Beneficiary Inducements and Financial Relationships with Patients

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Overview

1. Patient inducements: What can and cannot be offered?
2. Recent changes to OIG regulations and guidance
3. When is it appropriate to waive patient financial obligations?
4. Appendix: Resources and Other Sources of Guidance

1

Part 1: Patient Inducements –

What can and cannot be offered?

2

Illegal inducements

- Section 1128A(a)(5) of the Social Security Act, 42 U.S.C. § 1320a-7a(a)(5), provides that:
  - any person who offers or transfers
  - remuneration
  - to a Medicare or Medicaid beneficiary
  - that the person knows or should know (actual knowledge, deliberate ignorance, or reckless disregard)
  - is likely to influence the beneficiary's selection of
  - a particular provider, practitioner, or supplier of
  - Medicare or Medicaid payable items or services may be liable for CMPs of up to $10,000 per wrongful act.

3

What is remuneration?

Anything of value

- Transfers of value for free or for other than fair market value
- Waiver of coinsurance and deductible amounts (or any part thereof), unless certain conditions are met

4

What is remuneration? (cont.)

Examples—

- Kickbacks, Bribes
- Discounts
- Rebates
- Gifts, meals, freebies
- Furnishing of supplies, services or equipment for free, or above or below market
- Above or below market credit arrangements

5

What is not an inducement?

- De Minimis Transfers of Value: Inexpensive, non-cash gifts of less than $15 each and no more than $75 in the aggregate on an annual, per patient basis
- Practices permitted under the federal Anti-Kickback Statute (AKS), including regulatory safe harbors
- Practices that meet a beneficiary inducement exception

6

Knows/ Should know

- If the provider does not know – and should not know – a gift would induce a patient to use his or her services or the services of the facility, it would not violate the statute.
- Some factors that indicate remuneration is an inducement (that know/should know standard met) include—
  - conditioning the gift on the recipient's using other goods and services from the provider
  - steering the recipient toward a particular provider following receipt of the gift
  - offering a service without charge
  - obtaining a recommendation from the patient's own health care professional

7

Why does the government care?

- Cost concerns – may encourage the provision of medically unnecessary services
- Level playing field – larger providers can better afford inducements, which disadvantages smaller providers
- Quality concerns – concern that money that should be used for patient care is diverted to fund illegal inducement, reducing quality
- Sign of other compliance problems

8

Risk Areas

- Transportation
- Health Fairs/ Baby Showers/ Free screening
- Patient Discounts – waiving obligations
- Patient gifts and marketing practices
- Rule: Use common sense and assess how likely proposed remuneration (gift, service, discount, etc.) will be to influence beneficiaries

9

What can be offered?

Remuneration that meets an exception (including AKS safe harbors)

10

Beneficiary Inducement Exceptions

- Waivers of coinsurance and deductible amounts that are not advertised, not routinely waived, individual determination of financial need
- Incentives to individuals to promote the delivery of preventive care services
  - Cannot be tied to the provision of other Medicare or State health care program services.
  - No cash or "instruments convertible to cash."
  - No disproportionally large incentives.

11

Beneficiary Inducement Exceptions (cont.)

- Properly disclosed copayment differentials in health plans
- Reduction of copay amounts for covered OPD services under 1833(t)(8)(B) (20-year-old statutory exception, just added to regs in December 2016)
- AKS safe harbors
  - New safe harbor for free or discounted local transportation, 42 CFR 1001.952(bb).

12

New Bene Inducement Exceptions

- Remuneration that promotes access to care *and* pose low risk of harm
- Financial hardship exception (reasonable connection to individual's medical care)
- Retailer coupons, rebates, or other retailer rewards
- Part D Plan sponsor's first fill generics copay waivers

13

Safe Harbors vs Bene Inducement Exceptions

- AKS safe harbors protect transfers of value to patients or physicians
- The beneficiary inducement exceptions only protect remuneration given to patients
- You wouldn't be able to use these exceptions for remuneration to physicians
- For remuneration to patients—
  - Always do both analyses—beneficiary inducement and AKS

14

How is it enforced?

