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Compliance & Enforcement Issues in Managed Care

Trends in Managed Care

Medicare & Medicaid Managed Care

Revenue

- Medicare Advantage: \$123.7 billion in 2011 (= \$135 billion in 2012)
- Part D: \$62 billion in 2010
- Medicaid Managed Care: \$116 billion by the federal and state governments in 2011

Enrollment

- Medicare Advantage: 13 million enrollees in 2012 (27% of the total Medicare population)
- Medicaid Managed Care: 43.4 million enrollees in 2011 (74.22% of the total Medicaid population)
- Long Term Managed Care: By 2014, 26 states will likely have long-term managed care programs

Final New Compliance Guidelines

- Monthly checks for excluded individuals among employees and first-tier, downstream, and related entities
- Processes to identify, deny, prevent payment of claims from excluded providers at point of sale
- Requires disclosure by employees and first tier, downstream or related entities of new exclusions
- Establish SIU unit or perform SIU functions through compliance

Final New Compliance Guidelines: False Claims Act Risks

- Consider *Medco* and *Caremark* effect of compliance guidelines on False Claims cases and proof of corporate reckless disregard.
- *United States of America ex rel George Bradford Hunt et al. v. Merck-Medco Managed Care*, 336 F.Supp.2d 430 (E.D. Pa. 2004):
 - “Plaintiffs have sufficiently alleged that Medco submitted its false claims knowingly under this definition. At the very least, the Government has claimed that Medco’s compliance programs were either non-existent or insufficient, in satisfaction of the ‘reckless’ requirements of § 3729(b).” 336 F.Supp.2d at 441.
- “Part D plan sponsors must . . . [c]ertify in their contracts that they agree to comply with all federal laws and regulations designed to prevent fraud waste and abuse. 42 CFR 423.505(h)(1)” United States statement of interest in *USA ex rel. Spay v. Caremark* (E.D. Pa. December 20,2012)

United States of America, ex rel. Anthony R. Spay v. CVS Caremark Corp. (E.D. Pa. December 20,2012)

- “[A]s a condition for receiving payment, a Part D sponsor must certify the accuracy, completeness, and truthfulness of all data, including claims data, related to the requested payment from the government. When that claims data is generated by a subcontractor of a Part D Sponsor, such as a PBM, the subcontractor must similarly certify, as a condition of payment, the truthfulness, accuracy, and completeness of the data.”

United States of America, ex rel. Anthony R. Spay v. CVS Caremark Corp. (E.D. Pa. December 20, 2012)

- “This interpretation (i.e., that the data certification is a condition of payment) finds support in CMS’s Prescription Drug Benefit Manual. Section 80.1, entitled ‘The False Claims Act,’ specifically references section 423.505(k)(3) and provides as follows:
- Sponsors should devise their compliance programs so that their policies and procedures are consistent with the Federal Civil False Claims Act . . . When submitting claims data to CMS for payment, Sponsors and their subcontractors must certify that the claims data is true and accurate to the best of their knowledge and belief [footnote referencing section 423.505(k)(3)]. The False Claims Act is enforced against any individual/entity that knowingly submits (or causes another individual/entity to submit) a false claim for payment to the Federal government.

Spay: Claims Data Accuracy is a Condition of Payment Based on the Prescription Drug Manual

- “The plain import of this language suggests that 42 CFR 423.505(k)(3) was designed precisely to make a subcontractor’s certification of the truthfulness, accuracy, and completeness of claims data a condition of payment. Further, it indicates that false certification by a subcontractor of this information, which ‘causes’ the Part D Sponsor to submit a false claim for payment to the government, is grounds for an FCA claim.”

Affordable Care Act

- State exchanges, partner exchanges, federal exchanges
- Medicaid funding
 - Starting in 2014, in states that choose to implement the ACA’s expansion, individuals under 65 with income below 133% of the federal poverty level will be eligible for Medicaid
 - 100% funding for Medicaid expansion 2014-2016
 - April 2, 2013: The Final Rule for 42 CFR Part 433 is issued, with a comment period through June 1
 - 90% federal matching to improve state eligibility and enrollment systems
 - ACA increases the Medicaid payments for primary care doctors in fee-for-service and managed care plans

Recent Enforcement Cases

WellCare

- A civil and criminal investigation into alleged overbilling of Medicare and Medicaid by WellCare, a Medicaid managed care plan.
- In April 2012, Wellcare agreed to pay \$137.5M to the U.S. and nine states to settle FCA allegations. Criminal trials of executives are still pending.

Janke

- Allegations that the defendants submitted codes for MA reimbursement that were not supported and failed to look for erroneous diagnoses or delete codes upon learning that they were inaccurate.
- \$22.6M settlement in November 2010.

SCAN

- *Qui tam* relator alleged that SCAN inflated risk scores to increase its Medicare premiums.
- \$320M settlement in August 2012 (with \$4M related to MA allegations).

