Medicare Part C&D Compliance
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2016: Medicare Part C & D Compliance
Emerging Trends

• Medicare Part C: CMS subsidized managed healthcare
  – It’s all (mostly all) in the Encounter Data and Risk Scores.
  – What are you certifying?

• Medicare D: Government-funded pharmacy benefits
  – Who are the players?
  – What’s happening to ensure compliance in this $70 billion program?

Medicare Advantage (Part C)
Enforcement and Compliance
Managed Care Revenue and Enrollment Trends: Medicare Advantage & Medicaid

Expenditures

Enrollment

Medicare Part C Expenditures to Hit $250 Billion

CMS Must Ensure Complete & Accurate Encounter Data


• “...CMS contracts with MA organizations (MAO) to provide covered services to beneficiaries who enroll in one of their plans.
• As of April 2014, CMS had 571 contracts with MAOs that served nearly 15.5 million enrollees, accounting for approximately 30 percent of all Medicare beneficiaries.
• The Congressional Budget Office has projected that enrollment in MA plans will increase to about 21 million enrollees by 2023 and that Medicare payments to MAOs will grow from about $154 billion in 2014 to about $250 billion in 2023.
• As the MA program expands, setting appropriate payments to MAOs and making Medicare a more prudent purchaser of health care services will remain critical.”

Part C Requirements for MA Plans

• Managed Care Organizations (MAOs) must:
  – Be authorized under State law in the requested service area (SA) to operate as a risk-bearing entity that may offer health benefits;
  – Be licensed;
  – Meet minimum beneficiary enrollment requirements; and
  – Demonstrate administrative and managerial capabilities, including commitment to 7 Elements of Compliance.

• OIG Work Plan 2016: Compliance
  – Medicare Advantage Encounter Data
  – Risk Adjustment Data
  – Medicare Advantage Organization Practices in Puerto Rico
Part C Key Certifications

Medicare Advantage Annual Attestation, 42 C.F.R. § 422.504(l)

- MA organization must certify that risk adjustment data is accurate, complete and truthful (based on best knowledge, information, and belief)

Medicare Advantage Overpayment Attestation, 42 C.F.R. § 422.504(l)(5)

- MA plans “must certify (based on best knowledge, information, and belief) that the information the MA plan submits to CMS for purposes of reporting and returning overpayments is “accurate, complete and truthful”

Part C Requirements for MA Plans:

Medicare Advantage Encounter Data

- 2012: Plans required to submit encounter data, i.e. information on the services and items furnished to enrollees
  - More comprehensive and additional data elements than the beneficiary diagnosis data the agency previously used to risk adjust capitated payments.
- 2014 GAO report: CMS does not:
  - Analyze encounter data for completeness and accuracy;
  - Review medical records to verify encounter data; or
  - Summarize encounter data review findings.
- 2016 OIG Work Plan: “We will review CMS’s oversight of MA encounter data validation to assess the extent to which CMS Integrated Data Repository contains timely, valid, and complete data.”

Part C Requirements for MA Plans:

Risk Adjustment - Overview

- Risk adjustment is a mechanism used to adjust payments based on underlying health status in public and commercial programs
  - Models use data from a large pool of beneficiaries to estimate predicted costs on average for each of the component factors (e.g., age-sex, low income status, individual disease groups)
  - Diagnostic categories are clinically meaningful
  - Adjusts payments based on expected health care costs
  - Promotes access and reduces adverse selection
  - Utilizes multiple models to predict the costs of different benefits (for example, Parts C and D)
  - Incorporates demographic and disease factors
  - Generally reset annually
Part C Requirements for MA Plans: Risk Adjustment Coding Requirements

- Diagnosis codes must be documented in the medical record, following standard industry guidelines (ICD-9-CM and now ICD-10).
- Diagnosis codes must stem from an encounter between a provider and the patient:
  - Face-to-face encounter (exception of professional component for pathology services)
  - By a qualifying provider type
  - From an acceptable source

