



EDUCATIONAL RESOURCES

Offering Value-Added Services to Customers While Avoiding Prohibited Inducements

 PHARMACY



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Legal Guidelines



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.

Federal Statutes

- **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,” then the physician may not refer Medicare/Medicaid patients to the entity unless a Stark exception applies.
 - Designated health services include DME; parenteral and enteral nutrients; prosthetics, orthotics and prosthetic devices and supplies; out-patient prescription drugs; and home health.

Federal Statutes

- Federal Stark Physician Self-Referral Statute
 - 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).
 - One of the exceptions to Stark provides that a provider may provide non-cash equivalent items to a physician if such items do not exceed an established dollar amount during a calendar year. In 2024, that amount is \$507.

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.
- **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.

Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B

- In this Special Fraud Alert, the OIG stated that routine waiver of Medicare cost-sharing amounts “is unlawful because it results in (1) false claims, (2) violations of the AKS, and (3) excessive utilization of items and services paid for by Medicare.”
- The fraud alert lists some “suspect marketing practices,” including:
 - Advertisement stating “Medicare Accepted as Payment in Full.”
 - Routine use of “financial hardship” form with no good faith attempt to determine the beneficiary’s actual financial condition.
 - Collection of copayments and deductibles only from beneficiaries who have supplemental insurance.

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.

Example of Proper Value-Added Service

- Under the 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 from Medicare.
- The hospital can enter into an arrangement with a pharmacy to monitor/work with discharged patients so that they are not readmitted soon after being discharged.
- If the hospital asks the pharmacy to furnish post-discharge services to the patient that the pharmacy would normally not be expected to furnish, the hospital should pay fair market value (“FMV”) compensation to the pharmacy for the services.

Example of Proper Value-Added Service

- The pharmacy has several clinicians on staff (e.g., RTs, RNs).
- On a quarterly basis, each of the pharmacy's patients will have the opportunity to meet with a clinician—either in person or virtually.
- The pharmacy advertises that its COPD patients have the opportunity to meet with an RT once a quarter.
- Physicians and their staff can also interact with the pharmacy's clinicians in a collaborative effort to take care of patients.

Examples of Proper Value-Added Services

- Once a quarter, the pharmacy puts on a workshop covering a particular disease state for existing and prospective patients.
- Once a quarter, the pharmacy puts on a workshop for physicians' staffs.
- On a patient's birthday, the pharmacy mails to him a cookbook that is specific to the type of foods the customer needs to eat in order to help the patient overcome a particular health problem.
- Twice a year, the pharmacy sponsors lunch at a retirement home during which the pharmacy provides an educational program.
- Twice a year, the pharmacy sponsors lunch for a physician's staff during which the pharmacy provides an educational program.

Examples of Proper Value-Added Services

- Assume that the pharmacy furnishes DME.
- The pharmacy places an employee liaison at a facility.
- After a patient, before he is discharged, selects the pharmacy for post-discharge products and services, the liaison will facilitate a smooth transition to the service to be provided by the pharmacy.
- The employee liaison will not perform any services that the facility is required to perform.
- The physician sets up times during the year in which the patients can come to the physician's office and attend a class taught by a pharmacy that covers treatment of a particular disease state.

Examples of Proper Value-Added Services

- Assume that the pharmacy furnishes DME.
- A pharmacy 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 pharmacy 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.

Potential Pitfalls

- Waiver of Copayments and Deductibles
 - Instead of collecting the full copayment, some pharmacies only collect a flat rate.
 - By discounting the copayment owed by the patient, the pharmacy is essentially waiving the remainder of the copayment.
 - A waiver of copayment (whole or partial) should only be made when financial hardship is documented.

Potential Pitfalls

■ Charitable Contributions

- The OIG takes the position that charitable donations to not-for-profit entities are essential to “sustaining and strengthening the health care safety net.”
- The OIG believes that most donors, even those with business relationships with donation recipients, are generally motivated by bona fide charitable purposes and desire to help their communities.
- The fact that a business relationship exists between a donor and recipient does not make the donation automatically suspect.
- However, where the two entities are in a position to refer to each other, the arrangement does warrant additional scrutiny.

