Medicare Part C and Part D Investigations And False Claims Act Issues

2015 HCCA Southeast Regional Conference

William H. Jordan
Alston & Bird LLP
bill.jordan@alston.com
404-881-3494
202-239-3494

James Rose
Navigant
james.rose@navigant.com
317-228-8709

Agenda

- Part C and Part D Risk Areas
  - Lessons from the OIG Workplan
  - Risk Adjustment
  - Overpayments
  - MLR
  - Kickbacks
- Lessons from CIAs

Part C & Part D Investigations Increasing

Medicare Advantage Is FCA's Next Frontier

By **Jeff Overley** Law360, New York (June 04, 2014, 3:43 PM ET)

- Whistleblowers are increasingly bringing False Claims Act suits alleging Medicare Advantage plans and providers are ripping off taxpayers by exaggerating patient illnesses, according to attorneys and court records, suggesting that another multibillion-dollar front in the government's anti-fraud fight is looming. Lawyers were wary of speaking on the record about the trend, citing ongoing litigation and the strict confidentiality that is required when FCA complaints remain sealed. However, several confirmed to Law360 that a clear rise in suits aimed at Medicare Advantage plans and providers is emerging behind the scenes.

OIG Work Plan Initiatives for Parts C and D

Medicare Advantage Initiatives

- MA Encounter Data Reviews
  - OIG notes "vulnerabilities" in accuracy of risk adjustment data reporting by MAOs and that 2012 marked a transition time as reporting requirements moved from abbreviated set of diagnosis data to more comprehensive data.
  - Also plan to conduct medical record documentation review to look at CMS risk score calculations and whether diagnoses complied with federal requirements.
    - Note that these reviews can be painstaking, with reviewers applying criteria in different ways than an MAO might
    - CMS RADV Coders vs Healthcare Industry Coders vs OIG Coders

Part D Reviews

- Risk Corridor Reviews
  - Will review risk sharing payments between Medicare and Part D sponsors to determine whether to use existing risk corridor thresholds or widen them for other plan years.
- Retail Pharmacy Generic Drug Discounts
  - Will determine whether Part D sponsors receive same generic drug discounts from retail pharmacies as general public.
- Comparison of Part D and Medicaid Pharmacy Rebates
  - Discussed earlier in Medicaid portion. Review will be comparison of Medicaid and Part D drug rebates
- Prevention of Use of Copayment Coupons for Part D
  - Review will look at steps to prevent use of copay coupons for certain branded drugs

Part D Plan Sponsor Reviews

- Documentation of administrative costs in bid proposals
  - Review will examine sufficiency of documentation of admin costs to support the claimed costs
- Reporting of direct and indirect remuneration (DIR)
  - CMS requires that all DIR be reported during the payment reconciliation process
- Reopening of payment determinations for reconciliation
  - In 2013, CMS stated it will reopen 2007 and 2008 payments for reconciliation. CMS will also allow sponsors to submit additional prescription drug event data and DIR data.
- Review of dual-eligible access to drugs under Part D formularies

Other Part D Initiatives

- Documentation of pharmacies' prescription drug event data
- Review of duplicate claims sent under Parts A&B and Part D
- Questionable utilization for HIV drugs
- Quality of sponsor data used in calculating coverage-gap discount for the coverage-gap discount program created under ACA

Risk Areas for Part C and D Plans

Government Reports on Part C Payment Errors

- HHS: $10 Billion in MA payment errors
  - Primarily because of unsupported risk scores
- HHS-OIG 2012 Report
  - Looked at two MA plans and found $135 million in alleged overpayments in 2007 alone due to "unsubstantiated" risk scores
- 2013 GAO Report
  - MA risk scores 4.2% higher in 2010 under MA than under traditional FFS Medicare