- OIG's document and testimonial subpoena authority (can be used in any investigation of this type of conduct)
- CMPL: Administrative proceeding brought by OIG before an administrative law judge with appeal to Departmental Appeals Board and then to federal Circuit Court (Bene Inducement or AKS violation)
- AKS: Criminal or civil (FCA) proceeding by DOJ in federal District Court
- Settlements (or plea agreements) can be with either DOJ, OIG, or both

15

Penalties/ Remedies

- CMPL—
  - CMP up to $15,270 (inflation adjustment) per item or service for a bene who was offered/received remuneration in violation of prohibition;
  - Assessment of not more than 3 times the amount claimed for each item or service; OR 3 times the amount of the remuneration (if also AKS violation, CMP up to $74,792); and/or
  - Exclusion
- If DOJ prosecutes under AKS = criminal liability (which also leads to exclusion), or FCA liability, high penalties and 3 times damages.

16

Part 2: Recent Changes to OIG Regulations and Guidance

17

New OIG Regs and Guidance

- Part of broader OIG rulemaking, which included updates to exclusion and other CMP regs
- Adds exceptions to the definition of "remuneration" as used in the beneficiary inducement CMP
- Revises AKS safe harbor regulations—which are also included as exceptions to the beneficiary inducement CMP

18

New OIG Regs and Guidance (cont.)

- Most significant changes:
  - New beneficiary inducement exceptions to the definition of "remuneration"
    - Items or services that promote *access* to care and pose low risk of harm
    - Financial hardship exception (reasonable connection to individual's medical care)
  - A new safe harbor to protect free or discounted local transportation services provided to Federal health care program beneficiaries.

19

Promotes Access to Care/ Low Risk of Harm

- Items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the programs by—
  - (i) Being unlikely to interfere with, or skew, clinical decision making;
  - (ii) Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
  - (iii) Not raising patient safety or quality-of-care concerns.

20

Hypothetical 1

- A hospital (or other provider or supplier) hosts an informational program to help patients with diabetes learn more about controlling their disease.
- To encourage participation, dinner will be provided.
- Hospital will also give away flash drives, note pads, and tote bags with the hospital logo.
- Does any of this violate the beneficiary inducement prohibition?

21

Hypothetical 1 – Analysis

- Informational program?
  - OIG does not consider educational materials to be remuneration.
  - A provider or supplier may offer educational materials (such as written materials about disease states or treatments), or informational programs (such as a program to help patients with asthma or diabetes learn more about controlling their diseases) to patients or prospective patients without implicating the beneficiary inducement CMP. 81 Fed. Reg. at 88,396.

22

Hypothetical 1 – Analysis (cont.)

- Dinner?
  - De Minimis Exception?
  - OIG warned about offering attendees of educational program items/services of more than nominal value that offeror *knows or should know is likely to influence the patient to choose that provider*. 81 Fed. Reg. at 88,396.
  - Giving patients the tools they need to remove barriers.
    - Interpretation does not incorporate concept of rewarding patients for accessing care; protects items or services that should improve a patient's *ability* to access care and treatment, *not inducements to seek care*." 81 Fed. Reg. at 88,393.

23

Hypothetical 1 – Analysis (cont.)

- Flash drives, note pads, and tote bags with logo?
  - Remuneration given in connection with marketing is not low risk and therefore would not be protected under this exception. Such remuneration is given for the purpose of influencing and may induce overutilization or inappropriate utilization. 81 Fed. Reg. at 88,396.
  - OIG warning about offering items/services of more than nominal value at such programs.
  - De Minimis Exception?
    - Nominal value threshold of $15 per item? $75 per year? Other events during year to consider?

24

Hypothetical 2

- Hospital wants to encourage patients to go to their follow-up appointments. It is considering—
  - Reimbursing parking expenses or providing free child care during appointments.
  - Offering movie tickets to a patient for attending an appointment (reward for receiving care).

25

Hypothetical 2 – Analysis

- Items/ services that "promote access to care" give patients the tools they need to remove barriers.
- Does not incorporate the concept of rewarding patients for accessing care; the exception protects items or services that should improve a patient's *ability* to access care and treatment, *not inducements to seek care*.
- 81 Fed. Reg. at 88,392–88,393.