Risk Adjustment: Audit & Enforcement Environment

- Center for Public Integrity “Medicare Advantage Money Grab”
- Letters from Senators Grassley and McCaskill asking federal officials to step up oversight of Medicare Advantage health plans.
- Government Accountability Office estimated “improper payments” to Medicare Advantage plans at more than $12 billion in 2014.
- HHS subpoenas issued to MAOs

Recent Enforcement / Qui Tam Cases:
Managed Care Risk Area #1: Part C Risk Adjustment

- Whistleblower cases unsealed
  - 2015: Texas case accuses home health assessment company, Censeo Health LLC, of inflating risk scores.
  - 2016: FCA lawsuit unsealed, Thompson, No. 15-80012 (S.D. Fla.) (filed 2012): Both criminal and civil cases related to overbilling CMS’s Medicare Advantage program. Two types of defendants: Providers and Managed Care Organizations.
- Provider-Generated Submissions to Health Plan (Criminal)
  - Network provider allegedly submitted false diagnoses to health plan.
  - Provider pleaded guilty on 3/7/16 to one count of health care fraud; on 7/6/16, sentenced to 46 months imprisonment and two years supervised release.
- MCO-Generated Submissions to CMS (Civil), Unsealed three days before the provider’s guilty plea. FCA allegations led to criminal charges against the physician defendant. Civil case against Humana continues.
Recent Enforcement / Qui Tam Cases: Managed Care Risk Area #1: Part C Risk Adjustment

Chart Reviews: Medicare Advantage Organization (MAO) False Certification to CMS

- **Swoben**, No. 09-05013 (C.D. Cal.) (unsealed qui tam; DOJ declined, dismissed, overturned by 9th Circuit 8/10/16).
- Qui Tam Relator’s Allegations: health plans allegedly inflated risk scores through retrospective chart reviews, then submitted false certifications in violation of FCA;
- August 2012: $320M settlement with SCAN (99M related to MAO allegations);
- Trial court dismissed allegations against other MAO defendants; Relator appealed.
- August 2016: 9th Cir. Court of Appeals: “[T]he theory alleged by the Relator, that the defendants designed their retrospective review procedures to avoid erroneously reported diagnosis codes – adequately alleged that the defendants’ § 422.504(l) certifications were false and stated a cognizable legal theory under the False Claims Act. The panel also held that the proposed fourth amended complaint alleged sufficient factual matter to satisfy Fed. R. Civ. P. 8, 9(b) and 12(b)(6).” (emphasis added),

> Medicare regulations require a Medicare Advantage organization to certify that the data it submits are “accurate, complete, and truthful.” 42 C.F.R. § 422.504(l)(2)(emphasis added).

- Swoben alleged that the defendant organizations submitted false certifications by performing biased retrospective medical record reviews designed not to identify erroneously reported diagnosis codes

Part C Risk Adjustment Data “Risks”

- Incorrect data can cause inaccurate risk adjustment score, leading to overpayments.
- **2016 OIG Work Plan:**

> “We will review the medical record documentation to ensure that it supports the diagnoses that MA organizations submitted to CMS for use in CMS’s risk-score calculations and determine whether the diagnoses submitted complied with Federal requirements…

Prior OIG reviews have shown that medical record documentation does not always support the diagnoses submitted to CMS by MA organizations. MA organizations are required to submit risk adjustment data to CMS in accordance with CMS instructions.”

Risk Adjustment Data Validation (RADV) Audits

- CMS uses RADV audits to test the accuracy of risk adjustment.
- CMS uses the right to retrospectively audit for support of any risk-adjusted payments received by an MAO.
- RADV Audit encompasses review of medical records and clinical documentation that led to the payment.
- MAOs are formally notified of a RADV audit and have a set amount of time to provide the requisite support for the cases selected for audit.
- Risk adjustment evaluations begin with coding assessments but data submission and population health also assessed.
Compliance Program Standards:
Medicare Managed Care Manual

- Seven Elements of an Effective Compliance Program (e.g., policies and procedures, training, disciplinary standards, hotlines)

  - “Sponsors must … implement … a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements.”

