BAIRD HOLM LLP
ATTORNEYS AT LAW

Discounts, Health Fairs and Senior Membership Clubs

Just How Far Can a Hospital Go?

Julie A. Knutson
Baird Holm LLP
1700 Farnam Street, Suite 1500
Omaha, NE 68102
402.636.8327
jknutson@bairdholm.com

#1292634.2

BAIRD HOLM LLP ATTORNEYS AT LAW

Presentation Overview

- Applicable statutes
  - Civil Monetary Penalty (1128A(a)(5) of the Social Security Act; codified at 42 USC 1320a-7a(a)(5))
  - Medicare Anti-Kickback Statute (42 USC 1320b-7b)
  - Stark Law (42 USC 1395nn)
  - Patient Protection and Affordable Care Act (P.L. 111-148)
- Guidance
- Advisory Opinions
- Examples

Overview | Applicable Statutes* | AHLA & Current State | Advisory Opinions | Illustrative Examples | Physician Marketing | Conclusion

BAIRD HOLM LLP ATTORNEYS AT LAW

CMP Introduction

- Civil Monetary Penalty (CMP)
  - Section 1128A(a)(5) of the Social Security Act
  - Amended by the ACA
- Implementing regulations
  - 42 CFR § 1003.101

Applicable Statutes

BAIRD HOLM LLP ATTORNEYS AT LAW

CMP Introduction, cont.

- 42 USC 1320a-7a(a)(5). "Civil Monetary Penalties (CMP) – Improperly filed claims"
  - CMP applies to:
    - "Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5) of this section that – (5) offers to or transfers **remuneration** to any individual eligible for benefits under [Medicare or Medicaid] 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, under [Medicare or Medicaid]."

Applicable Statutes

What is Remuneration?

- 42 USC 1320a-7a(i)(6)
  - "[R]emuneration includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or other than fair market value."

Applicable Statutes

What is *not* Remuneration?

- 42 USC 1320a-7a(i)(6)
  - **Original** statutory/regulatory exceptions (5)
    - Waivers of cost-sharing based on financial need;
    - Properly disclosed copayment differentials in health plans;
    - Incentives to promote the delivery of certain preventive care services;
    - Practices permitted by statute or regulation under the Anti-Kickback Statute;
    - Waivers of hospital outpatient copayments in excess of the minimum copayment amounts

Applicable Statutes

What is *not* Remuneration?

- 42 USC 1320a-7a(i)(6)
  - **New** statutory/regulatory exceptions (3) (ACA additions)
    - Other remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs;
    - The transfer of items or services by a person (i) that consist of coupons, rebates, or other rewards from a retailer, (ii) that are offered or transferred on equal terms available to the general public regardless of insurance status, and (iii) that are not tied to the provision of other items or services reimbursed under a federal health care program.
    - •The transfer of items or services by a person (i) that are not offered as part of an advertisement or solicitation, (ii) that are not tied to the provision of other items or services reimbursed under a federal health care program, (iii) for which there is a reasonable connection between the items or services and the medical care of the individual, and (iv) for which the person providing the items or services determines in good faith that the individual is in financial need.
  - **And remember** OIG's bright line $10/$50 rule
    - No more than $10 on individual gifts
    - No more than $50 total per year

Applicable Statutes

CMP – Sanctions & Standard of Proof

- CMPs of up to $10,000 for each wrongful act
- *Should know* or *should have known* –
  - (1) Acts in deliberate ignorance of the truth or falsity of the information; or
  - (2) Acts in reckless disregard of the truth or falsity of the information
  - *For purposes of this definition, no proof of specific intent to defraud is required

Applicable Statutes

Beneficiaries

- The prohibition is limited to Medicare/Medicaid beneficiaries
  - However, be aware of MSP issues
- What about private pay?
- No general guidance on gifts
- "Insurance only" billing
  - Insurance companies have taken the position that their obligation is also reduced
- Managed Care Contracts may include an affirmation obligation to collect co-pays or deductible amounts

Applicable Statutes

Beneficiaries (cont.)

- HIPAA-CMP is interwoven with the Anti-Kickback Statute ("AKS")
- Advisory opinions often address both AKS and HIPAA-CMP issues

Applicable Statutes

Anti-Kickback Statute

The AKS is a "criminal statute that prohibits the exchange (or offer to exchange), anything of value, in an effort to induce (or reward) the referral of federal health care program business [Medicare or Medicaid]."