UnitedHealth

- Involved alleged violations of AKS and MA marketing regulations. The case was brought by *qui tam* relators.
- The DOJ declined to intervene and the case was dismissed after the parties reached a settlement agreement in principle. 2011 U.S. App. LEXIS 13322 (3d Cir. 2011).

Managed Care Compliance

The Story of WellCare and Thaddeus Bereday (In-House Counsel and Compliance Officer as Defendant)

Thaddeus Bereday: In-House Counsel as Criminal Defendant

- WellCare Secretary, General Counsel, Chief Compliance Officer
- Financial Reporting to State allegedly concealed violation of Florida's 80/20 Rule (requiring 80% of premiums to be paid out to health care providers)
- Payments to WellCare behavioral health subsidiary treated as provider payments in reports
- Indicted March 2011 (*an indictment is an accusation; defendant is entitled to presumption of innocence)

Thaddues Bereday

- May 2007 WellCare press release:
 - “We have zero tolerance for any verified compliance infractions,” said Bereday, “[w]e take our compliance practices seriously, and we will continue our aggressive oversight”
 - “[O]ur overall compliance strategy will continue to be best in class,” said CEO Todd Farha (indicted with Bereday).

WellCare Whistleblower

- June 2006
 - Sean Hellein, data analyst, files FCA whistleblower complaint
- August 2006
 - Sean Hellein meets with FBI.
 - Hellein wore a camera/recorder for the FBI for 18 months, and recorded 650 hours of conversations.
- January 2007
 - “. . . you have to be careful-this is fraud.”
- May 2007
 - Bereday’s zero tolerance policy
- October 2007
 - Federal search warrant-200 agents visit WellCare

“The 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 William Kale, former vice-president of Harmony Behavioral Health subsidiary.
- “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 Peter Clay, former WellCare vice-president of medical economics, and Hellein’s boss.

Quotes from Bloomberg News story November 20, 2012 “Fraud Trial for WellCare Ex-CEO Shows Medicaid Abuse.”

WellCare Outcomes

- 2009
 - WellCare accepted deferred prosecution, paid \$80 million, hired an outside monitor, Stan Twardy-mentorship ended early-April 2012
- 2011
 - Proposed \$137.5 million FCA settlement
 - Indictment of five former WellCare executives
- 2012
 - FCA settlement approved
 - \$200 million shareholder settlement
 - \$10 million to SEC
 - Hellein receives \$20.7 million

Reporting Violations (2011 settlement)

- The Government's Contentions:
- "Knowingly concealed its contractual obligation to pay . . . monies back. . . ."
 - "[C]onced and retained overpayments received from state Medicaid programs in violation of its contractual obligations to pay monies back to the state Medicaid programs"
 - "[F]iling false and misleading fraud prevention plans"

New Compliance Officer

- March 2010
 - Wellcare's March 5 press release: "WellCare has demonstrated an exemplary commitment to ethical business practices and regulatory compliance," said Blair W. Todt, new WellCare SVP and Chief Compliance Officer
 - Attorney-former Bearing Point (KPMG Consulting) deputy general counsel compliance and litigation
- March 2011
 - Indictment of five former executives

WellCare Trial

- February 2013
 - Four former WellCare executives (who ran its Medicaid managed care plans) accused of defrauding the Medicaid program of more than \$30 million started trial in Tampa.
 - Defense argument: "They did their best to cope with a lack of guidance from state bureaucrats."

Alleged WellCare False Claims

- Government's contentions in 2011 settlement: "[C]oncealed and retained overpayments in violation of its contractual obligations to pay monies back to the state Medicaid programs"
- Pre-ACA Section 6402 obligation (passed in 2010) to report, refund, and explain overpayments within 60 days of discovery
- Attorney role in reporting (or concealing)

False Claims Act

Relators Finding the Managed Care Target

False Claims Act

Civil False Claims Act

- Prohibits knowingly presenting a false claim or knowingly making a false record or statement material to a false claim
- “Knowingly” includes acting in reckless disregard or deliberate ignorance of the truth or falsity of the information
- Penalties include treble damages and civil penalties
- *Qui tam* provisions allow individuals (e.g., employees, contractors, providers) to sue and share in ultimate recovery

Overpayment Amendments (FERA & PPACA)

- FERA expanded FCA liability by including knowing retention of overpayments (same definition of “knowledge” as above)
- PPACA requires that overpayments be reported and repaid within 60 days after identification

FERA Overpayment Provision

Congressman Berman:

“Liability for all non-disclosed overpayments of the same type also should be imposed once an organization or other person is on notice that it has been employing a practice that has led to multiple instances of overpayment. For example, *if a corporation learns after-the-fact that it has been violating a billing rule or a contract requirement in its billing, and it nonetheless fails to comply with a legal obligation to disclose the resulting overpayments, this amendment renders the corporation liable under the Act for all overpayments resulting from the violation of the billing rule or contract requirement, even those not specifically identified or quantified.*”

155 Congressional Record E1295 (Monday, May 18, 2009) (emphasis added).

Legal Theories of Liability

Enrollment forms are claims

•“Al argues that enrollment forms cannot be claims because they do not demand payment and do not have the purpose of inducing the Government to immediately part with money. See 31 U.S.C. § 3729(c); *U.S. v. Neifert-White Co.*, 390 U.S. 228, 232, 88 S. Ct. 959, 19 L. Ed. 2d 1061 (1968). These arguments were rejected in the summary judgment opinion; the enrollment forms are claims because they were ‘submitted in order to receive payment,’ even if payment was not immediate.”

