

Patient Incentives or Inducements: Avoiding Pitfalls and Managing Risks

April 9, 2019

Agenda

- **What are patient incentives?**
- **What programs benefit from and rely upon patient incentives / waivers / benefit enhancements? Why are they so important?**
- **How should an organization design and implement effective patient incentives?**
- **What should the legal/regulatory analysis of the incentive include? What is allowable (and what isn't) based on who you are and what you're offering?**
- **What are some examples of patient incentives that we have seen?**

What are patient incentives?

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What is an incentive?

incentive noun

in·cen·tive | \ in-'sen-tiv ① \

Merriam-Webster

Definition of *incentive*

: something that incites or has a tendency to incite to determination or action

Synonyms & Antonyms for *incentive*

Synonyms

boost, encouragement, goad, impetus, impulse, incitation, incitement, instigation, momentum, motivation, provocation, spur, stimulant, stimulus, yeast

Antonyms

counterincentive, disincentive

<https://www.merriam-webster.com/dictionary/incentive>

What is a patient incentive?

- | | | |
|--|---|--|
| <ul style="list-style-type: none"> • The payment or receipt of some sort of “remuneration” to a patient by a provider/health plan in exchange for the performance of a specific activity or service by the patient. | <ul style="list-style-type: none"> • Remuneration is defined very broadly to include anything of value, directly or indirectly, overtly or covertly, in cash or in kind. | <ul style="list-style-type: none"> • This includes: <ul style="list-style-type: none"> <input type="checkbox"/> Cash <input type="checkbox"/> Gift certificates <input type="checkbox"/> Gifts <input type="checkbox"/> Products or goods <input type="checkbox"/> Services |
|--|---|--|

Legal Prohibitions for Incentives

So what's the big deal?

- Under the federal Anti-Kickback Statute (“AKS”), it is a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration (i.e., item of value) to induce or reward referrals of items or services reimbursable by federal health care programs.
- The Beneficiary Inducement provisions of the Civil Monetary Penalty also prohibit the payment of remuneration that a person knows or should know is likely to influence a beneficiary’s (i.e., patient or health plan member’s) selection of a particular provider or supplier of Medicare or Medicaid payable items or services.
- State specific laws and regulations may also apply.

Consequences for Non Compliance

- **Regulatory body may pursue enforcement and/or remedial action**
 - ❑ **Criminal Health Care Fraud 18 U.S.C. Section 1347**
 - ❑ **Civil False Claims Act 42 U.S.C. Section 1320a-7b(b)**
 - ❑ **Exclusion Authorities 42 U.S.C. Section 1320a-7 and 42 Code of Federal Regulations Section 1001.1901**
- **Removal from applicable program / termination of contract - may result in loss of investment and reputational harm**
- **Required termination of the suspect incentive/waiver – regulator may also amend without consent**

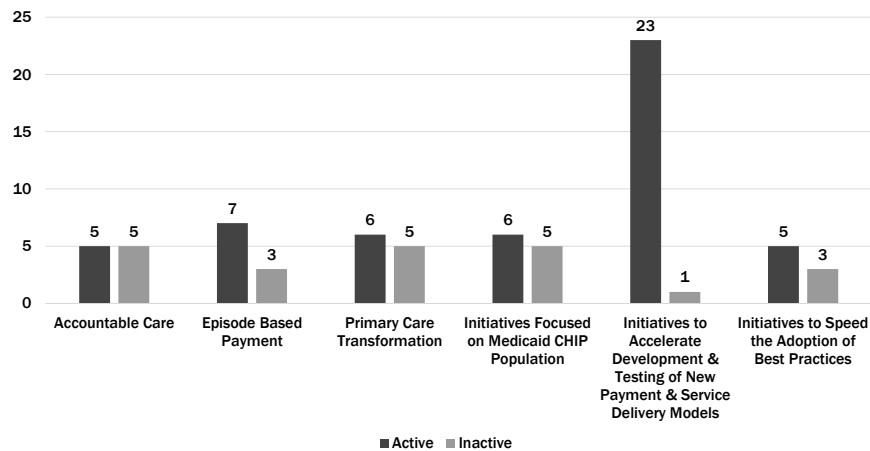
What programs benefit
from and rely upon
patient incentives?

Recent CMS Initiatives

CMS is very interested in....