  - “An effective program to control [Fraud, Waste and Abuse (FWA)] includes policies and procedures to identify and address FWA at both the sponsor and [First Tier, Downstream or Related Entity (FDR)] levels ….”

Part C Best Practices: Risk Adjustment

- Establish communications with providers; identify contact personnel for medical record requests or other RADV activities.
- Determine how medical records can and will be supplied to the MAO (i.e., hardcopy or electronic) based upon the technological capabilities of the MAO and the provider.
- Encourage continual education of both plan personnel and providers on the proper maintenance of medical records and coding accuracy and develop communication with providers on the RADV process and the possibility of a RADV audit by the plan or CMS.
  - Understand risk adjustment profile. Review and determine:
    - Top ten HCC’s by volume and intensity.
    - Top utilizing providers by provider type (physicians, hospitals).
    - Any claims or record rejections from CMS.
Managed Care Risk Area No. 2: Kickbacks

- **The Federal Anti-Kickback Statute**, 42 USC §§ 1320a-7b (b), is a criminal statute that prohibits any person from knowing and willfully, soliciting, receiving, offering or paying remuneration (anything of value) in exchange for referrals for services that are covered by federally insured health care programs (e.g. Medicare and Medicaid). A violation of the AKS is a felony punishable by up to five years in prison and/or fines up to $25,000.

- **The Affordable Care Act** codified and clarified that violations of the Anti-Kickback Statute can also result in civil liability under the Federal False Claims Act, 31 USC §§ 3729-3733 (the “FCA”) as well as administrative penalties under the Civil Monetary Penalties Law.

- Conviction under the AKS results in mandatory exclusion from federal health care programs.

- Example in MA context: Florida health plan self-disclosed and agreed to pay over a $250K fine in connection with allegedly offering “to increase the capitation rates paid to four physicians in exchange for the referral of their patients to [health plan] and . . . increas[ing] the capitation rates of two of the four physicians.”

Part C Risk Area No. 3: Medical Loss Ratio

ACA MLR:

\[
\text{Medical care claims} + \text{Quality improvement expenses} - \text{Premiums} - \text{Federal and state taxes, licensing, and regulatory fees}
\]

- MLR existed long before ACA; was used to evaluate performance of managed care companies.

- Affordable Care Act (ACA): Created consistent federal standard and modified the calculation.

- Plans that fail to meet the minimum MLR of 85% are required to remit partial payments to HHS.
  - ≤ 85% for three consecutive years, suspension of plan enrollment for two years;
  - Less than 85% for five consecutive years, the Secretary to terminates the plan contract.

- Quality improvement expenses include activities that improve patient outcomes, safety, wellness, quality, transparency, or outcomes through enhanced health information technology. Administrative expenses, e.g., insurance broker and agent compensation or fraud prevention activities not included.

Part C Risk Area No. 3: Medical Loss Ratio (cont’d)

Case Example: WellCare

- Allegations: WellCare misled Medicaid regulators in Florida and intentionally misstated and improperly attributed certain unallowable expenses in order to manipulate MLRs and avoid a refund to the state and, by extension, improperly inflated earnings.

- Civil and Criminal investigations of alleged Medicare and Medicaid overbilling.

- Outcomes:
  - 2009: DPA and $80MM ($40 MM restitution/ $40MM forfeiture).
  - 2010: Settled shareholder litigation for $200MM.
  - 2011: Five executives indicted (including former CEO, CFO, General Counsel).
  - 2012: Civil Settlement of FCA allegations for $137.5 MM.
  - 2013: Four executives tried and convicted.
  - 2014: Former CEO sentenced to 36 months in prison.
Medicare Managed Care Compliance Best Practices

1. Look to Your Certifications and Those Who Sign Them!
2. Review Data Submissions and Reports Sent to CMS and Other Government Agencies.
3. Consider Obligations to Investigate and Police Providers.
4. Examine Key Risk Areas, such as risk adjustment, kickbacks, etc.