Potential Pitfalls

- Charitable Contributions (continued)
 - The OIG has issued several advisory opinions related to the provision of charitable donations from one organization to another where either or both organizations are in a position to refer to the other.
 - These opinions have generally been favorable to the requesting entities where donations to charitable/not-for-profit entities
 - are for a bona fide charitable purpose
 - are made in a manner that does not take into account the value or volume of referrals
 - incorporate other safeguards to ensure that donations are not tied to referrals or other business generated between the organizations.

Potential Pitfalls

- Charitable Contributions (continued)
 - Notwithstanding the above, in Advisory Opinion No. 08-02 the OIG provides examples of potentially problematic contributions, including:
 - Contributions to private foundations or other charitable organizations directed or controlled by referral sources; and
 - Contributions determined in any manner that take into account past or expected orders or purchases of items or services payable by any FHCP.

Movement to Integrated Care Model

- Third party payors (“TPPs”) are pushing providers away from the traditional fee-for-service (“FFS”) 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 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.
- As pharmacies 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 (“ACA”), OIG regulations, and in two recent OIG Advisory Opinions.

Affordable Care Act and OIG Regulations

- Notwithstanding the prohibition contained in the beneficiary inducement statute, the ACA provides exceptions to what might constitute “remuneration” under the statute, including an exception for remuneration “that poses a low risk of harm and promotes access to care.”
- Further, in December 2016 the OIG issued final regulations regarding patient incentive arrangements.
- The OIG defines “care” (in the context of “access to care”) as “access to items and services that are payable by Medicare or a state health care program for the beneficiaries who receive them.”
- The OIG interprets “promoting access to care” as “improving a particular beneficiary’s, or a defined beneficiary population’s, ability to obtain items and services payable by Medicare or a state health care program.”

Affordable Care Act and OIG Regulations

- Promoting access to care includes the removal of “socioeconomic, educational, geographic, mobility or other barriers that could prevent patients from seeking care (including preventive care) or following through with a treatment plan.”
- As an example, the OIG makes a distinction between free childcare and movie tickets: “[P]roviding free child care [sic] during appointments also could promote access to care and help a patient comply with a treatment regimen. In contrast, offering movie tickets to a patient whenever the patient attends an appointment would not fit in the exception; such remuneration would be a reward for receiving care and does not help the patient access care, or remove a barrier that would prevent the patient from accessing care.”

Affordable Care Act and OIG Regulations

- The OIG set out different factors and analysis tests for the “low risk of harm” component.
- The OIG stated that remuneration would pose a low risk of harm to Medicare and Medicaid beneficiaries and federal health care programs by:
 - being unlikely to interfere with, or skew, clinical decision making
 - being unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization
 - not raising patient safety or quality of care concerns.

OIG Advisory Opinion 17-01

- In conjunction with its regulations, the OIG released Advisory Opinion 17-01 that expanded on its “low risk of harm” analysis by including additional factors to examine when assessing patient benefits.
- In addressing “skewing clinical decision making,” providers should look at whether
 - eligibility to receive the remuneration is conditioned on receipt of a particular service from the provider and/or
 - the physician receives remuneration that encourages referring eligible patients to the provider.
- In addressing “increased costs to federal health care programs,” the provider should look at whether the patient incentive arrangement will shift the remuneration cost to federal health care programs and whether the arrangement is likely to lead to overutilization of covered items and services.

OIG Advisory Opinion 17-01

- In addressing “overutilization,” the provider should look at whether
 - it is actively marketing the program to attract patients
 - the program is being offered before the patient decides to use the provider, and
 - the offered remuneration is encouraging patients to seek out unnecessary or poor quality of care.
- If the answer is “yes” to one or more of these factors, then it is likely that the patient incentive arrangement does not result in a “low risk of harm.”
- When discussing activities that facilitate access to care, the OIG says that “promoting access to care” constitutes “improving a particular beneficiary’s, or a defined beneficiary population’s, ability to obtain items and services....”