- ❑ Testing, transforming, and rewarding different models of care
- ❑ Understanding and working on the need to reward progressive, cost effective, and 'better' care (i.e., quality initiatives) for providers and health plans alike
- ❑ Creating exceptions for providers and ACOs to effectively implement initiatives in order to meet benchmarks and achieve **goals and better patient outcomes**
- ❑ Understanding how unique and different patient incentives or waivers may or may not impact each model, ACO, or initiative, including how each is carefully implemented
- ❑ Reward providers by measuring improved quality metrics

CMS Innovation Models



<https://innovation.cms.gov/initiatives/#/views=models> See Appendix A

Payments now based on quality of care

- Health systems now may offer a variety of financial incentive programs to encourage improvements in quality and efficiency, including those that help align incentives between hospitals and physicians.
- Health systems can use pay-for-performance programs to reward physicians for adherence to clinical protocols or objective improvement in individual patient care outcomes.
- Patient cooperation is essential to ensure that quality outcomes are in line with government expectations, particularly for patients who have chronic conditions or those that would benefit from preventative care. Incentives can help with this.
- Managed care / health plans (Medicare Advantage, Medicaid Programs, etc.) have quality programs, STARS, RAF, that financially reward efficiencies and improved quality metrics. Benchmarks are a moving target. Incentives can help with this.

Incentives can drive ACO performance

- ACOs are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high-quality care to their Medicare patients.
- Goal of coordinated care is to ensure that patients get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors.
- When an ACO succeeds both in delivering high-quality care and spending health care dollars efficiently, ACO will share in the savings it achieves for the Medicare program.
 1. Improving the experience of care
 2. Improving the health of populations
 3. Reducing per capita costs of health care (without any harm to individuals, families, or communities)
- **How?** By changing the behaviors of both providers and the patient.

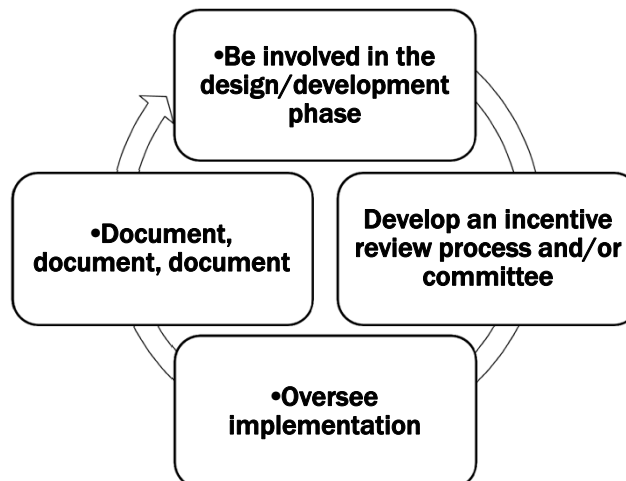
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/>

How to design and implement effective patient incentives?

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What should the process look like?



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Development and Design of the Incentive

- **Design/Development phase**
 - ❑ Get involved on the ground floor!
 - ❑ Compliance & Legal participation is key at this stage.
 - ❑ Make sure that Compliance is at the table when initial ideas are being vetted and approved, not just after the fact when a potential issue is flagged.
 - ❑ Operations likely will make the ultimate decision to proceed with an incentive.

Incentive Review Process

- **Develop a review process and/or committee to facilitate a formal review of the incentive.**
 - ❑ Need to research and conduct an analysis of the relevant laws, regulations and industry standards at play.
 - ❑ Establish an approval process that will fit the needs of the organization, but also meet the requirements of the applicable regulators.
 - ❑ Keep in mind that regulator approval of the incentive may also be necessary (i.e., Medicaid Managed Care Plans).

Incentive Implementation / Documentation

- **Oversee implementation**
 - Outreach - identify team that will communicate to members
 - Identify your cohort / beneficiary pool
 - Confirm your beneficiary pool is accurate - actually test it!
 - Develop appropriate communication protocols (i.e., call center, clinical staff)
 - Written documentation to be communicated to beneficiaries as required
 - Provide training on communication
 - Establish processes to monitor initiative - is it working the way it was intended?
- **Document, document, document**

What should the
legal/regulatory
analysis of the
incentive include?

