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Revisiting Charity Care and Beneficiary Inducements in the Light of New Guidance

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Civil Monetary Penalties Law

- The Civil Monetary Penalties law ("CMP") provides for monetary penalties against any person or entity that gives something of value to a Medicare or Medicaid beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider.
  - CMP applies to any person or entity, whether or not they are affiliated with the provider
  - Remuneration can include the transfer of items or services for free or less than fair market value
  - The CMP only prohibits inducements to Medicare and state health care program beneficiaries

CMP Penalties

- Violations of the CMP's beneficiary inducement prohibitions may result in fines up to $15,270 per item or service provided
- Intent/knowledge required:
  - Standard is “knows or should know” that the remuneration is likely to influence the beneficiary to order or receive items or services from a particular provider
  - The “should know” standard is met if a provider acts with deliberate ignorance or reckless disregard. No proof of specific intent is required

CMP Rationale

- Such programs can corrupt the decision-making process, resulting, for example, in over-utilization, increased costs, or inappropriate medical choices
- There is potential harm to competing providers and suppliers who do not, or cannot afford to, offer incentives to generate business
- Skewing patients' selection of providers by shifting focus to the value of the inducement as opposed the value or quality of the health care services
- These practices could negatively affect the quality of care given to beneficiaries. As providers and suppliers race to the bottom by offering increasingly valuable goods or services, the incentive to offset the cost of these inducements by cheating on the quality of the Medicare or Medicaid item or service increases proportionately

Anti-Kickback Statute

- Criminal statute that prohibits any person from knowingly and willfully offering, paying, soliciting or receiving anything of value in exchange for referring federal health care program business
- Offense is classified as a felony and punishable by fines of up to $25,000; imprisonment up to 5 years, violations may also result in civil monetary penalties up to $50,000 per violation
- Broad statute
  - Congress directed the OIG to limit AKS by adopting “safe harbors”
  - Conduct that falls under a safe harbor is not subject to sanctions under AKS, even if it is capable of inducing referrals
- AKS codified at 42 U.S.C §1320a-7b; safe harbors at 42 C.F.R.§1001.952

Recent Rulemaking

- Affordable Care Act ("ACA")
  - Amended the definition of "remuneration" by allowing exceptions for certain beneficiary inducements prohibited by the Civil Monetary Penalties law ("CMP") and enacted four new amendments to the CMP
- October 2014 Proposed Rule
  - Modified certain existing safe harbors to the Antikickback Statute by adding safe harbors that provide new protections or codify certain existing statutory protections
  - Elaborated on the ACA language and set forth additional interpretations and requirements for these CMP remuneration exceptions
- December 7, 2016 Final Rule
  - Created five new AKS safe harbors and makes a technical correction to an existing safe harbor for referral services
  - Finalized all of the proposed CMP exceptions and clarified existing exceptions

The Final Rule

- According to the OIG:
  - The Final Rule is intended to "enhance flexibility for providers and others to engage in health care business arrangements to improve efficiency and access to quality care while protecting programs and patients from fraud and abuse"
  - The Final Rule takes into account changes in health care payment and delivery, recognizing that "the transition from volume to value-based and patient-centered care requires new and changing business relationships among health care providers"
  - OIG will continue to monitor the changing payment and health care delivery landscape for possible future exceptions

Established CMP Exceptions

- The CMP contains several exceptions to the definition of "remuneration."
  - Waivers of cost-sharing amounts based on financial need
  - Any practice permitted under the AKS
  - Preventative care – incentivize preventative care
    - Must meet U.S. Preventative Services Task Force's *Guide to Clinical Preventative Service* or relate to prenatal/postnatal care
    - A disproportionately large incentive gives rise to an inference that at least part of the incentive is being provided as a prohibited inducement
    - No cash or cash equivalents

Waivers of Cost-Sharing Amounts

- Waivers of Federal health care program copayments
  - Not advertised
  - Not routine
- Requires an individualized determination of financial need, or
- Failure of reasonable collection efforts

