertainment, trips, meals, and similar items to a physician so long as the combined value of all of these items do not exceed $398 in a 12 month period.
- For example, if a pharmacist wants a physician to accompany the pharmacist on a trip to a continuing education conference, then the pharmacist can safely subsidize up to $398 of the physician's trip expenses.

WHAT A PHARMACY CAN SPEND ON(OR PAY TO) A PHYSICIAN

- The amount of the trip subsidy will be affected by other expenditures the pharmacy has made on behalf of the physician within the preceding 12 months.
- Separate from furnishing gifts and entertainment, and subsidizing trips, the pharmacy can pay the physician for legitimate services.
- For example, if the pharmacy has a legitimate need for a Medical Director, then the pharmacy and physician can enter into a Medical Director Agreement that complies with both the PSMC safe harbor to the Medicare anti-kickback statute and the Personal Services exception to Stark.

WHAT A PHARMACY CAN SPEND ON(OR PAY TO) A PHYSICIAN

- Another legitimate way for money to exchange hands between a pharmacy and a physician is for the physician to rent space to the pharmacy or vice versa.
- The rental arrangement needs to comply with the Space Rental safe harbor to the Medicare anti-kickback statute.
- This safe harbor is similar to the PSMC safe harbor.

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PAYING PHYSICIANS: GUIDANCE FROM A CRIMINAL CASE

CRIMINAL CASE

- A federal grand jury in Connecticut recently indicted Jeffrey Pearlman, a former sales manager for Insys Therapeutics, Inc.
- According to a Department of Justice ("DOJ") statement, Mr. Pearlman allegedly used bogus educational events as a "cover" for paying kickbacks to physicians in exchange for their increased prescriptions of Subsys®, a spray version of the opioid fentanyl.

CRIMINAL CASE

- The DOJ alleges that Mr. Pearlman arranged sham “speaker programs,” that were billed as gatherings of physicians to educate them about Subsys®.
- In reality, according to the DOJ, the events - usually held at high-end restaurants - mostly consisted of friends and co-workers who lacked the ability to prescribe the drug, and there was no educational component.

CRIMINAL CASE

- According to the DOJ, the "speakers" were physicians who were paid fees ranging from $1000 to several thousand dollars to attend the dinners.
- The indictment says that these payments were kickbacks to the speakers "who were prescribing large amounts of Subsys® and to incentivize those [physicians] to continue to prescribe Subsys® in the future."

CRIMINAL CASE

- Here are the “takeaways” from this criminal case:
  - Before the pharmacy provides “anything of value” to a physician, the pharmacy needs to consult with a health care attorney to ensure that the arrangement does not violate the Medicare anti-kickback statute or Stark.
  - “Anything of value” can be a payment of money, it can be a trip, it can be a set of golf clubs, it can be tickets to a Springsteen concert, and it can be services that the physician would normally have to perform himself.

CRIMINAL CASE

- It is permissible for a pharmacy to enter into a Medical Director Agreement ("MDA") with a physician who also refers Medicare patients to the pharmacy. The MDA needs to comply with the Personal Services and Management Contracts safe harbor and with the Stark Personal Services exception. Among other requirements,
  - (i) the MDA must be in writing and have a term of at least one year,
  - (ii) the physician must render valuable (not "made up") services to the pharmacy,
  - (iii) the compensation paid by the pharmacy to the physician must be fixed one year in advance, and
  - (iv) the compensation must be the fair market value ("FMV") equivalent of the physician's services.

CRIMINAL CASE

- If a pharmacy is going to pay a physician to put on an education program, then it must pass the "smell test." The physician must be qualified to make the presentation, the physician must actually make the presentation, the presentation topic must be substantive and timely, the audience must be in the position of benefitting from the presentation, and the compensation to the physician must be FMV.
- If a pharmacy submits a claim to a government program that arises out of an improper arrangement with a physician, then the claim is "tainted" and becomes a false claim. Penalties under the FCA can be massive.

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DIVERSION

DIVERSION

- Pharmaceutical “diversion” is a practice with a long history.
- Traditionally, pharmaceutical manufacturers relied on a multi-tiered network to move pharmaceuticals into the hands of the ultimate consumer.
- This network consisted of a few large wholesalers, which then either resold the product to the retail pharmacy or to a smaller wholesaler.
- The smaller wholesaler might sell the product directly to the retail pharmacy or might again resell to another yet smaller wholesaler.
- Thus, the pharmaceutical distribution network could be composed of only one intermediary between the manufacturer and the retail pharmacy or several.

DIVERSION

- Pharmaceutical manufacturers also directly entered into contracts with certain retail or institutional pharmacies, especially those with a large “captive” patient base.
- Because the manufacturers were able to eliminate a middle-man, they were able to offer very attractive pricing to those pharmacies with captive patient bases.
- This pricing was generally significantly below the pricing that the wholesalers were able to obtain from the manufacturer.

DIVERSION

- In this, the pharmacies and intermediate wholesalers saw an opportunity for additional profits.
- The pharmacies would order large quantities of drugs under the favorable pricing formula and would resell to the smaller wholesalers those drugs which could not be directly dispensed to patients.
- The pharmacy made a profit, while the wholesaler decreased its costs.
- However, pharmaceutical manufacturers soon caught on to this scheme.
- Accordingly, they required the pharmacies to sign contracts containing “own use” clauses.

DIVERSION

- The clauses limit dispensing of the pharmaceuticals purchased at the highly discounted price to certain circumstances.
- The contracts generally prohibit the pharmacy from selling, transferring or using the covered pharmaceuticals in any manner contrary to the “own use” provisions.

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QUESTIONS?

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THANK YOU

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