MEDICARE PART D ENFORCEMENT AND COMPLIANCE

Escalating Part D Spending 2006-2015
More than 15% of All Medicare Spending

Figure 1: Total Spending for Part D Drugs, 2006–2015
Spending in Billions

Source: GAO estimated Medicare Part D data 2016
Escalating Part D Spending 2006-2016
More than 15% of All Medicare Spending

- 2006 (First Year for Prescription Benefits):
  - Part D covered 28 million beneficiaries.
  - Cost the Government $47.4 billion, nearly 12% of all Medicare spending.

- Over the last decade, Part D spending has grown substantially:
  - 2009: $52.4 billion
  - 2014: $78.2 billion (11% of total Medicare payments)
  - 2016: $88 billion in expected spending (15.5% of all Medicare spending)

Medicare Part D Prescription Drug Benefit
(“Part D”) Program - Background

- Private government contractors, Part D Plans (PDPs) or Medicare Advantage Part D Plans (MAPDs) deliver pharmaceutical drugs to government healthcare program beneficiaries.
- The federal government (CMS) contracts with PDPs/MAPDs, which then contract with
  - “first tier,” (Pharmacy Benefit Managers, “PBMs”) and
  - “downstream” entities (Pharmacies).

- Role of the PDP or MAPD:
  - Share risk with government payors
  - Serve as gatekeepers between CMS and other stakeholders in the Part D chain (PBMS, pharmacies)
  - Help contain prescription drug costs

Part D Prescriptions –
What Happens at the Pharmacy in Real Time

- Prescription written by authorized, licensed (DEA) professional
- Patient has prescription drug benefits through a Part D Plan (“PDP”) or Part D (Medicare Advantage Part D, “MAPD”) Plan
- Pharmacy submits the pharmacy claim to the PDP/MAPD through a Prescription Benefits Manager (PBM) Claim submitted by pharmacy [there is a “switch,” involved]
- PBM: Part D claim processing includes drug utilization review (DUR)
- PBM provides a “response” to the pharmacy: responds that the claim is “paid” by the PDP or MAPD, and calculates patient co-pay OR there is some aspect of the claim that needs further attention, i.e., needs prior authorization.
- Pharmacy dispenses drug
- Beneficiary pays co-pay or processes secondary benefit
Part D Prescriptions – What Happens after the Beneficiary leaves the Pharmacy

- PBM waits to see if the Part D pharmacy claim is reversed. For example, the prescription is dispensed, but the beneficiary never picks it up. The pharmacy will reverse the claim.
- PBM creates a Prescription Drug Event (PDE) claim for submission to CMS, source is the paid pharmacy claim.
- PDEs are contained in files and submitted periodically to CMS, i.e., every two weeks.
- CMS automated system receives PDE files sends a PDE response file to the Sponsor/PBM.
- CMS accepts the PDE claim or rejects the PDE claim.
- Sponsor has an opportunity to correct PDEs and resubmit them.
- Reconciliation: Part D sponsor includes all accepted (not rejected) PDE claims.

Part D – Funding Based on Stage in the Process

- At the beginning of the month/benefit year:
  - Premium: Beneficiary pays portion of monthly cost, if Low Income.
  - Direct Subsidy: advance Per Member Per Month (PMPM) payment by CMS to the Part D sponsor. Risk-adjusted for the health status of the beneficiary.
  - Reinsurance Payment: Monthly subsidy to cover 80% of plan estimates for beneficiaries in the catastrophic phase.
- At the time the Rx is Dispensed (Depends on the phase the beneficiary is in):
  - Deductible: Beneficiary 100% (if LICS, CMS 100%);
  - Coverage: $400-$3700 for 2017: Beneficiary 25% (if LICS, CMS 25%); Plan 75%.
  - Coverage Gap (Donut Hole): Beneficiary 100% (Low Income)
  - Catastrophic: Beneficiary $0, CMS 80%, Plan 20%
- At the end of the year: Part D Annual Reconciliation: all Part D claims submitted.
- For the next year: Part D Bid Submission: based on estimated costs/risk adjustment.