Applicable Statutes

Anti-Kickback Statute

"(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind–

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both."

Applicable Statutes*

Anti-Kickback Analysis

- Is a safe harbor available?
- Do the facts conform to an AKS safe harbor?
  - Relevant safe harbors include
    - (k) Waiver of beneficiary coinsurance and deductible amounts
    - (l) Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans
- Are there positive facts to mitigate a finding of intent if analyzed under the "one purpose" test?

Applicable Statutes

Special Advisory Bulletin

- Guidance on beneficiary inducement, although not binding like regulations/statutes
- The Special Advisory Bulletin (08/2002) sets out four principles for application of the prohibitions
  - Medicare/Medicaid beneficiaries may be offered inexpensive gifts (no cash or cash equivalents) or services without violating the statute
    - $10/50 "Bright Line" rule
    - Tracking is necessary

Applicable Statutes*

Special Advisory Bulletin (cont.)

- The Special Advisory Bulletin (08/2002)
  - More expensive items or services may be offered if it fits within one of five exceptions in the statute:
    - Waivers of cost-sharing amounts based on financial need
    - Properly disclosed co-payment differences in health plans
    - Incentives to promote the delivery of certain preventive care/services
    - Any practice permitted under the federal AKS under 42 CFR 1001.952.4 (safe harbors) or
    - Waivers of hospital outpatient co-pays in excess of minimum co-pay amounts under the Medicare hospital outpatient fee schedule

Applicable Statutes*

Potential Risks

- Overutilization of Medicare & Medicaid services and increasing costs for federal health care programs;
- Improper influence on patient treatment decisions by offering items or services of value;
- Shifts patient focus to value of inducement and not the value or quality of the health care;
- Competitive disadvantage for providers unable to afford beneficiary programs.

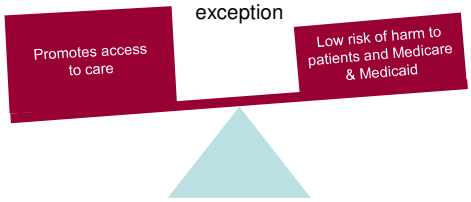
American Health Lawyers Association Public Interest Committee, Beneficiary Inducements in an Evolving Market: Assessing the Risks, Understanding the Benefits and Drawing the Lines 1, 4 (Oct. 2, 2013) available at http://www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Beneficiary%20Inducements%20White%20Paper.pdf (last visited Sept. 6, 2014).

Moving Target

- New exceptions under ACA
  - Apply only to CMP liability, not AKS

Current State & ACA Exception

AHLA recommends a "balancing" approach for new ACA exception



Advisory Opinion Overview

- Opinions are only binding on requesting parties
- Favorable opinions are expected to be limited to situations involving conduct very close to a statutory or regulatory exception
- Advisory opinions do not "approve" arrangements
  - Facts may indicate a "technical violation" of the statute but do not constitute grounds for CMPs or administrative sanctions under the AKS

Post-ACA Advisory Opinions

- Advisory Opinion No. 11-01
  - National network of nonprofit, tax-exempt specialty hospitals
  - Provide lodging and transportation assistance for eligible patients based on financial need and condition
  - First instance of OIG applying ACA changes to CMP
    - Exception for "any other remuneration which [1] promotes access to care and [2] poses a low risk of harm to patients and Federal health care programs [….]"

	Yes or No?	***Why?***
[1] Promote access to care?	Yes	Permits patients to complete pre- and post-operative care, and allows hospital to react appropriately to patient's management situation beyond its control.
[2] Low risk of harm to Federal health care programs?	Yes	Programs are not advertised and eligibility is determined *after* acceptance into treatment program based on financial need.

Post-ACA Advisory Opinions

- *See also*
  - Nonprofit community health center provided $20 grocery cards to eligible Medicaid managed care enrollees (OIG No. 12-21)
    - Gift card was of "relatively modest value" and program is only advertised to eligible Medicaid beneficiaries and not overall patient population
  - Internationally known not-for-profit institution provides transportation, meals, and lodging to children eligible for their treatment and research programs (OIG No. 11-16)
    - Low risk of harm to federal health care programs because only 23% of reimbursement provided by Medicare or Medicaid and services are not advertised.