Sample Analysis: Two Step Litmus Test

- **Step 1: What is the purpose for the incentive? Is the purpose legitimate?**
- **Step 2: What are the relative safeguards in place to ensure that the incentive will comply with relevant laws and regulations?**

Resource: AHLA Publication - [Beneficiary Inducements in an Evolving Market: Assessing the Risks, Understanding the Benefits and Drawing the Lines](#)

Look for a balanced approach

Will the patient incentive:

1. **Threaten the integrity of the federal health care program (i.e., increasing cost and undermining quality); or**
2. **Improve access, enhance patient health, improve coordination of care and reduce inefficiencies?**

Resource: AHLA Publication - [Beneficiary Inducements in an Evolving Market: Assessing the Risks, Understanding the Benefits and Drawing the Lines](#)

But first...Organization type is essential

- **When determining how to structure a patient incentive, the type of organization is key to determining the requirements you will need to follow.**
 - Managed Care Organizations**
 - Accountable Care Organizations**
 - Models Run at the State Level (e.g. Transforming Clinical Practices Initiatives, Multi-Payer Advanced Primary Care Program)**
 - Health Care Facilities where innovation models are being testing (e.g., ACO Investment Model, BPCI-AMI Model, Acute Myocardial Infarction (AMI) Model)**

Patient Incentive Analysis

Regulatory Criteria	Providers	MCOs	ACOs
Civil Monetary Penalties (CMP) Beneficiary Inducement	X	X	X
Federal Anti-Kickback Statute (AKS)	X	X	X
Stark Law	X	X	X
State Specific FWA Laws	X	X	X
OIG Guidance, Advisory Opinions, CIAs	X	X	X
Managed Care / ACO Contracts		X	X
Chapter 4 Medicare Managed Care Manual – Section 100; 42 CFR 438		X	
42 CFR 425 (MSSP)			X
CMS Guidance / Regional Officer / Monitor Guidance		X	X
Other Research (AHLA guidance, etc.)	X	X	X

Civil Monetary Penalty Law – Beneficiary Inducement

- Any person (including an organization, agency, or other entity, but excluding a beneficiary, that offers to or transfers remuneration to any Medicare or State health care program beneficiary that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, by Medicare or State health care program.
- What is REMUNERATION?
- Exceptions are critical!
- Enforced by the HHS OIG

42 U.S.C. 1320a-7a and the Act, Section 1128A(a)

Beneficiary Inducement Exceptions

Exception	Description
1. Nominal Value	<ul style="list-style-type: none"> • Incentives that are only nominal in value are not prohibited by the CMP Law. • "Nominal" is defined as no more than \$15.00 per item and \$75.00 total per year.
2. Preventive Care	<ul style="list-style-type: none"> • Incentives given to individuals to promote the delivery of preventive care services where delivery is not tied to the provision of other services reimbursable by federal health care programs are not prohibited by the CMP Law. • "Preventive care service" is any prenatal service or post-natal well-baby visit or a specific clinical service described in current U.S. Preventive Services Task Force's Guide to Clinical Preventive Services.

Beneficiary Inducement Exceptions

Exception	Description
3. Copayment Waiver	<ul style="list-style-type: none"> •“Remuneration” under the CMP Law does not include the waiver of coinsurance and deductible amounts by a person, if the: <ol style="list-style-type: none"> (1) Waiver is not offered as part of any advertisement or solicitation; (2) Person does not routinely waive coinsurance or deductible amounts; and (3) Person waives coinsurance and deductible amounts after determining in good faith that the individual is in financial need or failure by the person to collect coinsurance or deductible amounts after making reasonable collection effort.
4. Assistance to Needy	<ul style="list-style-type: none"> •The offer or transfer of items or services for free or less than fair market value does not constitute “remuneration” under the CMP Law if: <ol style="list-style-type: none"> (1) The items or services are not offered as part of any advertisement or solicitation; (2) The items or services are not tied to the provision of other services reimbursed in whole or in part by Medicare or Medicaid; (3) There is a reasonable connection between the items or services and the medical care of the individual; and (4) The person provides the items or services after determining in good faith that the individual is in financial need.

Beneficiary Inducement Exceptions

Exception	Description
5. Retail Rewards	<ul style="list-style-type: none"> •Retail rewards do not constitute “remuneration” under the CMP Law if the: <ol style="list-style-type: none"> (1) Rewards consist of coupons, rebates, or other rewards from a retailer; (2) Rewards are offered or transferred on equal terms available to the general public, regardless of health insurance status; and (3) Offer or transfer of the rewards is not tied to the provision of other items or services reimbursed in whole or in part by the Medicare or Medicaid programs.
6. Remuneration Promoting Access	<ul style="list-style-type: none"> •Any remuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs does not constitute “remuneration” under the Beneficiary Inducement CMP. It is unclear whether this exception is self-effectuating or if the OIG must issue an implementing regulation.

