ACHC U®
EDUCATIONAL RESOURCES

PHARMACY

Collaborative Arrangements with Physicians, Hospitals and Other Referral Sources

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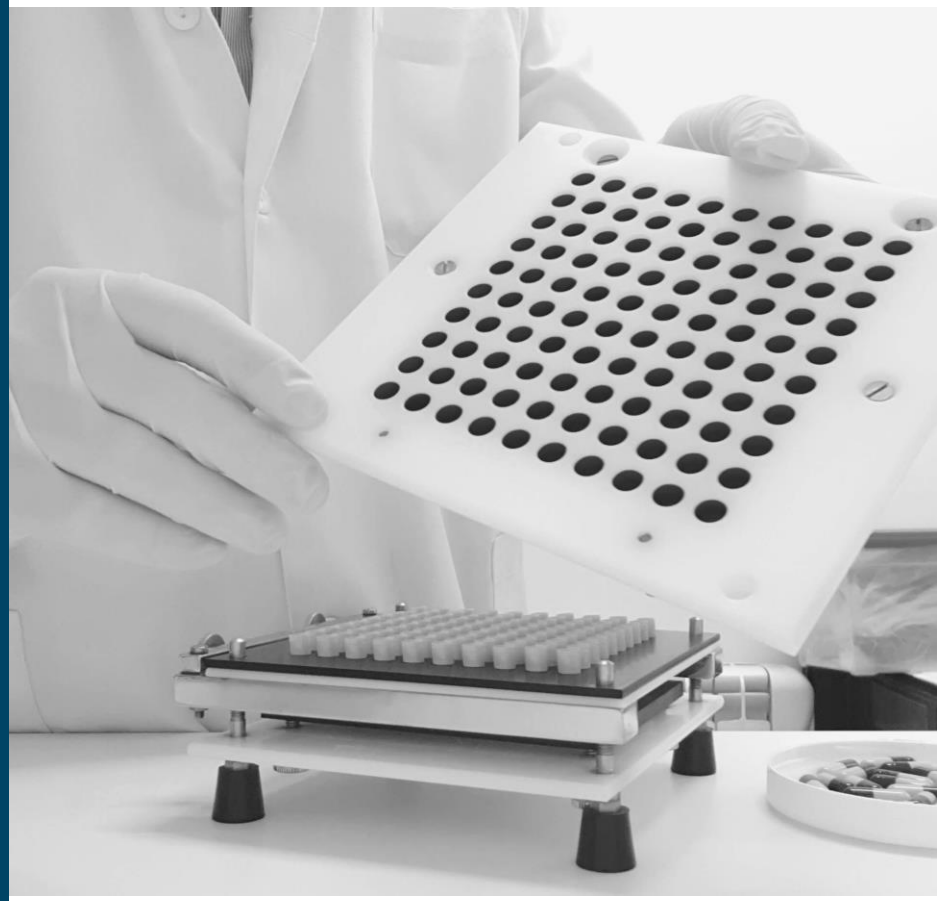

ACHC®

Introduction

- In order to succeed in today's hyper-competitive environment, the pharmacy must establish its niche. It must "think outside the box."
- The successful pharmacy must set itself apart from its competition.

Introduction

- One very important way to do this is for the pharmacy to enter into relationships with physicians, hospitals, DME suppliers, home health agencies, long term care facilities, and other referral sources.
- In doing so, it is critical that the pharmacy comply with federal and state anti-fraud laws.

Federal Anti-Kickback Statute

- 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 a federal health care program ("FHCP"), or the purchase or lease or the recommendation of the purchase or lease of any item for which payment may be made under a federal health care program.

Beneficiary Inducement Statute

- This statute prohibits a provider from offering or giving anything of value to an FHCP beneficiary that the provider knows, or should know, is likely to persuade the person to purchase an item covered by a federal health care program.
- 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.”

Beneficiary Inducement Statute

- The OIG defines “nominal value” as no more than $15 per item or $75 in the aggregate to any one beneficiary on an annual basis.
- “Nominal value” is based on the retail purchase price of the item.

Stark Physician Self-Referral Statute

- This statute provides that if a physician has a financial relationship with an entity providing “designated health services,” then the physician may not refer Medicare/Medicaid patients to the entity unless a Stark exception applies.
- Designated health services include out-patient prescription drugs; parenteral and enteral nutrients; prosthetics, orthotics and prosthetic devices and supplies; DME; and rehab therapy services.

Stark Physician Self-Referral Statute

- One of the exceptions to Stark provides that a health care provider may provide non-cash equivalent items to a physician if such items do not exceed an annual amount established by CMS. For 2024, such amount is $507.

Safe Harbors

- Because of the breadth of the federal anti-kickback statute ("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, then the AKS is not violated.

