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# Patient Access Programs: A Legal Perspective

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## Overview and Regulatory Context

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- > What types of patient access programs are there?
- > What federal and state laws apply to patient access programs?
- > What are the key steps in establishing and maintaining a successful patient access programs?

What types of patient access programs are there?

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- > Free products or services for all patients
- > Copay assistance
- > Caps on patient responsibility

Programs can differ based on whether they offer assistance for those facing financial hardship or assistance without regard to financial need.

# What federal laws apply to patient access programs?

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- > The federal anti-kickback statute:
  - Payments, credits or other forms of remuneration provided to Medicare/Medicaid beneficiaries can implicate the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b).
  - However, if no federal programs currently reimburse the test and you do not believe that any federal programs will pay for the test for an extended period of time, then, the federal anti-kickback statute is not applicable to the test.
- > Similar concerns under the federal Beneficiary Inducement Statute
- > Regulatory concerns also should focus on issues emanating from expected payments by private insurance and private individuals for the test.
- > False Claims Act issues for failure to report “usual and customary charge”

# What state laws apply to patient access programs?

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- > State anti-kickback statutes take two basic forms: state payor and any payor
- > Most states have “state payor” type statutes
- > Provisions that may be broader exist in:
  - California
  - Florida
  - Illinois
  - Massachusetts
  - Minnesota
  - Ohio
  - Pennsylvania
  - South Carolina
  - Texas.

# California anti-kickback laws and patient access programs

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- > California's anti-kickback statute is Section 650 of the California Business and Professions Code ("Section 650"):
  - [T]he offer, delivery, receipt, or acceptance by any person licensed under this division . . . of any rebate, refund, commission, preference, patronage dividend, discount or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients or customers to any person, irrespective of any membership, proprietary interest or co-ownership in or with any person to whom these patients, clients, or customers are referred is unlawful.
- > These state statutes are often just as complicated as the federal statutes and their application to specific facts is often more difficult, because there is little or no state interpretive guidance or case law. In this regard, however, analogies to the federal statute may still be helpful.

# Massachusetts' State Anti-Kickback Law

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- > The Massachusetts provision, Mass. Gen. L. ch. 175H, § 3:
  - Any person ... any person who offers or pays any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind to induce any person to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering of any good, facility, service, or item for which payment is or may be made in whole or in part by a health care insurer, shall be punished by a fine of not more than ten thousand dollars, or by imprisonment in a jail or house of correction for not more than two and one-half years or in the state prison for not more than five years, or by both such fine and imprisonment, and may be held liable in a civil action under section seven.

# OIG Advisory Opinion Process

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- > In the federal OIG Advisory Opinion process, proposed business arrangements can be reviewed and approved on a prospective basis, before potential criminal or civil liability under the federal anti-kickback statute is incurred.
  - Individual scenarios involving federal law can be reviewed.
  - While not binding, these opinions help create a sense as to what will be acceptable now and in the future.
- > While the federal anti-kickback statute is not the same as the Massachusetts or other state statutes, these advisory opinions also can provide suggestions as to how state law enforcement officials and courts might interpret their own state laws.



# What Does OIG Say About Patient Access Programs?

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“As we observed in our Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70623 (Nov. 22, 2005)), manufacturer PAPs that subsidize the cost-sharing amounts for the manufacturer’s drugs payable in whole or in part by the Part D program present all of the usual risks of fraud and abuse associated with kickbacks, including steering enrollees to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing enrollees’ incentives to locate and use less expensive, equally effective drugs.”

See OIG Advisory Opinion 2007-04 at 7.

# What Does OIG Say About Financial Hardship?

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## OIG Special Fraud Alert: “Routine Waiver of Copayments or Deductibles Under Medicare Part B”

- > It is acceptable for copays or deductibles to be waived in a particular case of financial hardship.
- > Cannot be routine.
- > Must be pre-set financial standards.
- > Good faith effort to collect the deductible or copay.

# How can you establish and maintain a successful patient access programs?

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- > Review with legal counsel before starting.
- > Document the process and the program.
- > Limit the duration of the program.
- > Review the program periodically, to determine that the legitimate reasons for the program still exist.

# A Typical Scenario

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- > Market has multiple tests.
- > Need experience to get Medicare/Medicaid reimbursement.
- > Physicians need to use a test in order to get used to a test.
- > Need limited activity for a limited time to establish a market presence.
- > The intent is not to “buy” market share.
- > Concern about collecting from patients, either for the whole amount of the cost or the deductible/copay.

Once the program is established, you need to revisit the program, as it could impact the amount that is ultimately reimbursed under the federal reimbursement mechanisms, in addition to the implications for the application of the federal anti-kickback statute.

# Thank you.

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> For follow-up, please contact:

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