Reverse False Claims and the 60-day clock

- Reverse FCA attaches to:
  - "Any person who … knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government…"
    - Obligation: "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor0licensee relationship, from a fee-based or similar relationship, or from the retention of any overpayment…."
  - FCA also applies to a "contractor, grantee, or other recipient, if the money or property is to be spent or used on the government's behalf or to advance a government program or interest."
  - PPACA establishes 60-day clock for return of "identified" overpayment (or date of corresponding cost report)
    - For MCOs, need to consider how this overpayment clock relates to: MLR calculations, payments to excluded providers, and assumptions underlying bid submissions for Medicare Advantage and managed Medicaid plans

Proactive Compliance

- Proactive compliance expectations essentially identical to standard FCA
  - Accounting control regarding government contracts, obligations, and receipts
  - Ethics Training and Hot Line in-take emphasize the expectation to identify and communicate uncertainty about government transactions immediately
  - Investigation and review processes must move with deliberate speed
  - Processes / protocols to identify, assess, and communicate should be outline and ready

Examples of overpayment identification issues

- "Identification" – does this mean the "fact" of the overpayment or the "amount" of the overpayment?
  - NY Medicaid Inspector General: 60-day clock runs from determination of "fact" of overpayment
  - Certification of compliance with requirement a condition of mandatory compliance program in NY
- Overpayment definition in CIAs
  - "If, at any time, [entity] identifies any Overpayment, [entity] shall repay the Overpayment to the appropriate payor within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification . . . To correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 30 days after identification, [entity] shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies."

Compliance Review and Assessment Regarding New ACA Reporting

- Express certifications of compliance
  - Eligibility to participate in exchanges
  - Data submission for web portal
  - Calculations of MLR (including valuation of third-party or inter-company arrangements)
- Implied certifications of compliance
  - Program participation requirements of certification with "all applicable rules and regulations" include things such HIPAA/HITECH, appeals, and Limited English Proficiency

Medicare Managed Care

- Medicare Advantage
  - For False Claims Act, follow the money
    - What data affects Medicare payments?
  - Risk adjustment
    - The Social Security Act requires CMS to adjust plan payment amounts for various factors, including age, disability status, gender, and "health status"
    - CMS risk adjustment model relies on member's "diagnosis"
      - Certain diagnoses are assigned to a "disease group" or "Health Condition Category" (HCC)
      - Beneficiaries are assigned a risk score based on age, demographic characteristics, and diagnoses submitted
      - Medicare Advantage organizations receive a higher capitation payment for higher risk scores

Medicare Managed Care

- Government cites risk adjustment as the main source of MA payment errors
  - CMS improper payments reports focus on risk adjusters
  - HHS OIG workplans include risk adjustment audits
- CMS conducting Risk Adjustment Data Validation audits
  - Audits are based on "one best medical record"
  - Proposals to extrapolate results has generated substantial questions about methods for measuring payment accuracy
  - Potential disconnects in how risk scores are calculated
  - American Academy of Actuaries and industry have questioned CMS's actuarial methodology

Modern Healthcare – Nov. 2014

Were patients really sicker? Lawsuits say Medicare Advantage plans inflated diagnoses to boost payments

By Lisa Schencker | November 22, 2014

For an 82-year-old man with diabetes and rheumatoid arthritis, the CMS will pay a Medicare Advantage plan a certain amount of money each month. Add renal failure and hemiplegia to the list of maladies, and the CMS' monthly payment to his plan skyrockets. It could mean $2,282 a month versus $1,149, experts say.

The CMS pays private Medicare Advantage plans under a severity-adjusted model designed to give insurers a financial incentive to take sicker enrollees. But critics, including HHS' Office of the Inspector General, say the severity-adjusted payment model is being abused by some plans and providers, costing taxpayers billions annually.

A few federal whistle-blower cases filed under the False Claims Act have become public, with more thought to be in the pipeline. The lawsuits allege that providers and Advantage plans, some operated by the nation's largest insurers, have defrauded the Medicare program by manipulating Advantage members' medical data to make the members appear sicker than they were to get higher capitation payments.