Incentives to Promote the Delivery of Preventive Care

- Provided for the purpose of inducing individuals to obtain preventive care
- Preventive care:
  - Prenatal service, or
  - Post-natal well-baby visit, or
  - Specific clinical service described in the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services,* if
  - Such services are covered by Medicare/Medicaid
- No particular limitations on the type or value of incentives

Nominal Value Dollar Limit

- The OIG has also interpreted the prohibition on remuneration to permit offering beneficiaries inexpensive gifts of nominal value without violating the statute
  - Historically no more than $10 per item or occasion/$50 annual aggregate per Beneficiary
  - Recently increased to $15 per item or service and $75 in the annual aggregate per Beneficiary
  - Items may not be cash or cash equivalents

New ACA CMP Exceptions

1. Any remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs;
2. The offer or transfer of coupons, rebates or other rewards from a retailer if the program meets certain requirements;
3. The transfer of items or services by a person that are not offered as part of an advertisement or solicitation, that are not tied to the provision of other items or services reimbursed under a federal health care program, for which there is a reasonable connection between the items or services and the medical care of the individual, and for which the person providing the items or services determines in good faith that the individual is in financial need; and
4. Waivers of cost-sharing for the first fill of a generic drug for Medicare Part D beneficiaries

Access to Care / Low Risk of Harm

- Promotes access to Care
  - Defines "promotes access" to mean improves a beneficiary's ability to obtain care
  - Defines "care" to mean items and services that are payable by Medicare or a state health care program
- Included:
  - Items or services provided to patients in order to assist with the compliance of a treatment plan
  - Items and services that support or help individual patients, as well as defined beneficiary populations
    - Ex: a PCP may make a food/activity tracker app available to diabetic patients to help patients access improved care planning

Access to Care / Low Risk of Harm (cont.)

- Not included:
  - Rewards for receiving care
  - Rewards for compliance with treatment
  - Promotes access to “healthy living”
- Nonclinical items such as social services are not considered “care”

Access to Care / Low Risk of Harm (cont.)

- Low Risk of Harm: defines "low risk of harm" to mean that the remuneration must be
  - Unlikely to skew clinical decision making,
  - Unlikely to increase costs to federal health care programs and beneficiaries through overutilization and/or inappropriate utilization, and
  - Not raise patient safety or quality of care concerns
- OIG clarified that entities can still encourage beneficiaries to access non-reimbursable care without implicating the CMP restrictions
  - Entities may provide educational or informational services to patients without implicating the CMP
  - Educational materials alone are not prohibited remuneration
  - Remuneration given in connection with marketing is not low risk

Access to Care / Low Risk of Harm (cont.)

- OIG cautions anyone asserting this exception as a defense:
  - Burden to prove that sufficient facts and analysis exist for OIG to determine that the arrangement promoted access to care and posed a low risk of harm
  - Other exceptions to the beneficiary inducements CMP, as well as Anti-Kickback Statute safe harbors, may cover activities that could be argued to "promote access to care and pose a low risk of harm to patients and federal health care programs"
  - These other exceptions and safe harbors addressing such activities will be benchmarked in order to determine whether the activities pose a low risk under this exception

Retailer Rewards

- OIG finalized the language as proposed to allow for retailer rewards programs, including coupons, rebates or other rewards, that meet certain criteria:
  - Interprets ‘‘coupon’’ as something authorizing a discount on merchandise or services, such as a percentage discount on an item or a ‘‘buy one, get one free’’ offer
  - Interprets ‘‘rebate’’ as a return on part of a payment, with the caveat that a retailer could not ‘‘rebate’’ an amount that exceeds what the customer spent at the store
  - Interprets ‘‘other rewards’’ primarily as describing free items or services (store merchandise, gasoline, f. f. miles, etc.)

Retailer Rewards (cont.)