OIG Advisory Opinion 17-01

- Examples of services that promote access to care:
 - A physician practice purchases a subscription to an internet-based food and activity tracker that offers information on healthy lifestyles for diabetic patients.
 - This helps the patient understand and manage interaction between disease state and lifestyle and creates a record that facilitates interactions with the physician for future care planning.
 - A hospital sends patients home with inexpensive devices that record data that is then transmitted to the hospital or the patient's physician.
 - This facilitates follow-up care and compliance efforts.
 - A pharmacy furnishes patients with an item that dispenses medications at a certain time with the correct dosage.
 - This assists with a patient's medication adherence.

OIG Advisory Opinion 19-03

- Patients who meet all eligibility criteria, and who choose to participate, receive two visits from a community paramedic each week to for approximately 30 days following enrollment.
- Each visit takes place in the patient's home or ALF and lasts approximately 60 minutes.
- Services offered include:
 - Medication review/reconciliation;
 - Patient assessment and identify need for follow-up;
 - Monitor compliance with the discharge plan of care or the patient's disease management;
 - Perform a home safety inspection;
 - Perform a physical assessment of the patient.

OIG Advisory Opinion 19-03

- With one exception, the services are not covered or reimbursed by federal health care programs when performed by a community paramedic.
- One Medicaid program reimburses for community paramedic services that the requestor represents are similar to the services, but the medical center stated that it does not and would not bill this Medicaid program for the services.
- Neither patients nor any payors are, or would be, billed for the services, and the medical center does not, and would not, shift any costs related to the arrangements to Medicare, Medicaid, other payors, or individuals.

OIG Advisory Opinion 19-03

- The OIG stated that the identified arrangements implicate both the beneficiary inducement statute and the AKS.
- However, the OIG concluded that it would not impose sanctions on the medical center for the identified arrangements.

OIG Advisory Opinion 19-03

- The OIG stated that the services provide a significant benefit to patients (in the form of free health care services and care management) and thus would be considered remuneration which could influence a patient to select medical center for items and services that are covered by FHCPs.
- But the OIG stated that any such risk is outweighed by the benefits of the programs. Further reducing risk:
 - the patient already selected the medical center as his/her follow-up provider;
 - patients are given provider choice with respect to all other services;
 - the arrangements foster integrated care delivery.

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 pharmacies 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.

Applicability to Pharmacies

- Pharmacies can enter into Preferred Provider Agreements (“PPA”) with hospitals that are designed to reduce the hospitals’ exposure under the Hospital Readmissions Reduction Program.
- “Value-added” services can include
 - reminding the patient and his caregiver that the patient needs to take his prescription medication;
 - reminding the patient and his caregiver about the patient’s upcoming physician appointments;
 - reminding the patient and his caregiver about the importance of hydration and healthy foods; and
 - notifying the treating physician if the patient is not adhering to his treatment plan.
- In addition to providing “value-added” services, the pharmacy can collect patient outcome data reflecting the patient’s progress ... or lack thereof.
- The pharmacy can provide this data to the hospital, the treating physician, and to the third party payor.

Applicability to Pharmacies

- In conjunction with, or separate from, a Preferred Provider Agreement with a hospital, the pharmacy can provide free products and services designed to promote access to care while avoiding problems under the beneficiary inducement statute.
- In doing so, the pharmacy needs to follow the guidance contained in AO 17-01 and AO 19-03.
- For example:
 - The pharmacy can direct a nurse, respiratory therapist, occupational therapist, paramedic, or other type of clinician to drive to patients' homes to check on their health and determine if they are adhering to the prescribed treatment plan.
 - The pharmacy can place equipment in the patient's home that is designed to monitor whether the patient is using the pharmacy's equipment or adhering to the pharmacy's services as prescribed.

Applicability to Pharmacies

- The pharmacy can place equipment in the patient's home that allows the pharmacy to have real time visual/audio communications with the patient and his caregiver.
- The pharmacy can direct a dietician/nutritionist to work with the patient and his caregiver on eating healthy.
- The pharmacy can give the patient access to intent-based education programs relevant to the patient's medical condition.

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 1 year.
 - The rent paid must be fixed 1 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, 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.

Questions?





EDUCATIONAL RESOURCES

Thank you

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