WellCare and Lessons To Learn

- **WellCare**
  - Allegations that WellCare misled Medicaid regulators in Florida and intentionally mis-stated and improperly attributed certain unallowable expenses in order to manipulate MLRs and avoid a refund to the state and, by extension, inflating earnings
  - Five executives, including the GC, indicted in March 2011
    - Will likely assert advice of counsel defense
  - Lower-level billing employee pled guilty in 2007 to conspiring to defraud Medicaid by mis-reporting and inflating expenses
  - Company paid $137.5MM in civil settlement, entered Deferred Prosecution Agreement and $80MM criminal fine, settled shareholder litigation for $200MM, and agreed to CIA
  - Interesting fact – AHCA reports that from7/1/05-11/30/09, 97% of its Medicaid program integrity cases were fee-for-service related and only 3% were MCO related

WellCare Whistleblower

- Sean Hellein, a data analyst, filed an FCA whistleblower complaint in June 2006.
  - Hellein met with the FBI in August 2006 and then wore a camera/recorder. Tapes included the so-called "Golden Meeting":
    - "We've danced around this, and we send 'em a check every year . . . [w]e never have formally been asked to justify, or we've never been audited for this." - Defendant and former VP of a wholly-owned subsidiary of WellCare
    - "Every year we've fed the gods. We've paid them a little money to keep them happy. We've paid them a million bucks a year, or whatever," and "[i]f WellCare provided encounter data prices, 'we're gonna show a 50% loss ratio.'" - Defendant and former WellCare VP of medical economics

WellCare Executives' Criminal Liability

- Indictments of five former WellCare executives, including the former general counsel of WellCare, in 2011
- In 2013, four were tried, convicted, and sentenced to the following:
  - Former CEO: two counts of healthcare fraud – 3 years imprisonment
  - Former VP: two counts of healthcare fraud – 1 year, 1 day imprisonment
  - Former CFO: two counts of healthcare fraud; two counts of making false statements – 2 years imprisonment
  - Former VP of Medical Economics: making false statements – 5 years' probation.
- The former General Counsel's trial awaiting results of 11th Cir. appeals of convictions

WellCare Corporate Integrity Agreement

- **IRO to Conduct Program Report Reviews**
  - Reviews include analysis of every report submitted by WellCare in areas:
    - Program-mandated reports of costs and expenditures
    - Bids to federal or state programs in response to RFPs
    - State Medicaid special reports
    - Reports with data used for Medicare or Medicaid rate-setting
    - Reports providing encounter data detailing services provided to beneficiaries
    - Reports with pharmacy claims and other data for year-end reconciliation with Part D
  - IRO analyzes content of each report
    - Compares with best practices in industry
    - Determines accuracy and completeness of each report
    - Provides findings and recommendations to improve processes
  - Special focus is to document and recommend improvements that WellCare takes to ensure accuracy and completeness of reports

WellCare CIA Cont'd

- **Other Requirements**
  - If report involves program where reimbursement depends on reporting of costs or expenditures, IRO analyzes all costs submitted as part of report including costs for admin v. medical services
  - If report involves reimbursement or rate-setting involving claims or encounter data, IRO will review whether information provided is supported by documentation
- **IRO Program Review Report includes:**
  - Analysis of accuracy and completeness of report
  - Analysis of internal controls to verify that proper information is provided
  - Description of documentation reviewed and personnel interviewed
  - Description of WellCare's systems, policies, processes, and procedures related to the report
  - Description of control and accountability systems and written policies related to specific report, along with weaknesses in the process
  - whether money is owed to federal program
  - Summary and recommendations
- **Similar analysis for review of bid documents**

CareSource Settlement – Feb. 2011

- **$26MM Ability to Pay Settlement Involving Allegations of Submission of False Documents**
  - CareSource is Ohio Medicaid MCO. FCA case brought by two LPNs who assessed medical and psychiatric needs of children with special needs
  - Allegations that CareSource failed to provide screening, assessment, case management, data submissions, data reconciliations, and other services for beneficiaries but submitted documentation to make it appear it did so. This enabled it to retain incentive portion of capitation payments and avoid penalties.
  - Quotes: "We first talked to lawyers because we were being required to sign off on documents we knew were not true. I told the company's lawyer in 2005 that we were made to submit data to state falsely showing that kids had been assessed for special needs. This continued until at least end of 2006." "We felt our license was in jeopardy."