Part D Data Reporting by Sponsors/ Their PBMs

- Annual contract bidding, application, or renewal (Part D Sponsor):
- PDE Data (Part D Sponsor/PBM):
  - Risk Adjustment Data:
  - Direct and Indirect Remuneration (DIR): price concessions (offered to purchasers by drug manufacturers, pharmacies, or other sources) that serve to decrease the costs incurred by the Part D sponsor for prescription drugs.
  - Coverage Gap Discount Program
  - Key certifications 42 CFR § 423.505(k) “certification of data that determine payment”
    - Certification of claims [PDE] data, 42 CFR § 423.505(k)(1)(3)
    - Enrollment information, 42 CFR § 423.505(k)(2)
    - Bid submission information, 42 CFR § 423.505(k)(4)
    - Allowable costs for risk corridor and reinsurance information, 42 CFR § 423.505(k)(5)
“Risk Adjustment” Part C Versus Part D

- Risk adjustment accounts for differences in expenditures incurred by a plan due to differences in the health status of the beneficiaries enrolled.
- Risk adjustment is employed in both Part C and Part D to calculate prospective payments.
- However, different risk adjustment models apply to Part C and Part D because of significant differences in the programs:
  - The impact of health status factors
  - The benefit design.
- Part D benefit design:
  - Risk adjusted advance monthly payments
  - Reinsurance: when an individual enrollee hits a set out-of-pocket threshold (catastrophic cap), Medicare covers the majority (80%) of costs
  - Plan risk corridors: after the plan year is over, based on actual costs (PDEs), plans share aggregate losses or gains with the Government.

Part D Statutes and Regulations
Requirements For All Part D Plans

- Compliance with all Part D laws and regulations:
  - Dispense Part D drugs only upon prescription;
  - Compliance with State Pharmacy law and standards;
  - Submit accurate Part D data required for payment, including Prescription Drug Event (PDE) records; and
  - Employ Comprehensive Fraud, Waste, & Abuse Plan.
- Compliance with federal Anti Kickback Statute (AKS) and False Claims Act (FCA).

“Improper Payment” Defined
Improper Payments Elimination and Recovery Act of 2010 (IPERA), Pub. L. No. 111-204

“(2) IMPROPER PAYMENT.—The term ‘improper payment’—
  - ‘(A) means any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and
  - ‘(B) includes any payment to an ineligible recipient, any payment for an ineligible good or service, any duplicate payment, any payment for a good or service not received (except for such payments where authorized by law), and any payment that does not account for credit for applicable discounts.

(Emphasis added)
Improper Payments by CMS
Enforcement to Recover Significant Losses

“One fundamental requirement that agencies must meet is to recover any Federal dollars that should not have gone out the door.”

“If an agency deems a program susceptible to significant improper payments, the agency is required to estimate and report improper payments for that program annually, in addition to implementing corrective actions to reduce its improper payments...”

Part D – Improper Payments

- 2006 - 2010: CMS did not report a payment error rate for the Medicare Part D Program.
- 2011: CMS reports Part Error Rate = 3.2% ($1.68 billion based on CY 2009 final payments of $52.4 billion).

Part D Payment Error Rate – CMS Identified Four Error Sources for 2015

- Payment Error Related to Low Income Subsidy Status (PELS);
- Payment Error Related to Incorrect Medicaid Status (PEMS);
- Payment Error Related to Prescription Drug Event Data Validation (PEPV); and
- Payment Error Related to Direct and Indirect Remuneration (DIR)
“Negotiated Prices” in Part D?

