The Evolving Landscape of OIG Oversight and Regulatory Concerns

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Agenda

• Overview of Patient Support Programs

• Overview of OIG Special Advisory Bulletin and Report

• Examples of recent compliance issues

• Future issues?
The Federal Anti-Kickback Statute

• The anti-kickback statute prohibits the knowing and willful solicitation, receipt, offer, or payment of remuneration to induce the purchase of any item or service for which payment may be made in whole or in part under a “Federal health care program.”
• Manufacturers may be liable under the anti-kickback statute if they offer anything of value to induce the purchase of drugs paid for by Medicare Part D or any other Federal health care program.
• Penalties up to $25,000 in fines, plus imprisonment.
• Commercial plans generally exempted.
Patient Support Programs

• Patient Assistance Programs (PAPs)
  • Independent Charities or Foundations
  • Manufacturer Sponsored (including coalitions)

• Coupon and Offset Programs

• Reimbursement Support Services (Hubs)
Patient Assistance Programs

- Entities or groups that provide free or discounted drugs to individuals meeting certain eligibility requirements (typically income based).

- While OIG acknowledges that PAPs may serve an important function in providing safety net resources, PAPs also may implicate fraud and abuse issues.
  - Improper steerage
  - Improper beneficiary subsidization
Patient Assistance Programs

• Independent Charities
  • Manufacturer cash donations to independent charities or foundations can be used to provide reimbursement support to federal program beneficiaries if:
    • No manufacturer exerts any direct or indirect influence over the charity.
    • The charitable assistance to individuals is independent from any manufacturer’s funding.
    • The assistance is not tied to using a particular manufacturer’s product, or patient’s use of a particular provider, supplier or product.
    • Assistance is rendered based on reasonable measures of financial need and applied uniformly to patients.
    • The manufacturer may not receive any data from the charity that would allow the manufacturer to determine a correlation between the manufacturer’s donations and the number of scripts.
Patient Assistance Programs

• Renewed focus on manufacturer relationships with independent charities.
  • Bloomberg series of articles on PAPs
• Recent trend of independent charity PAPs operating narrow disease funds that cover only a few products.
• Although OIG has issued several recent favorable advisory opinions, DOJ is very active
  • Subpoenas received by Gilead, Biogen, Jazz, Valeant in connection with relationships with independent charities
Patient Assistance Programs

• Manufacturer PAPs (outside Part D)
  • Program excludes federal beneficiaries or product provided outside of Part D.

• Key considerations:
  • PAP notification of Part D plans of beneficiary participation (including CMS data sharing agreement to facilitate coverage inquiries)
  • Beneficiary cannot count the cost of free/discounted product towards TrOOP.
  • Beneficiaries would stay in the program for at least the Part D program year.
  • Assistance is rendered based on reasonable/uniform measures.
Coupon and Offset Programs

- Operate to reduce the out of pocket cost for a drug without regard to a patient’s financial need
- Available for use in commercial plans, HIX plans
- Variety of co-pay offset programs that have grown in number in recent years
  - Dollars off
  - Pay no more than
  - Free trial offer
The Fundamental Dilemma

• Competing views of manufacturer coupon programs
  • Manufacturers’ efforts to subsidize consumers’ out of pocket costs via drug coupons and co-pay cards serve as a legitimate means to promote new starts and/or product adherence, while…
  • Insurers, plans and their PBM partners view coupon programs as a means to distort and skew formulary controls that may ultimately lead to higher overall costs for the entire healthcare system.
• Regulators’ view: The subsidization of a beneficiary’s cost sharing amount may be a prohibited inducement that could support a violation of the federal anti-kickback statute.
The OIG Report and Special Advisory Bulletin

• Study commissioned by OIG in 2013 to identify the safeguards manufacturers employ to prevent their copayment coupons from being used for drugs paid for by Medicare Part D and to identify vulnerabilities in those safeguards.

• Conduct of the study included:
  • Survey of 30 manufacturers
  • Review of selected safeguards implemented to prevent impermissible redemption
  • Interviews of staff at companies involved in pharmacy claims adjudication
The OIG Report and Special Advisory Bulletin

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Principal Findings by OIG

• All manufacturers surveyed provide notices aimed at beneficiaries and pharmacists that coupons may not be used in Federal health care programs.
• Most manufacturers surveyed use claims edits to prevent coupons from being processed for drugs covered by Medicare Part D, but most of these edits may not prevent all coupons from being processed for Part D covered drugs.
• Part D plans and other entities cannot identify coupons within pharmacy claims.
Principal Findings by OIG

• Current safeguards may not prevent all coupons from being used for drugs paid for by Medicare Part D.
  • Regardless of future action by CMS, the offerors of coupons ultimately bear the responsibility to operate these programs in compliance with Federal law. Pharmaceutical manufacturers that offer copayment coupons may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services, including, but not limited to, drugs paid for by Medicare Part D. Failure to take such steps may be evidence of intent to induce the purchase of drugs paid for by these programs, in violation of the anti-kickback statute.
Clear Guidance to Manufacturers?