Safe Harbors

- If an arrangement does not fall within a safe harbor, then 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 Bulletins

- 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.

Advisory Opinions, Special Fraud Alerts and 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-fraud statutes only apply when the payer is a government health care program.
- Other state anti-fraud statutes that apply regardless of the identity of the payer.

States

- All states have a set of statutes and regulations that are specific to pharmacies.
- Most states have physician self-referral statutes similar to Stark.
- All states have a set of statutes and regulations that are specific to physicians.

W-2 Employee vs 1099 Independent Contractor

- It is a violation of the AKS for a provider to pay production-based compensation (e.g., percentage commission) to a 1099 independent contractor marketing rep that generates patients for the provider for the purchase of products/services payable by a federal health care program.
- On the other hand, it is acceptable for a provider to pay a base salary plus discretionary bonuses (based on a number of factors, including generation of business) to bona fide W-2 employees.

What a Pharmacy Can Spend on a Physician

- While the Stark non-monetary compensation exception allows a pharmacy to spend up to a set amount per year (e.g., $507 in 2024) 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.

What a Pharmacy Can Spend on a Physician

- In addition to complying with Stark and the AKS, the pharmacy and the physician also need to comply with applicable state law.
- Even though the pharmacy and the physician will need to confirm this, it is likely that compliance with the non-monetary compensation exception will avoid liability under state law.

What a Pharmacy Can Spend on a Physician

- And so the bottom line is that a pharmacy can provide gifts, entertainment, meals, and similar items to a physician so long as the combined value of all of these items do not exceed the annual amount set by CMS ($507 in 2024).

What a Pharmacy Can Spend on a Physician

- While the Stark non-monetary compensation exception applies to expenditures on behalf of a physician, the exception does not apply to expenditures on behalf of the physician's staff.
- In fact, Stark does not apply to the physician's staff. Expenditures on behalf of the physician's staff must be examined in light of the AKS.
- Separate from furnishing gifts and entertainment, and subsidizing trips, the pharmacy can pay the physician for legitimate services.

What a Pharmacy Can Spend on a Physician

- 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 (“MDA”) that complies with both the Personal Services and Management Contracts (“PSMC”) safe harbor to the AKS and the Personal Services exception to Stark. Among other requirements:

What a Pharmacy Can Spend on a Physician

- The parties will sign an MDA with a term of at least one year.
- The physician must provide substantive services.
- The methodology for compensating the physician must be fixed one year in advance.
- The compensation must be the fair market value equivalent of the physician's services.

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 fair market value equivalent of the time and effort the physician expended to (i) prepare for the program and (ii) present the program.

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, then the hospital can be subjected to future payment reductions for Medicare.
- A hospital can contract with a pharmacy to monitor/work with discharged patients so that they are not readmitted soon after being discharged.

Paying for a Facility's EHR

- In order for a long-term care facility ("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."

Paying for a Facility's EHR

- 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 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 certain requirements are satisfied.

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 on a post-discharge basis.

Employee Liaison

- 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.

Medical Director Agreement

- A pharmacy can enter into an independent contractor Medical Director Agreement with a physician.
- The MDA must comply with the (i) PSMC safe harbor to the AKS and (ii) the Personal Services exception to Stark.

Renting Space

- A pharmacy can rent space to/from a physician so long as the rental agreement complies with the (i) Space Rental safe harbor to the AKS and (ii) space rental exception to Stark.
- A pharmacy can rent space to/from a non-physician referral source so long as the rental agreement complies with the Space Rental safe harbor to the AKS.

Renting Space

- Among other requirements:
  - The parties will sign a written lease agreement with a term of at least one year.
  - The rent will be fixed one year in advance.
  - The rent will be fair market value.

Joint Venture With Hospital

- A hospital and a pharmacy can jointly set up and own a pharmacy ("JV Pharmacy") so long as the JV Pharmacy is not a "sweetheart deal" for the hospital.
  - Ideally, the JV Pharmacy will comply with the Small Investment Interest safe harbor to the AKS.
  - If the safe harbor cannot be met, then the requirements of the OIG's 1989 Special Fraud Alert ("Joint Ventures") and April 2003 Special Advisory Bulletin ("Contractual Joint Ventures") must be met.

Joint Venture With Physician

- When forming a joint venture with a physician, then not only must the arrangement comply with (i) the Small Investment Interest safe harbor or (ii) the 1989 Special Fraud Alert/April 2003 Special Advisory Bulletin, but the arrangement must comply with Stark.

Joint Venture With Physician

- If the JV Pharmacy is located in a rural area, then the physician can refer Medicare/Medicaid patients to the JV Pharmacy.
- If the JV Pharmacy is not located in a rural area, then the physician cannot refer Medicare/Medicaid patients to the JV Pharmacy.