Spay v CVS Caremark (MTD):

- 42 C.F.R § 423.104 requires that a Part D sponsor “provide its Part D enrollees with access to negotiated process for covered Part D drugs included in the Part D plan’s formulary”
- the Part D sponsor then places a similar obligation on the PBM by contracting with the PBM for “negotiated” pricing on certain Part D drugs.
- Part D regulations and PDE instructions: the PDE claim must include pricing data: the ingredient cost paid, dispensing fee and sales tax.
- When the Part D sponsor/PBM inaccurately charges above the negotiated pricing to beneficiaries, the pricing data on the PDE can be deemed ‘inaccurate’ because the Part D beneficiary did not receive the negotiated price.
- Because Part D price data is generated by the PBM, the PBM must certify the truth, accuracy, and completeness of that information. 42 C.F.R. 423.505(k)(3).

Part D Emerging Issues

- Beneficiary Directed Copay Offsets (Co-Pay Cards, Coupons, etc.)
  - Prohibited from use in Federal Health Care Programs because considered an incentive / inducement and violate the AKS;
  - 6-7% of Medicare beneficiaries used coupons; and
  - Current infrastructure and controls not adequate in preventing coupon use.
  
  
  Related sources:
  
  

- Compounded Products
  
  - Compounded products - In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient
  
  http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm#what

  - Examples are: topical drugs, intravenous drugs, oral drugs, and injectable drugs.

  - Between 2006 and 2015, Part D spending for compounded drugs climbed from $70.2 million to $508.7 million, an increase of 625 percent.

  - Part D spending for compounded topical drugs, which include creams, gels, and ointments, increased 3,466 percent since 2006.

  https://oig.hhs.gov/oei/reports/oei-02-16-00290.pdf


RECAP: Part D Risk Areas

- Coupons, etc. - AKS liability;
- Compounds – Potential false claims;
- Opioids;
- Pharmacy Related Fraud;
- Billing and Payment data –
  - False PDE data,
  - Coverage Gap Discount Program,
  - DIR accuracy.

OIG Focus for Part D Enforcement 2016
Medicare Part D Sponsors and Downstream Practices

OIG 2016 Medicare Part D Beneficiaries’ Exposure to Inappropriate Drug Pairs. (NEW)

- OIG will to determine whether Medicare Part D beneficiaries are being prescribed drugs that should not be prescribed in combination with other drugs. I.e., drugs that have a severe interaction when used in combination with other drugs and drugs that should not be co-prescribed with component drugs (drugs containing more than one active ingredient and another prescription contains the same active ingredient); (OAS; W-00-15-35750; expected FY 2017)
- Sponsors contracts with first tier entities (PBMS) provide for PBMs to provide drug utilization review (DUR), to include drug-to-drug interactions. PBM contracts with downstream entities (pharmacies) also include the particular DUR services provided at the time of dispensing.
OIG Work Plan 2016 – Part D
Sponsor Compliance with Part D Requirements

Reconciliation of Payments—Sponsor Reporting of Direct and Indirect Remuneration (DIR).

• OIG to determine whether Part D sponsors complied with Medicare requirements for reporting DIR:
  – Medicare calculates certain payments to sponsors on the basis of amounts actually paid by the Part D sponsors, net of DIR. (42 CFR pt. 423, subpart G.)
  – DIR includes all rebates, subsidies, and other price concessions from sources (including, but not limited to, manufacturers and pharmacies) that serve to decrease the costs incurred by Part D sponsors for Part D drugs.
  – CMS requires that Part D sponsors submit DIR reports for use in the payment reconciliation process. (OAS; W-00-13-35508; W-00-14-35508; expected FY 2016)

Part D Pharmacy Enrollment (NEW)

• Since the 2006 inception of Part D, numerous OIG reports have raised concerns about the oversight of Part D and pharmacy-related fraud.
  – June 2015: OIG national health care fraud takedown in history, resulted in over 240 subjects being charged with defrauding Medicare and Medicaid. Much of this alleged fraud involved prescription drugs and pharmacies.
• OIG to review CMS’s ability to oversee Part D pharmacies;
• OIG to determine the extent to which pharmacies that bill for Part D drugs—especially those identified as high risk—are enrolled in Medicare. (OEI; OEI-02-15-00440; expected FY 2017).