- “Retailer” is an entity that sells items directly to consumers
  - ‘‘Retailer’’ does not include individuals or entities that primarily provide services
  - Hospitals and physicians are not considered "retailers" unless the entity has a separate retail element, such as a convenience store or pharmacy
- Rewards offered on equal terms to the public
- Rewards provided by the retailers cannot be tied to the provision of other reimbursable items or services for reward or redemptions

Hypotheticals

1. Patient accumulates rewards based on purchases in the pharmacy and uses rewards to obtain a free blood pressure monitor
2. Free box of test strips when filling an insulin prescription
3. Patient accumulates rewards based on purchases of prescription medication
4. Coupon for $20 off of a copayment for prescription medications
5. Coupons to transfer prescriptions
6. Rewards program enrolls only uninsured individuals

Financial Need-Based Exception

- Mirrors the language set forth in the ACA
- Requires an unbiased determination of financial need
- Item or service being offered must not be tied to the provision of other services that may be reimbursed by Medicare or a state health care program
- Program may not be advertised

Financial Need-Based Exception (cont.)

- Items or services that are provided pursuant to this exception must be reasonably related to the patient's medical care
  - Standard includes a reasonableness evaluation of the value of the items or services provided to the beneficiary in relation to the harm the incentive is designed to prevent
  - Providers do not need to provide documentation of the actual determination of need for each patient
  - Programs that offer lodging or transportation that is conditioned on the patient's receipt of a particular service and concluded that these programs would not be protected by this exception

Hypotheticals

- Hospital website states that cancer center provides free wigs to children based on financial need
- Physician learns that a financially needy patient has trouble remembering when to take his medications and provides him with a tool to help
- Providing free lodging to a transplant patient
- Pharmacist provides financially needy diabetic patient with free test strips until a refill is authorized
- Providing free backpacks or toys to financially needy children

First Fill of a Generic Drug

- Waiver of copayments owed by certain beneficiaries for the first fill of certain prescription drugs does not constitute remuneration to a beneficiary
  - Part D Plan sponsors and Medicare Advantage plans may waive enrollee copayments for the first fill of a covered Part D generic drug starting in coverage on or after January 1, 2018 without violating the CMP
  - Plans are free to negotiate reimbursement terms with their network pharmacy providers

Hypothetical

Medical Center offers membership card for free with following membership discounts and perks:

- 25% off membership at hospital affiliated health center
- $3 off valet parking at medical center
- 50% off personal training at health center (valid once per calendar year)
- 10% off pregnancy, childbirth and infant care classes
- 20% off retail items in Equipment and Supply retail store located at medical center campus

New AKS Safe Harbors

- Final Rule creates five new AKS safe harbors, expands the existing safe harbor for cost-sharing waivers, and makes a technical correction to an existing safe harbor for referral services
  - Pharmacy Cost-Sharing Waivers
  - Public Ambulance Cost-Sharing Waivers
  - Relationships between Medicare Advantage ("MA") Organizations and Federally Qualified Health Centers ("FQHCs")
  - Medicare Coverage Gap Discount Programs
  - Free or Subsidized Local Transportation Services

Pharmacy Cost-Sharing Safe Harbor

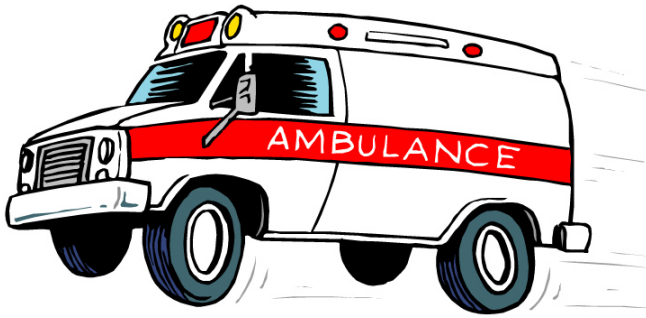
- Protects pharmacies that waive financially needy beneficiaries' coinsurance, copayment or deductible payments for drugs that are covered under a federal health care program (including both Medicare and Medicaid)
- Applies only to
  - Unadvertised waivers
  - Non-routine waivers granted on an individualized basis
  - Good faith determination of financial need or failure to collect
- Specifically applies to drugs provided by pharmacies
  - Cannot be relied upon by providers/physicians (who often provide beneficiaries with drugs covered under Medicare Part B)

Pharmacy Cost-Sharing Safe Harbor (cont.)