Pharmacy Owned/Managed Physician Clinic

- In some states, a pharmacy can own a physician clinic … and employ the physician.
- Other states have adopted the Corporate Practice of Medicine doctrine that prohibits a physician from being employed by a pharmacy. In those states:

Pharmacy Owned/Managed Physician Clinic

- The medical practice will be owned by a legal entity (e.g., Professional Association or “P.A.”) owned by a physician.
- The physician will be employed by his/her P.A.
- The pharmacy will (i) rent the space to the P.A., (ii) rent furniture, fixtures and equipment to the P.A., and (iii) provide services to the P.A.

Stark Rural Provider Exception

- In entering into an arrangement with a physician in a rural area, the pharmacy needs to focus on the rural provider exception.
- The rural provider exception states that an ownership interest by a physician in a rural provider is not considered a “financial relationship” under Stark.

Stark Rural Provider Exception

- Rural providers are defined as those that furnish at least 75% of the designated health services (“DHS”) they provide to residents of a “rural area.”
- Thus, whether this exception applies depends on whether at least 75% of the patients that the pharmacy’s services are located within a “rural area.”

Stark Rural Provider Exception

- “Rural area” is defined as “an area that is not an urban area as defined in 42 CFR 412.62(f)(1)(ii) which states that “the term urban area means a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget ….”

Annual Wellness Visits/Remote Patient Monitoring/Chronic Care Management

- Assume that the physician (i) has AWVs with patients, (ii) provides RPM to patients and/or (iii) provides CCM to patients.
- Assume that the pharmacy assists the physician in (i) conducting AWVs and (ii) providing RPM and CCM.

Annual Wellness Visits/Remote Patient Monitoring/Chronic Care Management

- It is the physician that is paid for AWVs, RPM and CCM. If the pharmacy assists with AWVs, RPM and CCM for free, or for below fair market value compensation, then such assistance constitutes “something of value” to a referral source, thereby implicating the AKS and Stark.
- In order to avoid AKS and Stark problems, the physician must pay fair market value compensation to the pharmacy for the pharmacy’s services.

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 (i) products and services offered by the pharmacy and (ii) how the pharmacy's products/services can treat specific conditions.

Education Workshops

- 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.

Sponsoring Physicians at Educational Events

- Scenario #1
  - Dr. Smith refers FHCP patients to ABC Pharmacy (“ABC”). Dr. Smith requests ABC to sponsor his trip to a conference in Palm Springs.

Sponsoring Physicians at Educational Events

- Scenario #2
  - ABC is holding its annual meeting in Aspen in July for its employees. ABC asks Dr. Jones to speak at the annual meeting. Dr. Jones refers FHCP patients to ABC. In so doing, ABC offers to (i) pay Dr. Jones for his time in preparing for and presenting his program and (ii) reimburse Dr. Jones for his travel expenses.

Sponsoring Physicians at Educational Events

- Analysis of Scenario #1
  - Dr. Smith refers FHCP patients to ABC. If ABC compensates Dr. Smith, then the transaction creates a financial relationship between Dr. Smith and ABC. As such, the arrangement violates Stark unless an exception is met.

Sponsoring Physicians at Educational Events

- ABC would like to reimburse Dr. Smith for his expenses in attending the Palm Springs conference. The Nonmonetary Compensation exception only applies to compensation paid to a physician in the form of items or services, not cash or cash equivalents. Further, Dr. Smith reached out to ABC to request the compensation. The exception does not apply if the physician solicits an entity for the compensation. Accordingly, the arrangement does not fall within the Nonmonetary Compensation exception.

Sponsoring Physicians at Educational Events

- Analysis of Scenario #1
  - This scenario also would likely not meet the Personal Services exception or the Fair Market Value exception. Both exceptions require the physician to provide a service to the entity. Dr. Smith's attendance at the Palm Springs conference does not constitute a "service" for ABC.

Sponsoring Physicians at Educational Events

- Dr. Smith refers FHCP patients to ABC, and if ABC agrees to cover some of Dr. Smith's expenses to attend the Palm Springs conference, then Dr. Smith is receiving renumeration … thereby implicating the AKS. To avoid problems under the AKS, the arrangement would need to meet an AKS safe harbor. Because Dr. Smith is not providing a service to ABC, the PSMC safe harbor is not met.

Sponsoring Physicians at Educational Events

- Analysis of Scenario #2
  - Like the first arrangement, Dr. Jones refers FHCP patients to ABC and a financial relationship will form if ABC compensates Dr. Jones. As such, the arrangement implicates Stark unless an exception is met.