Common Questions and Examples

General Principles

1. Is it really remuneration?
   - Newsletters
   - Birthday cards
   - Claim filing assistance
   - Volunteer opportunities
2. Value of the benefit and tracking for bright line rule
3. Discounts/gifts from third parties
4. Educational/preventive health programs – community benefit?

Illustrative Examples

Senior Programs

- Focused largely on Medicare-eligible individuals
- May or may not include fees to join or for certain benefits
- Laundry list of benefits; each requires analysis
- Bright line rule may apply to some

Illustrative Examples

Athletic Trainer Services and Sports Injury Clinics

- Brief 2-3 hour walk-in clinic staffed by hospital employed athletic trainers, and orthopedic surgeons (employed and private practice)
  - Services provided to all community members
  - Walk-in patients who required further treatment directed to their personal physician
- Potential CMP and AKS violations with private physician and relationship between athletic trainers/physicians
- Recommended to classify clinic as part of charitable mission/community benefit under IRS Form 990

Illustrative Examples

BAIRD HOLM LLP ATTORNEYS AT LAW

Issues/Safeguards

- EMTALA – licensed space, on-campus, no appointment
- Informed consent
- HIPAA
- Board approval of community benefit plan
- Agreements with schools
- Involving physicians very risky

Illustrative Examples

BAIRD HOLM LLP ATTORNEYS AT LAW

Health Fairs

- Health screenings and lab tests at community health fair
- Wellness screenings
  - Cost is an issue
  - Can be considered non-covered when results are provided only to participant
  - Waivers are necessary
  - Okay to charge covered beneficiaries if notified in advance
- ACA exception for access to care and low risk to federal health care programs applicable

Illustrative Examples

BAIRD HOLM LLP ATTORNEYS AT LAW

Health Fair Screenings – Evaluation

- Increasing number of screening tests are being included as a Medicare covered benefit
- Health fairs are starting to include screening tests of increased sophistication and expense, making it important to fall within the preventive exception
- Tests directly linked to Hospital services, e.g., CV screening/new hospital cardiology program, are suspect
- Have the advantage/safeguard of being infrequently offered
- Adv. Op. 9-11 re: free blood pressure screenings

Illustrative Examples

Home Health & DME

- Potential remuneration for inducements to beneficiaries
- Examples from OIG opinions:
  - Free safety equipment/pagers to hemophilia patients
  - Free medical alert pagers/monitoring to home health patients
  - Free pre-operative in-home safety assessment
  - Free pre-operative educational video on home safety/recovery
  - Free in-home congestive heart failure assessment
  - Free oxygen for patients until they qualify for Medicare oxygen coverage
- OIG Analysis: Remuneration, prosecution

Illustrative Examples

Analysis

- Look to $10 per item/$50 aggregate limit
- Consult Advisory Opinions
  - Something on point?
  - Structure similarly
- Available ACA exception?
- Structure as a community benefit

Illustrative Examples

Red Flags

- Direct link to hospital service, e.g., free in-home PFT linked to hospital pulmonary service
- Direct physician involvement
  - Increases value
  - Solidifies link to Medicare/Medicaid services
  - May create Stark, AKS, tax-exempt issues with physicians

Illustrative Examples

Red Flags (cont.)

- Incentives directly tied to transferring care, e.g., pharmacy incentive to transfer prescriptions
- Targeting of Federal health care program beneficiaries
- Tracking referrals to hospital program (roadmap for prosecution)

Illustrative Examples

Prevention = Planning

- Consider legal perspective **before** structuring program
- Incorporate safeguards from OIG guidance; try to meet requirements of AKS safe harbors
- It's not OK because you know others are doing it
- Even minor structure changes can change legal analysis

Physician Marketing

Conclusion

- Conform arrangement to ACA exceptions, Section 231(h) exceptions of AKS safe harbor or advisory opinion facts
- Incorporate "positive facts" cited by Adv. Op. to minimize risk of perceived intent to induce
  - Offering benefit broadly rather than to targeted groups
  - No prior advertising of benefit, e.g., giveaways
  - Timing of benefit; offered after beneficiary has selected provider
  - Benefit conferred by independent third party which makes its own independent selection of beneficiaries
  - Minimal impact on Medicare/Medicaid beneficiaries
  - Minimal cost/value even if over bright line limits
  - Infrequently offered
  - Caps on aggregate benefit

Conclusion (cont.)

- Cost of benefit not included in cost report
- Subject matter consistent with Federal initiatives

Questions and Discussion