- **Note:** There remains significant ambiguity in how this Safe Harbor will be implemented:
  - OIG declined to clarify when waivers occur frequently enough to be considered "routine"
  - Did not provide a uniform method for measuring a patient's financial need
    - good faith, individualized case-by-case basis

Public Ambulance Cost-Sharing Safe Harbor

- State, municipal and tribal ambulance providers and suppliers may reduce or waive beneficiaries' cost-sharing obligations for emergency services payable by a federal health care program on a fee-for-service basis
  - Ambulance provider is owned and operated by state, political subdivision of the state or federally recognized tribe
- Reduction / waiver must be offered uniformly to all of the ambulance provider's residents / tribal members



Public Ambulance Cost-Sharing Safe Harbor (cont.)

- Cost of the waiver cannot be shifted to the federal government or any other individual or payer
  - Cannot be waived as bad debt
- While the Safe Harbor is limited in its scope, it could be a means for public entities that directly operate their own ambulance services to reduce the cost of those services to their community members

MA Organizations and FQHCs Safe Harbor

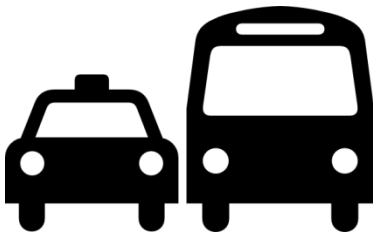
- Created in statute by the 2003 Medicare Prescription Drug, Improvement, and Modernization Act
- Protects any remuneration between an FQHC and an MA Organization pursuant to a written agreement between them
  - Under their written agreement, the MA Organization must provide the FQHC with a payment for services that is at least as much as it would provide to a non-FQHC
  - Does not set a maximum limit on such payments
- Services provided by third-party entities may be protected
- Only protects monetary payments related to treatment for MA enrollees

Medicare Coverage Gap Discount Program Safe Harbor

- Established by the ACA in 2010
- Medicare Coverage Gap Discount Program discounts Part D covered drugs for beneficiaries while they are in the Part D coverage gap or "donut hole"
- Expands the scope of patient assistance programs
- Drug manufacturers need not be in full compliance with all requirements of the Program
  - Minor, technical or temporary noncompliance with the Program's requirements does not preclude safe harbor protection
- Safe harbor allows for discounts provided to "applicable beneficiaries" for "applicable drugs" of a manufacturer

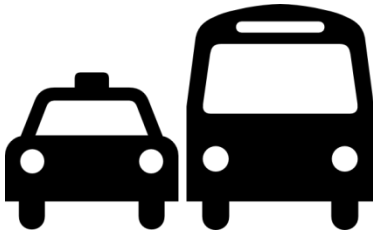
Local Transportation Safe Harbor

- Safe Harbor protects the provision of local or shuttle transportation (excluding ambulance, luxury and air transportation) provided to existing patients by eligible entities for the purpose of obtaining medically necessary services
  - Transportation to services and back home
  - Transportation may be provided on an as-needed basis or as a shuttle service
- Presents an opportunity for providers to help their patients get to their appointments, provided the requirements of the safe harbor are met
- Eligible entity is any individual or entity, except those that primarily supply health care items
  - **EXCLUDED:** DME suppliers, pharmaceutical companies, retail pharmacies



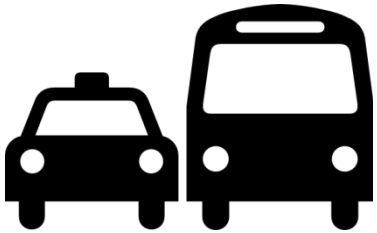
Local Transportation Safe Harbor (cont.)