- OIG validated certain approaches taken by manufacturers to combat impermissible redemptions of coupons by Medicare beneficiaries.
  - Notices and legends on coupons and literature
  - the use of claims edits to block redemptions by beneficiaries
- But, OIG failed to provide guidance on “appropriate steps” to be taken to ensure that such coupons do not induce the purchase of Federal health care program items or services.
Industry Response to OIG Report

• Wake up call to manufacturers to assess the sufficiency and adequacy of their current practices to prevent coupon use by Medicare beneficiaries, and the potential risks of liability under the anti-kickback statute.

• Industry efforts led by NCPDP and others to develop strategies to address the needs of the industry and create best practices designed to ensure that the industry is compliant with the OIG’s recommendations.

• **BUT**, DOJ has issued subpoenas to multiple manufacturers in connection with coupon programs.
Industry Response to OIG Report

• Manufacturers and program administrators more sensitive to responsibility for trying to block federal program beneficiaries from using coupons.
  • Exploration of new technologies.
  • Increased scrutiny of contractual provisions, like audit rights, allocation of risk and indemnification.
• CMS access to certain Part D plan information.
• CMS reluctant to provide access to Part D eligibility files.
Recent OIG Advisory Opinion on Savings Cards

- OIG Advisory Opinion 16-07 (issued June 2016).
  - Savings card program for ED product available to Part D beneficiaries.
  - OIG found the arrangement permissible in large part because product was statutorily excluded from Part D coverage.
  - In other words, individuals using the savings card “are essentially cash-paying customers when filling” scripts.
OIG Advisory Opinion 16-07

Key Considerations:

- Arrangement operated entirely outside of Part D benefit.
- Savings card vendor contractually required to use claims data to detect attempted use by Part D beneficiaries.
- Part D beneficiaries advised not to submit claims and out of pocket costs cannot be applied to TrOOP.
- Pharmacy certifies that it not to submit claims for Part D reimbursement.
- Drug company certified that it does not use the program as a vehicle to market other drug products to federal beneficiaries.
Reimbursement Support (Hubs)

• Combination of a variety of services designed to drive marketing, education, sales and product utilization.
  • Benefit investigations
  • Prior authorization support
  • Home delivery (through specialty pharmacy)
  • Care management and coordination
  • Management of co-payment issues
  • Education and instruction
Reimbursement Support (Hubs)

• From manufacturer’s perspective, hubs provide a patient centered approach to encourage brand loyalty.

• The alternate view of regulators and PBMs suggests that hubs can improperly interfere with the patient-physician relationship and the PBM/plan relationship, thereby leading to increased health care costs.
Current Enforcement Issues

• Novartis (November 2015)
  • Settlement of $465M based upon alleged kickback scheme involving distribution of two products through a patient assistance program through certain specialty pharmacies.
  • Distribution handled by three specialty pharmacies that were utilized to provide specialty pharmacy services such as refill reminders, drug administration instruction and reimbursement support services.
  • Pharmacies collected data on patients who stopped ordering product which led to development of “patient recovery program” by specialty pharmacies designed to increase persistency and adherence rates.
  • Pharmacies were paid performance related payments based on increased adherence and refill metrics.
Current Enforcement Issues

• Warner Chilcott (October 2015)
  • Settlement of $125M to resolve criminal and civil allegations under Anti-Kickback Statute and False Claims Act.
• But, individual employees indicted for roles in improper reimbursement support activities.
  • Submission of false PA requests and other coverage requests to federal health care programs
  • Sales reps completed PAs for product using “canned” medical justifications which often were inconsistent with the patients’ medical conditions.
  • Sales reps posed as physicians to submit PAs directly to insurance companies.
  • Sales reps took patient charts home to prepare PAs
Compliance Lessons

• Use of pre-printed or auto-populating forms.

• Completing or preparing PA forms or other appeal documentation on behalf of physicians, their staff or patients.

• Access to patient records or PHI.
Access to PHI

• While the principal Warner Chilcott official was acquitted last month on criminal charges arising from the PA and kickback scheme, another employee pleaded guilty to criminal HIPAA violations for his role in the PA scheme.
  • Sales manager who directed sales reps to fill out PAs if a physician refused to do it.
  • He also filled out PAs by accessing patient PHI without patient consent.

• Currently awaiting sentencing (up to 10 years in prison and fines up to $50,000 per violation)
Other HIPAA Issues: How Can a Manufacturer Use PHI?

• Statistical De-identification (Section 164.514 (b)(1)(i-ii) of the HIPAA Privacy Rule)
  - Health information is not individually identifiable if “a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
    (i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
    (ii) Documents the methods and results of the analysis that justify such determination
Other HIPAA Issues: How Can a Manufacturer Use PHI?

• In order to qualify as de-identified under the alternative HIPAA de-identification provision at with Section 164.514 (b)(1), generally accepted statistical and scientific principles and methods for rendering information not individually identifiable must be employed to determine that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual.

• Typically performed by outside statistician consultants.
Questions

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