Federal Anti-Kickback Statute

- The **Anti-Kickback Statute** prohibits asking for or receiving anything of value (remuneration) in exchange for referrals of Federal health care program patients.
- **Kickbacks** can include:
 - Cash or cash equivalent (gift cards, certificates, or vouchers)
 - Gifts or any physical item
 - Travel, meals, or entertainment
 - Access to opportunities or events that would not normally be available
 - Free clerical or clinical staff services
 - Free or below fair market value rent
 - Excessive compensation

42 U.S.C. Section 1320a-7b(b) and 42 CFR §1001.952

Federal Anti-Kickback Statute

- Both asking for and receiving anything of value in exchange for referrals is a crime under the Anti-Kickback Statute. **It applies to both payers and recipients of kickbacks.**
- Simply asking for or offering a kickback could violate the law. Numerous physicians have been sanctioned for selling their product loyalty to pharmaceutical companies, medical device companies or other vendors.
- **AKS Safe Harbors** to consider reviewing for applicability:
 1. Waiver of beneficiary coinsurance and deductibles by hospitals and selected other providers (42 CFR §1001.952(k))
 2. Increased coverage, reduced cost sharing or reduced premiums offered by health plans (42 CFR §1001.952(l))
 3. Local Transportation (42 CFR §1001.952(bb))

Stark - Physician Self-Referral Law

- The Stark Law (Physician Self-Referral Law) prohibits the referral of Federal health care patients for designated health services to entities with which the physician (or their immediate family member) has a financial relationship.
42 U.S.C. Section 1395nn
- Financial relationships include ownership and investment interests and compensation relationships.
- Designated health services include:

<ul style="list-style-type: none"> <input type="checkbox"/> Inpatient and outpatient hospital services <input type="checkbox"/> Clinical laboratory services <input type="checkbox"/> Radiology and certain other imaging services <input type="checkbox"/> Physical therapy services <input type="checkbox"/> Occupational therapy services <input type="checkbox"/> Outpatient speech-language pathology services 	<ul style="list-style-type: none"> <input type="checkbox"/> Radiation therapy services and supplies <input type="checkbox"/> Durable medical equipment and supplies <input type="checkbox"/> Parenteral and enteral nutrients, equipment, and supplies <input type="checkbox"/> Prosthetics, orthotics, and prosthetic devices and supplies <input type="checkbox"/> Home health services <input type="checkbox"/> Outpatient prescription drugs
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State Specific Fraud, Waste, Abuse Laws

- Both a federal and state law analysis must be completed.
 - State specific fraud, waste, and abuse laws such as a kickback statute or other false claims laws must also be reviewed before any patient incentive is implemented.
 - There may be state specific restrictions (i.e., Medicaid, Department of Insurance) that need to be considered in relation to patient inducements.
 - Consider other state specific enforcement mechanisms:
 1. Single state agency such a state specific Program Integrity Unit
 2. State Auditor, Comptroller, or Inspector General
 3. Medicaid Fraud Control Units
 4. False Claims Act* (state and local); <https://oig.hhs.gov/fraud/state-false-claims-act-reviews/>

OIG Guidance

- Offering valuable gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider raises quality and cost concerns.



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TO BENEFICIARIES

- Providers may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services.
- The use of giveaways to attract business also favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses.”

- “The OIG has interpreted the prohibition to permit Medicare or Medicaid providers to offer beneficiaries inexpensive gifts (other than cash or cash equivalents) or services without violating the statute

- Nominal value” is defined as having a retail value of no more than \$15 per item or \$75 in the aggregate per patient on an annual basis. The items may not be cash or cash equivalents. If a gift has a value at or below these thresholds, then the gift need not fit into an exception to section 1128A(a)(5).

OIG Guidance

- Providers may offer beneficiaries more expensive items or services that fit within one of the five statutory exceptions:
 1. Waivers of cost-sharing amounts based on financial need;
 2. Properly disclosed copayment differentials in health plans;
 3. Incentives to promote the delivery of certain preventive care services;
 4. Any practice permitted under the federal antikickback statute pursuant to 42 CFR 1001.952; or
 5. Waivers of hospital outpatient copayments in excess of the minimum copayment amounts.



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- The OIG is considering several additional regulatory exceptions. The OIG may solicit public comments on additional exceptions for complimentary local transportation and for free goods in connection with participation in certain clinical studies.

