New AKS Safe Harbors Create Opportunities for Providers

Ohio Hospital Association
June 12, 2017
Agenda

• Context- Era of health care reform
• Overview of Anti-Kickback Statute ("AKS") and Civil Monetary Penalties ("CMP") Law
  – Previous OIG advisory opinions
  – Affordable Care Act
  – AKS proposed rules
  – Recent rulemaking
• AKS final rules
• CMP final rules
• Practical takeaways
New safe harbors and exceptions issued in an era of health care reform ("HCR")

HCR promotes the collaboration of providers and patients to achieve the triple aim
  - Improving the patient experience
  - Improving the health of populations
  - Reducing the per capita cost of healthcare

Recent scrutiny of rigidity of fraud and abuse rules; relaxation of Stark Law rules in 2015

Remember this stuff requires some unlawful "intent"
We believe the safe harbors in this rule further the goals of access, quality, patient choice, appropriate utilization and competition while protecting against increased costs, inappropriate steering of patients and harms associated with inappropriate incentives tied to referrals.

- 81 Fed. Reg. 88369
AKS – Background

• 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; violations may also result in civil monetary penalties
• 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
CMP Law – Background

• Mechanism to impose civil monetary penalties for violations of different laws

• Standalone provisions of the CMP Laws
  – Prohibit the offer of remuneration that the offeror *knows or should know* is likely to influence another individual to choose a certain provider, practitioner or supplier
    • Applies only to inducement of Medicare and state health care program beneficiaries
  – Prohibit a hospital or critical access hospital from paying a physician to reduce *medically* necessary care (gainsharing rule)

• CMP Laws codified at 42 U.S.C. § 1320a-7a; exceptions at 42 U.S.C. § 1320a-7a(i)(6)
Recent Self-Disclosures

• (11-18-2016) Dignity Health, CA, agreed to pay $368,364.69 for allegedly violating the CMP Law including provisions applicable to beneficiary inducements, physician self-referrals and kickbacks

• (01-07-2016) Trilogy Health Services, LLC and PCA-Corrections, LLC, KY, agreed to pay $80,526 for allegedly violating the CMP Law provisions applicable to beneficiary inducements and kickbacks

• (08-27-2015) Laser Spine Institute, LLC, FL, agreed to pay $145,127.45 for allegedly violating the CMP Law provisions applicable to physician self-referrals and kickbacks
Manhattan U.S. Attorney Announces $50 Million Settlement With Walgreens For Paying Kickbacks To Induce Beneficiaries Of Government Healthcare Programs To Fill Their Prescriptions At Walgreens’ Pharmacies

Preet Bharara, the United States Attorney for the Southern District of New York, Scott J. Lampert, Special Agent in Charge of the New York Office of the U.S. Department of Health and Human Services, Office of Inspector General ("HHS-OIG"), and Craig Rupert, Special Agent in Charge of the Northeast Field Office of the Defense Criminal Investigative Service, Department of Defense, Office of Inspector General ("DoD-OIG"), announced today a $50 million settlement in a civil fraud lawsuit against WALGREEN CO. ("WALGREENS"), a nationwide retail pharmacy chain that owns and operates thousands of retail pharmacies throughout the United States. The settlement resolves claims that WALGREENS violated the federal Anti-Kickback Statute ("AKS") and False Claims Act ("FCA") by enrolling hundreds of thousands of beneficiaries of government healthcare programs ("government beneficiaries") in its Prescription Savings Club program ("PSC program"). Specifically, the Government’s Complaint alleges that Walgreens violated the AKS and FCA by providing government beneficiaries with discounts and other monetary incentives under the PSC program, in order to induce them to patronize WALGREENS’ pharmacies for all of their prescription drug needs. The Complaint further alleges 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. The settlement will also resolve numerous state law civil fraud claims.
Previous OIG Advisory Opinions

- OIG Advisory Opinion No. 12-21
  - Patients received grocery gift cards after receiving health screening, regardless of health status
  - OIG approved
    - No further marketing to general public
    - Did not result in increased costs to federal health care programs

- OIG Advisory Opinion No. 15-13
  - Integrated health system offered free van shuttle service to medical facilities
  - OIG approved
    - Not based on use of services
    - Did not include air, luxury, or ambulance-level transportation
    - Drivers not paid on a per-person/patient transported basis
    - Only offered locally
Previous OIG Advisory Opinions

- String of advisory opinions has addressed some of the or similar arrangements covered by the new rules
- Public ambulance cost-sharing arrangements
  - AOs 14-09, 13-17, 13-14, 12-11, etc.
- Waiver/assistance with Part D co-payment obligations
  - Modifications to AOs 06-04 (2015), 11-05 (2015), 06-13 (2015), and 06-10
  - Special bulletin on Independent Charity PAPs
- Free local transportation
  - AOs 15-13, 11-15, 11-02, 11-01, 00-7, etc.
- Special Fraud Bulletin on Offering Gifts and Inducements to Beneficiaries (2002)
Affordable Care Act