Sponsoring Physicians at Educational Events

- Unlike the first arrangement, Dr. Jones is providing ABC a service by speaking at an ABC sponsored meeting attended by ABC's employees. The purpose of his presentation is to educate and train the ABC employees on clinical and related issues.

Sponsoring Physicians at Educational Events

- Analysis of Scenario #2
  - Since Dr. Jones is providing ABC a service, the arrangement can be structured to fall under the Personal Services exception. The written agreement must include: (i) a detailed description of Dr. Jones's presentation, how it will be given, and the intended audience; (ii) a set compensation amount that is fair market value; and (iii) an agreement term for not less than one year. The Personal Services exception also requires that the service be reasonable and necessary for the legitimate business purposes of the arrangement.

Sponsoring Physicians at Educational Events

- Analysis of Scenario #2
  - ABC's arrangement may also fall within the Fair Market Value exception to Stark. It is reasonable to assume that Dr. Jones's presentation is commercially reasonable and furthers a legitimate business purpose. Note that the Fair Market Value exception also requires compliance with the AKS. The arrangement can be structured to comply with (or substantially comply with) the PSMC safe harbor. This is so long as the arrangement is put in writing and the agreement includes the safe harbor's requirements.

Sponsoring Physicians at Educational Events

- Analysis of Scenario #2
  - To reduce the risk of an enforcement action, ABC should include significant detail on the amount of time Dr. Jones will be paid to prepare and give his presentation. For example, the agreement can require Dr. Jones to submit his presentation for approval by ABC prior to the Aspen meeting. The agreement should also limit Dr. Jones's expenses to reasonable amounts and require Dr. Jones to submit an invoice of his time and expenses to ABC. This will allow ABC to review Dr. Jones's expenses and ensure that his costs are reasonable and within the compensation amount set forth in the agreement. Only after ABC's review and approval of the invoice should ABC compensate Dr. Jones.

Questions?

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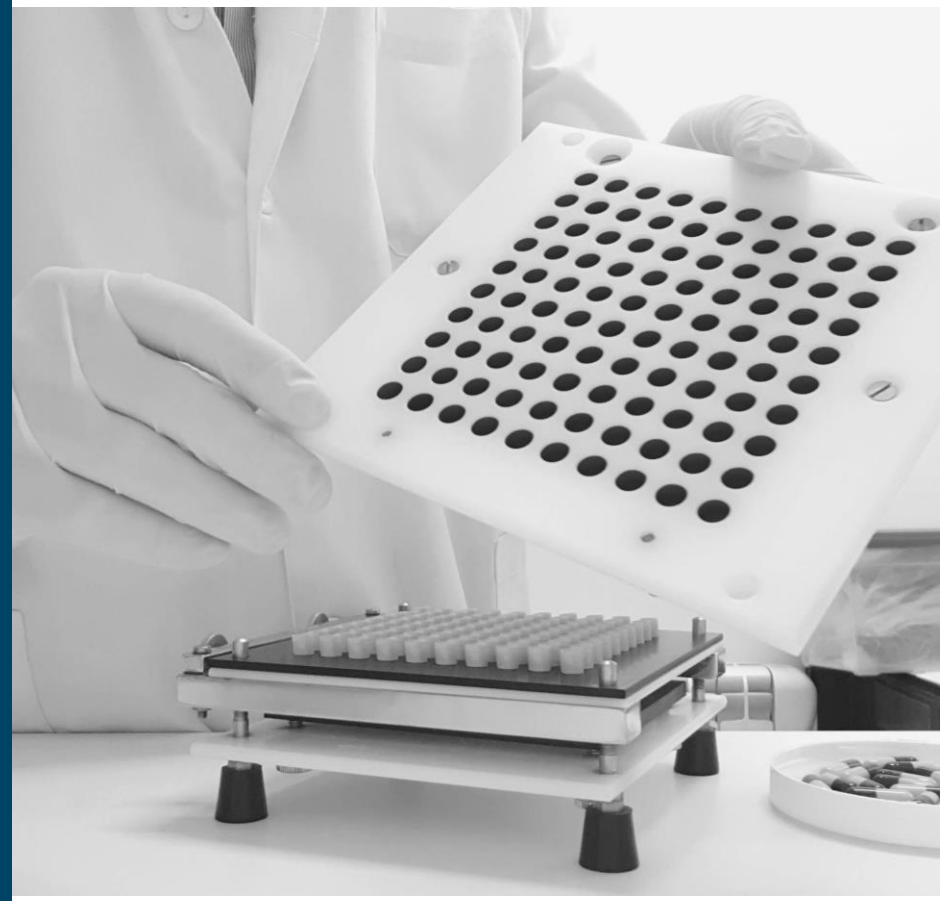

Thank you

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