Source: *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719 (N.D. Ill 2007)

Legal Theories of Liability

Fraudulent Inducement

•Plaintiffs presented sufficient evidence for a reasonable jury to have found that the non-discrimination provisions were conditions to participation. "If a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork."

Source: *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719 (N.D. Ill 2007)

Fraudulent Inducement as False Claims Violation

- (1) signing the 2000 MCO Contract (which included a marketing restriction against health-based discrimination) and (2) stating in a letter that "AMERICAID will not discriminate against clients with health issues which includes pregnant women" resulted in the submission of documents supporting false claims (i.e., enrollment forms)
- (1) the nondiscrimination provisions were prerequisites to participation in the Medicaid HMO program under federal law, see 42 U.S.C. § 1396(m)(2)(A)(v); (2) that AI knew about the nondiscrimination provisions and statutes and told IDPA that it would comply with them; and (3) that Amerigroup planned to violate (and was already violating) the non-discrimination provisions.

Source: *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719 (N.D. Ill 2007)

Look to Your Certifications

Medicare Advantage Annual Attestation

•MA organization must certify that risk adjustment data is accurate, complete and truthful (based on best knowledge, information, and belief). (42 C.F.R. § 422.504(l))

New York

- New York State Model Managed Care Contract:
 - "Covered services provided by the Contractor under this Contract shall comply with all standards of the New York State Medicaid Plan established pursuant to Section 363-a of the State Social Services Law and satisfy all other applicable requirements of State Social Services and Public Health Law"

What About Duty to Investigate Providers?

Medicare Advantage

- “Sponsors are required to investigate potential FWA [Fraud, Waste, Abuse] activity to make a determination whether potential FWA has occurred. Sponsors must conclude investigations of potential FWA within a reasonable time period after the activity is discovered.”
 - CMS Medicare Managed Care Manual

Texas

•1 T.A.C. §§ 353.501 - 353.505

- Each managed care organization (MCO) subject to this section must develop a plan to prevent and reduce waste, abuse, and fraud and submit that plan annually to the Health and Human Services Commission (HHSC), Office of Inspector General (OIG) for approval.
- The MCO is responsible for investigating possible acts of waste, abuse, or fraud for all services, including those that the MCO subcontracts to outside entities.

Topic No. 1: Risk Adjustment

Risk Adjustment

Background

- Risk adjustment is based on demographic factors and health risk
- Under Medicare Advantage, diagnoses submitted for payment must be documented in a medical record that was based on a face-to-face encounter between a patient and a healthcare provider

Expansion

- Policies issued under the Affordable Care Act
- Medicaid managed care

Discussion Topics

Relationships with Providers

- Compensation
- Health plan reports to providers
- Education & training
- Quality of care

Encounter Processing

- Health plan processing systems
- Filtering
- Deletions

Retrospective Chart Reviews

- Chart selection
- Scope of review
- Coding standards

Topic No. 2: Kickbacks

Kickbacks

Elements

- Offer, pay, solicit, or receive
- Remuneration
- Intent (knowingly and willfully)
- Induce
- Referral or recommendation
- Item or service reimbursable by a Federal Health Care Program

Affordable Care Act

- "[A] person need not have actual knowledge . . . or specific intent to commit a violation . . . [of the Anti-Kickback Statute]." ACA § 6401(f)
- "[A] claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." ACA § 6401(f)

Discussion Topics

Provider Contracting

- Anti-kickback safe harbor
- Fair market value
- Exclusivity
- Other payments

Marketing Efforts

- Co-marketing
- Provider involvement in enrollment

Topic No. 3: Medical Loss Ratio

Mandatory Reporting - Medical Loss Ratio

- ACA requires insurers to pay a minimum percentage of premium dollars towards health care expenses and quality improvement activities, limiting the amount spent on administrative and marketing costs and profit.
 - 85% for large group plans
 - 80% for small group plans
- These ratios are known as the Medical Loss Ratio (MLR).
- Excess premiums must be rebated to policyholders.
- CMS will publish aggregate reports from each insurer.

Discussion Topics

Classifying Expenses

- Administrative expenses
- Activities that improve health care quality
- Anti-fraud efforts

Recent Claims

- *MRI Scan Center, LLC v. Nat'l Imaging Assocs., Inc.*
 - Filed January 2013.
 - Alleges manipulation of Explanation of Benefits and Remittance Advices to avoid paying MLR rebates under ACA.

Questions?