- ACA, Section 6402(d)(2)(B) – “Clarification of treatment of certain charitable and other innocuous programs”
- New exceptions
  - Access to care and poses low risk of harm to federal health care program patients
  - Offer or transfer of items or services for free or less than fair market value
    - Rebates
    - Assistance to the financially needy
- New rules proposed in 2014 and (finally) finalized in 2016
Recent Rulemaking

- **Affordable Care Act ("ACA") and Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA")**
  - Statutes include exceptions to the Antikickback Statute

- **October 2014 Proposed Rule**
  - Modified certain existing safe harbors to the Antikickback Statute by adding safe harbors that provide new protections and codifying 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
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
Cost-Sharing Waiver Safe Harbor

• The Final Rule expands the existing safe harbor to cover cost-sharing waivers issues to all Federal health care program beneficiaries:
  – Medicare
  – Medicaid
  – State Children's Health Insurance Program
  – TRICARE
  – Veterans' Health Administration
  – Indian Health Service program

• Expands the Safe Harbor protection to waivers of from “copayments” as well as “coinsurance” and “deductibles”
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)
  – Requires good faith determination of financial need OR
  – Failure to collect the cost-sharing amount after making reasonable collection efforts
Pharmacy Cost-Sharing Safe Harbor (cont.)

• 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
Practical Takeaways

• Suggest a written policy for pharmacies offering waivers of coinsurance, copayment or deductible payments
  – Prescription medications only
  – No advertising
  – Establish guidelines for extending the waivers on a non-routine basis
  – Establish guidelines for objective, financial need determination
    • Document for each patient
  – Establish collection procedures that must be followed prior to waiver
    • Document for each patient
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 Indian 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
Public Ambulance Cost-Sharing Safe Harbor (cont.)

- Safe harbor is unlikely to apply to private entities providing ambulance services on behalf of public entities, OIG did not foreclose the possibility that a relationship between a private ambulance provider and a public entity may be structured so that it is not covered by the AKS at all.
OIG Compliance Program
Guidance for Ambulance Suppliers

• A municipality cannot contract with private company and require a cost-sharing waiver

• It may pay uncollected, out-of-pocket copayments on behalf of its residents
  – Such payments may be made through lump sum or periodic payments, if the aggregate payments reasonably approximate the otherwise uncollected cost-sharing amounts

Arrangement A

- Basic life support ambulance supplier ("BLS Supplier") would not bill township residents for emergency ambulance cost-sharing amounts, but would instead accept payment from the township for such cost-sharing amounts.

Arrangement B

- BLS Supplier would waive otherwise applicable cost-sharing amounts when providing backup emergency ambulance services to certain patients pursuant to mutual aid partnerships with towns in the surrounding area.
OIG Advisory Opinion No. 13-11

• **Arrangement A**
  – Township would use the Residents’ tax revenues to finance the annual donation to BLS Supplier
  – Donation would reasonably approximate the Residents’ uncollected cost-sharing obligations

• **Arrangement B**
  – BLS Supplier provides backup EMS on an unscheduled and sporadic basis

OIG: The proposed arrangements would not constitute a routine waiver of cost-sharing obligations
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
MA Organizations and FQHCs Safe Harbor (cont.)

• Services provided by third-party entities may be protected
  – Depends on the structure of the arrangement
• Only protects monetary payments related to treatment for MA enrollees
  – In-kind goods, services and space unrelated to enrollees' treatments are not protected
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
Medicare Coverage Gap Discount Program Safe Harbor (cont.)

- Safe harbor allows for discounts provided to "applicable beneficiaries" for "applicable drugs" of a manufacturer
  - Applicable beneficiary is a Part D enrollee that does not receive income-related subsidies under the Social Security Act, has reached or exceeded their initial coverage limit and has not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold
  - Applicable drug must be an FDA-approved drug or biologic and be available to the beneficiary through the beneficiary's Medicare prescription drug plan
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
Local Transportation Safe Harbor (cont.)

- Eligible entity is any individual or entity, except individuals or entities (or family members or others acting on their behalf) that primarily supply health care items
  - Physicians, physical therapists, dialysis centers, home health agencies
  - Hospital with an on-site pharmacy may be able to offer transportation to established patients to its own location for items or services provided by the entity. In other circumstances, restrictions could apply
  - Health plans, MA organizations, ACOs, integrated networks, charitable organizations
  - **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
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
CMP – Exceptions

• Affordable Care Act Exceptions
  – An exception that protects “any other remuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs. . .”
    • Access to care
    • Low risk of harm
  – Retailer rewards exception
  – Financial need-based exception
  – Co-payment waiver for first fill generics exception
• Nominal value exception limits raised to $15/occurrence; $75/annual aggregate
Practical Takeaways

• Context is important
  – Understand what the government is trying to do here when analyzing AKS and CMP issues
  – “Intent” is still required for violation

• Providers should review all current incentives provided to beneficiaries to ensure compliance with finalized regulations
  – Any incentives involving the provision of transportation, lodging or rewards for seeking health care services should be reviewed with caution
  – Providers should review Ohio Medicaid’s covered services to determine the types of services that may be considered "care"
Please visit the Hall Render Blog at http://blogs.hallrender.com for more information on topics related to health care law.

Rachael A. Ream
(216) 513-1314
rream@hallrender.com

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