- Available only to “established” patients
  - Includes new patients who have requested an appointment or had one made on their behalf
  - May not be used to recruit new patients
  - For the purpose of obtaining medically necessary services
- May transport to other providers if patient is established with other provider, but may not take referrals into account
- Entities must maintain a consistent policy for offering transportation that must be applied uniformly



Local Transportation Safe Harbor (cont.)

- No public advertising or marketing
  - No marketing of health care items or services during the course of the transportation
  - "Targeted" information to patients is not marketing
- Private v. nonprivate transport
  - Drivers or others involved in arranging private transportation may not be paid on a per-beneficiary transported basis
- Protects "local" transportation
  - 25-mile distance in urban areas
  - 50-mile distance in rural areas



Local Transportation Safe Harbor (cont.)

Shuttle Transportation

- ‘‘Shuttle’’ is a vehicle (not air, luxury, or ambulance) that runs on a set route, on a set schedule
- Established patient requirement will not apply to shuttles
- Does not mandate where the shuttle can or cannot make stops (grocery, hospital, clinics, etc.)
- Transportation be local—no more than 25 miles between any stop on the route and any stop at health care provider
- Marketing prohibitions apply

OIG Advisory Opinion 18-08

- OIG did not impose CMPs for government-operated fire departments and fire protection districts to enter into a mutual aid agreement to provide backup emergency ambulance services
  - Fire Departments 1-4 bill both residents and nonresidents for cost-sharing amounts; Fire Departments 5 and 6 bill only nonresidents for such cost-sharing amounts
  - Under the Agreement, services are billed according to the billing practices in the jurisdiction where services are rendered
- Arrangement presents a low risk of fraud and abuse under the anti-kickback statute:
  - Would not take into account the volume or value of Federal health care program referrals or other business between the Departments
  - Unlikely to increase utilization of emergency ambulance services or to increase costs to the Federal health care programs

OIG Advisory Opinion 18-05

- OIG did not impose CMPs for hospital established caregiver center that provides or arranges for free or reduced-cost support services to caregivers in the local community
  - Funded by nonprofit hospital foundation
  - Free services include access to a resource library, education workshops, support groups, equipment lending program, free on-site respite care during Center-sponsored events attended by Caregivers
  - Financial assistance for fee-based services in the community
- Promotes Access to Care Exception and Financial Need-Based Exception do not apply
- Combination of safeguards reduces the risk that offering free or reduced-cost services will influence Caregivers' or Care Recipients' choice of provider for federally reimbursable items or services in the future

OIG Advisory Opinion 18-05

- Safeguards:
  - Services provided under the Arrangement have little, if any, tie to federally reimbursable services
  - Center does not recommend any particular service providers who provide medical services
  - Does not take into account whether Caregivers or Care Recipients are Federal health care program beneficiaries or whether they have or will seek federally reimbursable services
  - Center does not actively market the Arrangement
  - Unlikely to increase costs to Federal health care programs

OIG Advisory Opinion 17-05

- OIG did not impose CMPs for retail pharmacy chain's proposal to allow Federal beneficiaries to participate in a paid discount membership program
  - If Members pay entirely out-of-pocket:
    - Members have access to discounts on retail prices for generic drugs, other prescription drugs on Member's formulary, pet prescriptions, nebulizer devices and supplies, blood glucose meters and supplies, and immunizations
    - Members have access to a 10% discount on Clinic services: physicals, immunizations, and health screenings and lipid panel testing
  - Members earn 10% credit toward future retail purchases when they purchase certain chain-branded products and in-store photo-finishing
- Retailer Rewards Programs Exception applies:

  (i) rewards consist of coupons, rebates, or other rewards from a retailer;

  (ii) rewards are offered on equal terms available to the general public, regardless of health insurance status; and

  (iii) offer of the rewards is not tied to the provision of other items or services reimbursed in whole or in part by the Medicare program or a State health care program

OIG Advisory Opinion 17-02

- OIG did not impose CMPs for a hospital outpatient facility's proposal to reduce or waive, on a non-routine, unadvertised basis, cost-sharing amounts owed by financially needy Medicare beneficiaries for items and services furnished in connection with a clinical research study