Part D Billing and Payments

Documentation of Pharmacies’ Prescription Drug Event Data

– Drug plan sponsors must submit the information necessary for the Secretary to determine payments to the plans. (Social Security Act, § 1860D-15(f)(1).) (Reviews of selected retail pharmacies identified in a prior OIG report as having questionable Part D billing.

– Determine whether Medicare Part D PDE records submitted by the selected pharmacies were adequately supported and complied with applicable Federal requirements.

– OAS; W-00-13-35411; expected issue date: FY 2016
Risk Areas for Medicare Part D

• Violations of Controlled Substances Act/ False Part D Claims: May 2015: PharMerica Corp agreed to pay $31.5 million to resolve a lawsuit alleging violations of Controlled Substances Act by dispensing controlled drugs without a valid prescription and violated the FCA by submitting false claims to Medicare. U.S. ex rel. Denk v. PharMerica Corp., No. 09-cv-720 (E.D. Wis.).

• Violations of AKS Cause the Submission of False Claims for Prescription Drugs
  – Feb. 2015: AstraZeneca agreed to pay $7.9 million to resolve allegations that it paid kickbacks to pharmacy benefit manager to maintain its drug Nexium as the “sole and exclusive” on the PBM’s formularies. United States ex rel. DiMattia et al. v. AstraZeneca LP, No. 10-910 (D. Del.).
  – August 2015: Los Angeles pharmacy owner/operator sentenced to 18 months in prison for his role in a Medicare Part D fraud scheme that resulted in $644,060 in overpayments: from January 2008 to November 2014, he paid illegal cash kickbacks to Medicare beneficiaries to induce them to submit their prescriptions to his pharmacy (Westaid), and also submitted false and fraudulent claims to Medicare Part D plan sponsors for prescriptions that he did not actually fill.
  – December 2015: Miami resident was sentenced to 108 months in prison. He and co-conspirators owned 8 pharmacies that submitted or caused the submission of $20 million in false and fraudulent claims to Medicare. The scheme involved patient recruiters who received kickbacks in return for referring Medicare Part D beneficiaries to the pharmacies. The patient recruiters then purchased the prescriptions for the medically unnecessary pharmaceutical items that the pharmacies billed to Medicare.

DOJ’s Focus for Prescription Healthcare Benefits
Off-Label and AKS Enforcement

• Jan 2009 – Sept 2015: Result of “six years concentrated enforcement by the DOJ”
• DOJ Focus Prescription Benefit Fraud
  – AKS and Off-label
    • $9.5 billion in civil resolutions
    • $5.3 billion criminal fines
  – Drug Pricing/Safety: $1 billion
• Example, US ex rel Bilotta v Novartis, 1:11-cv-0071 (SD NY)
  – Medicare and Medicaid recovery based on AKS violations related to rebates and discounts
  – Patient harm factor: failure to give black box warnings
  – Defendants
    • Bioscrip (Jan 2014) $15 million
    • Accredo (May 2015) $60 million
    • Novartis (Nov 2015) $422.5 million

Medicare Part D: Other Cases to Watch

• Interaction of Part D and Anti-trust laws:
  • US. ex rel. Radice v. Astellas Pharma, Inc., et al., 2:14-CV-05389 (C.D. Cal.).
    – Relator is John Radice, an attorney who has represented companies asserting that reverse payment settlements raise prices for pharmacies and other retailers in violation of antitrust laws.
    – Reverse payment settlements: pay-for-delay settlements between manufacturers that resolve patent enforcement actions.
    – FCA complaint alleges that “reverse payment settlement agreements” intentionally cause the Medicare and Medicaid programs to overpay for drugs.
    – US and plaintiff states declined to intervene
Questions?