26

Hypothetical 2 – Analysis (cont.) Examples

- Items/services that promote access to care:
  - Purchasing web-based food/activity trackers for diabetic patients.
  - Reimbursing parking expenses or providing free child care during appointments.
- Items or services that do not promote access to care:
  - Offering movie tickets to a patient for attending an appointment (reward for receiving care).
  - Offering patients a $20 gift card for selecting specific provider to perform a procedure.

27

Hypothetical 2 – Analysis (cont.)

- OIG explained the distinction between promoting access to care and rewarding access to care:

  "A patient might not be able to attend the appointment without child care assistance, but the movie tickets do not improve the patient's ability to attend the appointment."

  81 FR 88,392.

28

Financial-Need-Based Exception

- The offer or transfer of items or services for free or less than fair market value by a person, if—
  - (i) Not offered as part of advertisement or solicitation
  - (ii) Not tied to the provision of other items or services reimbursed in whole or in part by the programs
  - (iii) Reasonable connection between the items or services and the individual's medical care; and
  - (iv) Only provided after determining in good faith that the individual is in financial need.

29

Overlap with "Promotes Access to Care?"

- Overlap among "financial need based," "promotes access to care," and "promotes the delivery of preventive care."
- Distinctions among these exceptions.
  - Financial-need-based exception does not require that the remuneration "promote access to care," or "promote the delivery of preventive care."
  - Those two other exceptions do not require that the recipient of the remuneration have a financial need.
  - "Remuneration might meet some criteria of multiple exceptions, but it is protected only if it meets all criteria of any one exception." 81 Fed. Reg. 88,402.

30

Hypothetical 3

- A doctor asks a patient who had Medicaid to track his activity in a health app that will send the info to the doctor. The patient cannot afford the app. The provider gives the patient a voucher to buy the app.
- Would this be allowed?
- Can the hospital do this for all patients who receive Medicaid?

31

Hypothetical 3 – Analysis

- Financial Need Criteria:
  - Advertised?
  - Tied to the provision of other items or services?
  - Reasonable connection to the individual's medical care?
  - Is the individual in financial need?
- Is the voucher a cash equivalent? Is it only for that specific app? Or is it a gift card?
- All Medicaid patients? No. Financial Need Based Exception requires an individualized determination.

32

Hypothetical 3 – Analysis

- The Financial Need Based exception is not designed to induce the patient to seek additional care, but rather to help financially needy individuals access items or services connected to their medical care. 81 Fed. Reg. 88,403.
- "Reasonable connection to medical care of the individual" can be interpreted broadly.
  - Can include items related to prevention of illness or injury, or medical treatment (*e.g.,* extra bandages for wound care), or items crucial to a patient's safety (such as car seats for infants)
  - Not everything beneficial to a patient is connected to medical care (e.g., school backpack not connected)

33

Hypothetical 3 – Analysis

- Depending on individual circumstances, could be reasonably connected to a particular patient's medical care—car seats, diapers, specialized clothing, baby formula or particular food items, books, weight monitors, gas cards, and glucose monitors.
- Not reasonably connected to individual's medical care—strollers, school supplies, and (usually) toys or clothing.
  - But these items (among others) may fit under another exception—for example they can be offered to patients who attend necessary preventive care appointments. 81 Fed. Reg. 88,403.

34

Local Transportation Safe Harbor

- Protects free or discounted local transportation by Eligible Entities to established patients to obtain medically necessary items or services.
- Local: within 25 miles "as the crow flies" of provider/supplier transported to or from, or 50 miles if patient resides in rural area.
- Eligible entity: any individual or entity, except for individuals or entities that primarily supply health care items (or related persons).
- Established patient: selected and initiated contact to schedule an appt or previously attended an appt with the provider/supplier.
  - Must be an established patient of the entity providing the transportation and the entity the patient is transported to or from.