CareSource CIA

- **IRO Performance Review**
  - **Review of reports submitted to state Medicaid program, including case files, medical records, nurses notes, physician orders, computer system entries**
  - **IRO randomly selects 75 case files along with the data submissions to Medicaid program relating to these files. IRO evaluates files to determine whether CareSource correctly complied with its provider agreement**
  - **If any case file lacks sufficient documentation, it will be considered an error and the total amount of payments received, including capitation, maternity, and incentive payments shall be deemed an overpayment**

Other Recent Cases

- **US v. Janke** – settlement of $22.6MM by providers and owners of Medicare Advantage plan. Claims submitted and diagnosis codes were not justified by the medical record and other documentation
  - Important issue here is that Janke was on both sides of the claim – manipulated (upcoded) medical record and then knowingly submitted to government to justify higher payment
- Some cases where reverse is true – that is, government contends that overly restrictive criteria have been applied to avoid compliance with government criteria in areas of, for example, enrollment (**Amerigroup of Illinois**) or medical necessity and denials of certain procedures/inpatient admissions (**Peoples Health Network**)
- Other declined cases:
  - **Silingo – S.D. Fla.** (case subject of Modern Healthcare article)
  - **MedMX**

Other Cases in Managed Care -

- **US ex rel Wilkins v. UnitedHealth** – Third Circuit, June 2011
  - FCA case alleging that United violated FCA by submitting claims for monthly capitation while in violation of MA marketing regulations and Anti-Kickback Statute. Motion to dismiss granted and then 3rd Circuit partially reversed.
    - Adopted implied certification theory – that is, claims may be submitted and may be false where submitter has certified compliance with all "applicable rules and regulations." But this is not a "blunt instrument" and courts should look at administrative guidance to determine whether government would pay claim if it knew of violation. Court found that compliance with marketing regulations was not a condition of payment, therefore affirmed motion to dismiss
    - Claim under Anti-kickback statute, however, survived motion to dismiss. AKS compliance is a condition of payment. Court repeats Justice Holmes's maxim that "men must turn square corners when dealing with the Government."
      - AKS claims later dismissed by district court on 9(b)

Part D Issues

Medicare is doing more to police Advantage and Part D lapses, but does it matter?

By Bob Herman | December 4, 2014

Last month, the CMS quietly fined a small health insurer in Arizona $146,600 for violating several Medicare rules. In somewhat fiery language for a government agency, the CMS called the company's lapses "systemic."

The insurer, Phoenix Health Plans, offers a few different Medicare Advantage HMOs for seniors and the disabled. Its membership is nominal, covering about 10,600 people.

But insurance companies of all sizes are increasingly finding themselves in similar situations with the government. This year, nearly three dozen health insurance companies have faced similar fines (called civil money penalties) or, worse, temporary suspension from enrolling or marketing to new Medicare members. Critics of Medicare Advantage view the increased oversight from the CMS as acknowledgment of serious flaws in the program (also known as Medicare Part C) and the Part D prescription drug program. Others say most of the problems identified are easily fixed.

In the case of Phoenix Health Plans, the CMS said (PDF) the plan failed to provide protections to its members on multiple occasions. For example, the company inappropriately denied or delayed medical services and prescription drugs that should've been covered. And it didn't provide the right outlets for people to appeal those decisions. The CMS said those failures led to higher out-of-pocket costs for its members and choked off members' due process.