OIG Advisory Opinions

- The OIG entertains requests for advisory opinions related to the prohibition on inducements to beneficiaries.
- Considering the difficulty in drawing principled distinctions between categories of beneficiaries or types of inducements, favorable opinions are limited to situations involving conduct that is very close to an existing statutory or regulatory exception.



Advisory Opinions for 2019

01-29-2019

> [Advisory Opinion 19-02](#) (regarding a pharmaceutical manufacturer's proposal to loan, on a temporary basis, a limited- functionality smartphone to financially needy patients who do not have the technology necessary to receive adherence data from a sensor embedded in prescribed antipsychotic medication)

01-14-2019

> [Advisory Opinion 19-01](#) (regarding a charitable pediatric clinic's arrangement under which the clinic waives cost-sharing amounts in certain circumstances)

Medicare Managed Care Manual

- Medicare Managed Care Manual – Chapter 4 – Benefits & Beneficiary Protections, Section 100, Rewards and Incentives
- *“An MA plan may create one or more Rewards and Incentives (RI) Programs that provide rewards and/or incentives to enrollees in connection with participation in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources. The overall goal of RI Programs is to encourage enrollees to be actively engaged in their health care and, ultimately, improve and sustain their overall health and well-being.”*
 - Health Related Services and Activities (not health outcomes but behaviors or activities)
 - Non-Discrimination
 - Offering Rewards In Connection with the entire Service or Activity
 - Valuing Rewards and Incentives (no specific \$ value assigned by CMS)
 - Permissible Rewards and Incentives
 - Marketing Rewards and Incentives Programs
 - Reporting to CMS
- Part C only 42 CFR §422 - not Part D 42 CFR §423
- Must be implemented in a manner consistent with managed care program requirements; 42 CFR §438

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

Medicaid/CMS Managed Care Contract

4.17 MARKETING



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4.17.4 Without Prior Approval, Contractor shall not engage in otherwise prohibited Marketing activities, including:

4.17.4.1 providing cash to Potential Enrollees, Prospective Enrollees, or Enrollees, except for reimbursement of expenses and stipends, in an amount approved by the Department, provided to Enrollees for participation on committees or advisory groups;

4.17.4.2 providing gifts or incentives to Potential Enrollees or Prospective Enrollees unless such gifts or incentives are also provided to the general public and do not exceed US \$10 in value per individual gift or incentive and no more than a cumulative annual value of US \$50;

4.17.4.3 providing gifts or incentives to Enrollees unless such gifts or incentives are provided conditionally based on the Enrollee receiving preventive care or other health-related activity, are not in the form of cash or an instrument that may be converted to cash;

<https://www.illinois.gov/hfs/SiteCollectionDocuments/2018MODELCONTRACTAdministrationcopy.pdf>

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ACO Beneficiary Incentives

- **In the ACO world, patient incentives are also known as benefit 'waivers'**

- Exceptions to fraud, waste and abuse (FWA) laws at the **federal** level
- Federal waivers only apply to federal FWA and patient incentives or waivers
- Separate analysis is necessary against state specific FWA laws
- If you are a Medicare Shared Savings Organization, you need to ensure that incentives are implemented in a manner consistent with program requirements outlined in 42 CFR §425
- Excellent ACO specific resources include:

Centers for Medicare & Medicaid Services: Fraud and Abuse Waivers

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>

Office of Inspector General, U.S. Department of Health & Human Services

<https://oig.hhs.gov/compliance/accountable-care-organizations/index.asp>



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Note on Benefit Enhancements

- **Benefit Enhancements**

- Means to offer certain covered services to beneficiaries with changes to the coverage requirements
- Receipt by a Medicare beneficiary of a Medicare-covered service does not implicate the beneficiary inducements CMP or the Federal AKS with respect to the arrangement between the provider furnishing the covered service and the Beneficiary
- Next Generation ACO Context / Example: Arrangements between Next Generation Participants, Preferred Providers, and others to furnish Benefit Enhancements must comply with fraud and abuse laws, and may qualify for protection under the Participation Waiver, if all waiver conditions are met
 1. Telehealth Expansion Waiver
 2. Post-Discharge Home Visit Waiver
 3. Three-Day Skilled Nursing Facility Waiver

"With respect to Benefit Enhancements,...provided by a Next Generation Participant or Preferred Provider to Beneficiaries, we do not believe that protection under this Waiver is necessary."