35

Local Transportation Safe Harbor

- Other Key Requirements:
  - No luxury, air, or ambulance
  - Uniform policy applied consistently
  - Eligibility not based on vol/val of FHCP business
  - No marketing (of transportation or during transportation) (no per-bene transported payments)
  - No shifting of costs to FHCPs or others
- Separate criteria for "shuttle service" some requirements overlap (*e.g.*, "local") but others are different (*e.g.*, no "established patient" req.)

36

Local Transport. Safe Harbor, Shuttle Service (set route and schedule)

- No luxury, air, or ambulance
- No marketing (of transportation or during transportation) (not paid on per-bene transported basis)
- Entity's local area = 25 miles urban, 50 miles rural
  - No more than 25 miles (50 miles if rural) from any stop on the route to any stop at a location where health care items or services are provided
- Eligible Entity bears costs, no cost shifting to others

37

Hypothetical 4

- A hospital wants to offer free rides to patients who need transportation to appointments.
- Is this allowed under the local transportation safe harbor?
- Can the hospital advertise this service?
- Can it define "need for transportation" as patients with Medicaid?

38

Hypothetical 4 – Analysis (cont.)

- Must meet all criteria for local transportation safe harbor to be protected.
- Can the hospital advertise this service? – No
- Can the hospital define "need for transportation" as patients with Medicaid? – No
  - Patient's status as a Medicaid (or Medicare) beneficiary should not be used as a proxy for establishing transportation need, in part because this would be transportation offered on the basis of volume or value of FHCP business.
  - Does not establish need for transportation.

39

Hypothetical 4 – Analysis (cont.)

- "While eligible entities are free to tailor their transportation programs to the needs of their own patient populations and communities (including setting caps on available transportation), they may not do so in a way that is linked to status as a Federal health care program beneficiary." 81 Fed. Reg. 88,386.
- Same analysis if it were a shuttle service?
  - Cannot use Medicare/Medicaid status.
  - Cannot advertise.
  - Can post shuttle schedule and route.

40

When two exceptions could apply?

- Example: promotes access to care vs local transportation safe harbor vs financial need?
- OIG recognized overlap, noted distinctions, said must meet all requirements of one exception to be protected.
- When an arrangement could be protected under promotes access to care and another exception, the more specific exception applies:
  - "[The promotes access to care] exception should be read in the context of those more specific exceptions and safe harbors: We would look to other applicable exceptions to consider whether the remuneration in question poses a low risk of harm." 81 Fed. Reg. at 88,390-91.

41

When two exceptions could apply? (cont.)

- For free transportation that promotes access to care
  - Local transportation safe harbor includes requirements OIG finds necessary for transportation to be "low risk."
- OIG recognizes the need for case-by-case analysis.
- Takeaway: the Promotes Access to Care exception will allow many more opportunities to provide items and services to increase access to care, but it will not significantly expand existing exceptions.
  - Anyone asserting the promotes access to care exception as a defense will have the burden of presenting sufficient facts and analysis for OIG to determine whether the arrangement meets the exception.

42

Hypothetical 5

- A hospital wants to provide free lodging and transportation to patients receiving cancer treatment who have a financial hardship.
- Which exception or safe harbor would you use?
  - Tying to service to the transportation and lodging.
  - Local transportation safe harbor, financial need exception, promotes access to care exception?

43

Hypothetical 5 – Analysis

- Promotes access to care exception should be read in the context of more specific exceptions and safe harbors.
- Transportation = if a local transportation arrangement did not meet all of the safe harbor requirements, it would not likely be low risk under the promotes access to care exception (e.g., if long-distance transportation or advertised).

44

Hypothetical 5 – Analysis

- OIG addressed a similar scenario in the preamble discussion of the Financial Need Based exception—
  - "Programs that offer lodging or transportation that is conditioned on receiving a particular service are 'tied' to the particular service and would not be protected under [the financial need] exception. *However, other exceptions, such as the exception that allows remuneration that promotes access to care and poses a low risk of harm could apply, as could the anti-kickback safe harbor related to local transportation*." 81 Fed. Reg. at 88,402.