- Arrangement satisfies all of the criteria of the exception to the Beneficiary Inducement CMP's definition of "remuneration" for waivers of cost-sharing amounts
  - Cost-sharing reduction or waiver as part of any advertisement or solicitation
  - Reduction or waiver of cost-sharing amounts under the proposed arrangement would not be made routinely;
  - Reduction or waiver would be contingent on the Medicare beneficiary's inability to pay the cost-sharing amounts owed
  - Center would reduce or waive the cost-sharing amounts after determining, in good faith, using objective criteria, that the individual is in financial need

Advisory Opinion 17-01

- OIG did not impose CMPs for hospital providing free or reduced-cost lodging and meals to certain financially needy patients
  - Reside 90 or more miles from hospital and live in either a medically underserved area or health professional shortage area
  - Meet financial need criteria and other patient care qualifying circumstances
- Met promotes access to care exception

Ad. Op. 17-01 (cont.)

- Promotes access to care:
  - Lodging and meals improve ability to obtain care
  - Remove socioeconomic and geographic barriers
  - Facilitate obtaining necessary care and attendance at treatment
- Low risk of harm:
  - Eligibility not conditioned on particular services provided
  - No remuneration to clinicians to refer eligible patients
  - No shifting costs to federal health care programs
  - No advertising or marketing
  - No patient safety or quality of care concerns

OIG Advisory Opinion 16-10

- OIG did not impose CMPs for subsidized transportation provided to patients with financial need back and forth to hospital.
- Subsidies present low risk:
  - Modest amount 50 cents - $2 per trip
  - Only available to patients with financial need
  - Limited public transportation operated by county to and from hospital
  - Not advertised
  - Help patients access health care services not available within medically underserved area

OIG Advisory Opinion 15-13

- No CMPs for free van shuttle service for patients offered by health system
  - Minimal risk of fraud and abuse:
    - Not related to anticipated volume of value of referrals
    - Does not include air, luxury, or ambulance transportation
    - Drivers not paid per patient transported
    - Only offered locally within primary service area
    - No advertising or marketing
    - No cost shift to federal health care programs
    - Facilitates access to care by offering alternative to limited public transportation

Practical Takeaways

- Providers should review all current incentives provided to beneficiaries to ensure compliance with finalized regulations
  - Prohibition on advertising
  - Any incentives involving the provision of transportation, lodging or rewards for seeking health care services should be reviewed with caution
  - Written documentation of the incentive program's compliance with the requirements of the exception is recommended
  - Providers should review their state Medicaid's covered services in order to determine the types of services that may be considered "care"

Questions

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Rachael A. Ream, J.D., Ph.D. has represented hospitals, physician groups, pharmacies, and other health care clients in strategic transactions, such as mergers and acquisitions, private equity transactions, joint ventures and physician contracting matters, including co-management arrangements, physician recruitment agreements, and employment and medical director agreements. Ms. Ream regularly assists clients with Medicaid audits, pharmacy audits, and responding to Statements of Deficiency. She also drafts and negotiates strategic supply management and equipment leasing and purchase agreements.

Ms. Ream represents clients on compliance matters, including defense of Medicare and Medicaid fraud and abuse cases, EMTALA, audits. She also advises clients regarding Anti-Kickback Statute and Stark Law compliance and HIPAA and HITECH compliance. She has experience conducting compliance risk assessments and GAP analyses, drafting compliance policies and procedures, and conducting compliance training.

Ms. Ream has extensive background in academic research and has represented clients in the area of research law, including negotiating Material Transfer Agreements, IRB Agreements, Clinical Trial Agreements, and the Common Rule. She earned a Ph.D. in Biological Sciences from Stanford University and completed a post-doctoral research fellowship in Biochemistry at Stanford University School of Medicine. Prior to graduating from Case Western Reserve University School of Law, Ms. Ream worked as a medical writer and editor in clinical research and helped clients prepare for FDA advisory panels.