Six largest Medicare Advantage/ Part D civil money penalties (2014)

Lifetime Healthcare	$447,450
Aetna (Coventry)	$407,800
Aegon	$370,400
Express Scripts Medicare	$334,300
Moda Health	$312,300
Blue Cross and Blue Shield of N.C.	$290,250

Source: CMS

Other Risk Areas

- **SEC Investigations** – Investigations being conducted into whether areas that were typically for DOJ or HHS-OIG review should be investigated by SEC because of revenue-recognition/earnings issues
  - SEC investigation of home health companies
  - SEC review of CVS/Caremark's PDP and MAPD businesses
- **Congressional Investigations –** wild west of investigations and, for the most part, procedure-less
  - Usually accompanied by letters or press statements from Members
  - Hearings may be conducted depending on the issue
  - Important to develop contact with staff-level attorneys

In-house / FDR functions that relate to the Sponsor's Medicare Parts C and D contracts

- Sales and marketing;
- Utilization management;
- Quality improvement;
- Applications processing;
- Enrollment, disenrollment, membership functions;
- Claims administration, processing and coverage adjudication;
- Appeals and grievances;
- Licensing and credentialing;
- Pharmacy benefit management;
- Hotline operations;
- Customer service;
- Bid preparation;
- Outbound enrollment verification;
- Provider network management;
- Processing of pharmacy claims at the point of sale;
- Negotiation with prescription drug manufacturers and others for rebates, discounts or other price concessions on prescription drugs;
- Administration and tracking of enrollees' drug benefits, including TrOOP balance processing;
- Coordination with other benefit programs such as Medicaid, state pharmaceutical assistance or other insurance programs;
- Entities that generate claims data; and
- Health care services.

Many Areas of Data Management

- Systems / Data Sets
  - Electronic Medical Record
  - Health Information Exchange
  - Predictive Modeling Applications / Data Analytics
  - Enrollment Systems
  - Risk Adjustment Data
  - Medical Loss Ratio
    - Allocation Decisions
    - Quality Validation
  - Investigations / Payment Error Tracking Data
  - Part C & D Data Set Reporting
  - HEDIS Reporting
  - Inventory Data Submissions

» Data Governance
  › Data Inventory
  › Data Classification
  › Data Stewards
  › Data Validation / Certifications

» Security of Data
  › Data in Flight
  › Data at Rest

» Data Use Agreements
  › Authority to Collect
  › Authority to Transfer
  › Authority to Use
  › Disclosures
  › Breach Protocols

Tips To Avoid Inaccurate Filings & Submissions

- Establish a program for data submissions to demonstrate that they are being made in good faith
  - Use SOX-like certifications and sub-certifications
  - Develop process map for filings
  - Periodic education and training, especially new employees
  - Disclose to government assumptions made regarding the information that is contained in the submission
  - Document discussions with the government and informal interpretations provided
  - Don't wait until last-minute – leave plenty of time between data gathering and submission; otherwise, it is nearly impossible to obtain certainty about the reliability of the data, and may very well look "fishy"
  - Where possible, limit scope of attestation (disclaim personal knowledge of all information and disclose assumptions/limitations in data)
  - Regular auditing and monitoring of policies and procedures related to filing

Data Risk Mitigation: Compliance Program Elements

1. Written Policies and Procedures
   - **Data governance expectations**
2. Compliance Officer, Compliance Committee and High Level Oversight
   - **Review of data submissions, discussions of data governance**
3. Effective Training and Education
   - **General compliance and ethics training**
   - **Targeted training to data stewards, key data set owners**
4. Effective Lines of Communication
   - **Certifications and sub-certifications from data stewards (operational leaders vs IT)**
   - **IT system / database change management protocols**
5. Well Publicized Disciplinary Standards
   - **Certifications have meaning**
6. Effective System for Routine Monitoring and Identification of Compliance Risks
   - **Conduct data validation audits**
   - **Review data submissions to the government**
   - **Baseline reports**
7. Procedures and System for Prompt Response to Compliance Issues.
   - **Triage and document all investigations and concerns over data integrity**