45

Hypothetical 5 – Analysis

- Lodging before a procedure, or transportation to appointments, also could be protected under appropriate circumstances. The local transportation safe harbor . . . sets forth a number of factors that, taken together, would render transportation low risk. It would be prudent to structure any free or reduced-cost transportation arrangements to comply with the safe harbor because transportation to obtain Federal health care program-covered items and services generally will implicate the anti-kickback statute. 81 Fed. Reg. 88,397.
- Answer = With appropriate policies (and intent), the transportation could be protected with the local transportation safe harbor, and lodging could be protected by promotes access to care/low risk of harm exception.
- Adding a financial need requirement to policies related to local transportation or remuneration that promotes access to care is ok – even though there is a separate financial-need-based exception.

46

Part 3: Waiving Patient Financial Obligations

47

Waivers of copays/deductibles

- Beneficiary Inducement Prohibition Exception
- 42 C.F.R. 1003.110
- Waivers of coinsurance and deductible amounts, if—
  - Not advertised
  - Not routinely waived
  - Only after a good faith determination that patient is in financial need (or after reasonable collection efforts fail)

48

Reduction in Copay for OPD Services

- Beneficiary Inducement Prohibition Exception
- 42 C.F.R. 1003.110
- A reduction in the copayment amount for covered OPD services under section 1833(t)(8)(B) of the Act

49

Other Waivers

- Beneficiary Inducement Prohibition Exceptions
- 42 C.F.R. 1003.110
- Differentials in coinsurance and deductible amounts as part of a benefit plan design (as long as the differentials have been disclosed in writing to all beneficiaries, third party payers and providers), to whom claims are presented;
- Waivers by a Part D Plan sponsor of any copay for the first fill of a covered Part D generic drug or an authorized generic drug for individuals enrolled in the Part D plan, as long as such waivers are included in the benefit design package (applies to coverage years starting on or after January 1, 2018)

50

Safe Harbor for Waiver of Copays, etc.

42 C.F.R. § 1001.952(k) *Waiver of beneficiary copayment, coinsurance and deductible amounts.* Any reduction or waiver of cost-sharing amounts protected if—

(1) Owed to hospital for inpatient hospital services paid for by a FHCP under the prospective payment system, the hospital must—
   (i) Not cost shift to FHCPs, other payers, or individuals (and not claim the amount reduced or waived as a bad debt for payment purposes under a FHCP).
   (ii) Make offer without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for reimbursement is filed.
   (iii) Not make offer as part of price reduction agreement between hospital and a third-party payer (including health plan), unless agreement is part of a contract for furnishing of items/services to a beneficiary of a Medicare supplemental policy.

51

Safe Harbor for Waiver of Copays (cont.)

(2) FQHC may reduce or waive the cost-sharing amounts for items or services paid for in whole or in part by a FHCP for an individual who qualifies for subsidized services under Title 5, Medicaid, or Public Health Services Act . (Applies to other health care centers under same titles and PHSA)

(3) Pharmacy for cost-sharing imposed under a Federal health care program, the pharmacy may reduce or waive the cost-sharing amounts if certain conditions are met.

(4) Ambulance provider or supplier for emergency ambulance services for which a Federal health care program pays under a fee-for-service payment system if certain conditions are met.

52

Appendix: Sources of Guidance

53

Resources

- Beneficiary Inducement Civil Monetary Penalty, 42 U.S.C. § 1320a-7a(a)(5)
  - 42 CFR Part 1003.1000 et seq.
- Antikickback Statute, 42 U.S.C. § 1320a-7b(b)
  - 42 C.F.R. § 1001.952 (safe harbor regulations)

54

Other Sources of Guidance

- 2016 Preamble to Final Rule
  - 81 Fed. Reg. 88,396 (Dec. 7, 2016)
- 1991 Special Fraud Alert
- 2002 Special Advisory Bulletin, *Offering Gifts and Other Inducements to Beneficiaries*
- 2016 *Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries*
- Compliance Program Guidance
- Advisory Opinions

55

Preamble to Final Rule

- 81 Fed. Reg. 88,396 (Dec. 7, 2016)
- Provides guidance on exceptions to the beneficiary inducement statute
- Shows OIG's thinking process with respect to new exceptions to the definition of remuneration in the beneficiary inducement prohibition and how OIG would interpret the new exceptions in light of existing exceptions and AKS safe harbors.