CMS Guidance / Regional Officer / Monitor

- **Use all available CMS Guidance**

- Research written guidance (more established for MCOs)
- For MCOs and ACOs this includes your Regional Officers and Monitors
- For ACOs (depending on type) use monthly regional calls as a sounding board
- Use / research available monthly publications, databases and portals (e.g., HPMS)

Real World Examples of Patient Incentives

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Patient Incentives offered by Providers

- So many questions about patient transportation!
- Under the “Local Transportation” safe harbor of the AKS, “remuneration” does not include **free or discounted local transportation** made available by an eligible entity to Federal health care program beneficiaries if certain criteria are met. See ALL the criteria at [42 CFR §1001.952\(bb\)](#).
- Common questions:
 - Can it be an Uber? Or does it need to be public transportation? What about a shuttle service?
 - Can the patient bring family members?
 - Is the patient going to a medical clinic or somewhere else?
 - Can the patient request other stops made along the ride?
 - Are the services that the patient is getting going to be “medically necessary”?



Patient Incentives offered by MCOs

- Proposal to offer free car seats to pregnant Medicaid beneficiaries in exchange for attendance at prenatal appointments
- Proposal to offer membership for Medicaid beneficiaries who are children to local children's organizations (i.e., Boys and Girls Club of America)
- Proposals for the provision of food and transportation in order to have Medicaid beneficiaries participate in quarterly Member Advisory Council meetings



Next Generation ACO Example

Permissible	Prohibited
<ul style="list-style-type: none"> • Must be reasonably related to medical care, and be either preventive care items or services OR advance one or more specified clinical goals • Maintain a record for each in-kind item or service • Item or service (1) is preventative item or service; or (2) advances clinical goals • Protects only items and services provided by NGACO / Participant directly to a Beneficiary or through an agent <ul style="list-style-type: none"> <input type="checkbox"/> Does not protect the provision of an item or service if a reasonable Beneficiary would perceive it as being from the agent, rather than from the NGACO or Participant 	<ul style="list-style-type: none"> • Impermissible to induce participation (i.e., complete a voluntary alignment form to receive incentive) • No cash or cash equivalents; must be in-kind (i.e., no gift cards, coupons, cash, equivalents) <ul style="list-style-type: none"> <input type="checkbox"/> In-kind means that the beneficiary must receive the actual item or service and not funds to purchase the item or service <input type="checkbox"/> Cost-sharing waivers (i.e., copays and deductibles) not protected • Not otherwise expressly prohibited

Examples:

1. No cash for transportation for bus, taxi/bus/public transport fares, gas; prepaid vouchers OK
2. Technology in the form of a device to monitor / transmit medical indications and symptoms is fine; device solely to play game is not
3. Transportation to medical appointments is permissible but not for other purposes

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/next-gen-aco-2nd-amended-waivers-12122018.pdf>

Enforcement Action - Walgreens

- **Walgreens (January 2017)**



- Manhattan U.S. Attorney \$50 Million settlement for paying kickbacks to induce beneficiaries of government healthcare programs to fill prescriptions at Walgreens pharmacies
- Settlement resolves claims that Walgreens violated federal AKS and FCA by enrolling hundreds of thousands of beneficiaries of government healthcare programs in its Prescription Savings Club program
- Providing government beneficiaries with discounts and other monetary incentives under the program, in order to induce them to patronize Walgreens' pharmacies for all of their prescription drug needs
- Complaint alleged that Walgreens understood that allowing government beneficiaries to participate in the PSC program was a violation of the AKS, but that it nevertheless marketed the program to government beneficiaries and paid its employees bonuses for each customer they enrolled in the program, without verifying whether the customers were government beneficiaries
- Government joined a private whistleblower lawsuit

<https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-50-million-settlement-walgreens-paying-kickbacks-induce>

Enforcement Action - Lincare

- **Lincare (August 2018)**



- DME Provider (oxygen and other respiratory therapy services) Lincare Pays \$5.25 Million to Resolve FCA and Federal AKS Allegations by offering illegal price reductions to Medicare beneficiaries
- The government alleged that, from 2011 to 2017, Lincare attempted to gain a competitive advantage by unlawfully waiving or reducing co-insurance, co-payments, and deductibles for beneficiaries who participated in a Medicare Advantage Plan operated through a private insurer
- Legal theory is that these practices violated AKS and further caused the submission of false claims for payments to Medicare
- Whistleblower lawsuit

<https://www.justice.gov/usao-sdil/pr/durable-medical-equipment-provider-lincare-pays-525-million-resolve-false-claims-act>

Questions?



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