56

1991 Special Fraud Alert

- 1991 Special Fraud Alert, *Routine Waiver of Copayments or Deductibles under Medicare Part B*
  - 59 Fed. Reg. 65,372 (Dec. 19, 1994) (publishing previously issued Special Fraud Alerts), available on OIG website, under the Compliance tab.
- Addressed routine waivers of Part B copayments and deductibles, which result in (1) false claims, (2) AKS violations, and (3) excessive utilization
- Beneficiaries who have cost-sharing obligations are better health care consumers
- Introduced financial hardship exception

57

1991 Special Fraud Alert (cont.)

- Suspect marketing practices (not exhaustive)—
  - Advertisements that state—
    - "Medicare Accepted As Payment in Full"
    - "Insurance Accepted As Payment in Full"
    - "No Out-of-Pocket Expenses"
  - Advertisements promising "discounts" for Medicare benes
  - Routine use of financial hardship waivers without good faith attempt to assess need or reasonable collection efforts

58

1991 Special Fraud Alert (cont.)

- Collecting co-pays/deductibles only when bene has Medicare supplemental insurance ("Medigap')
- Charges to benes higher than other patients (with higher charges offset with waivers)
- Waiving co-pays/deductibles for a group of benes (e.g., from a specific hospital)
- Sham "insurance programs" to cover copayments and deductibles (from the entity offering the insurance, not based on actuarial risks)

59

2002 Special Advisory Bulletin

- Announced original nominal value limits
- Expect to limit favorable advisory opinions to situations very close to existing exceptions
- Provider funding of independent patient advocacy group or other organization to help beneficiaries okay so long as independent determination of need and receipt of remuneration not dependent on use of a particular provider
- Concern about indirect or word of mouth promotion or passive marketing

60

2002 Special Advisory Bulletin (cont.)

- No special exception for beneficiaries with chronic medical conditions
- Expressed concern about escalating inducement
- At time, was considering new exceptions for:
  - Complimentary local transportation
  - Government-sponsored clinical trials
  - Purchase of Medicare supplemental insurance by dialysis providers for persons with ESRD

61

2016 Statement

- *OIG Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries*, available on OIG's website (Dec. 2016).
- De Minimis Transfers of Value: Inexpensive, non-cash gifts of less than $15 each and no more than $75 in the aggregate on an annual, per patient basis.

62

Compliance Program Guidance

- Examples include –
  - Hospital CPG: Addresses free transportation, cost-sharing waivers, discounts to uninsured patients (which are often confused with beneficiary inducements), and preventive care services.
  - DMEPOS CPG: Addresses gifts to beneficiaries and marketing practices that potentially implicate the beneficiary inducement prohibition.

63

Advisory Opinions

- Advisory Opinion 17-02 (favorable – non-routine, unadvertised reduction or waiver of cost-sharing amounts for financially needy beneficiaries for items/ services furnished in connection with a clinical research study)
- Advisory Opinion 17-01 (favorable – free or reduced-cost lodging and meals to certain financially needy patients)
- Advisory Opinion No. 11–16 (favorable – domiciliary services including transportation, lodging, meal assistance, and others without regard to financial need)

64

Advisory Opinions (cont.)

- Advisory Opinion No. 11–01 (favorable – waivers of copays and deductibles, lodging and transportation assistance program at pediatric hospital)
- Advisory Opinion 10-18 (favorable - free one night post-surgical accommodations for pediatric tonsillectomy patients)
- Advisory Opinion 09-11 (favorable – free blood pressure screenings to walk-in visitors at hospital)
- Advisory Opinion 09-01 (favorable – complimentary local transportation program for friends and family of SNF residents)

65

Advisory Opinions (cont.)

- Advisory Opinion 08-03 (favorable – prompt pay discounts)
- Advisory Opinion 06-01 (unfavorable – free preoperative home safety assessments)
- Advisory Opinion 01-14 (favorable – waiver of copayment related to certain cancer screening services)

66

Questions?

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67