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Medicare and Medicaid Repayments and Disclosures

Meeting Refund and Reporting Obligations to Comply with FERA, FCA and the ACA

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HEALTH CARE LAWYERS

Medicare and Medicaid Repayments and Disclosures: Meeting Refund and Reporting Obligations to Comply with FERA, the FCA and the ACA

Strafford Publications Webinar
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Goals for Today's Presentation

- Briefly review legal authorities
  - Federal False Claims Act ("FCA")
  - 60 Day Rule and 2012 NPRM – Medicare Parts A & B
  - May 23, 2014 Final Rule – Medicare Parts C & D
  - Administrative finality
- legal uncertainties given absence of the final rule for Medicare Parts A & B
- Discuss practical issues practitioners face.
  - How far back
  - Sampling issues
  - Where to disclose

Goals for Today's Presentation

- First Enforcement of the 60-Day Rule
- Self-Disclosure Issues and Update
  - Options
  - Process
  - Risks and Benefits
  - Likely Outcomes

Introduction

Three Sources of Liability for Failure to Report/Repay Medicare and Medicaid Overpayments

- Overpayment liability under 42 U.S.C. §1320a-7k(d)) – Added by the ACA
- FCA liability under 31 U.S.C. §3729(a)(1)(G) – Added by FERA
- Civil Monetary Penalty and Exclusion liability under 42 U.S.C. §1320a-7a(a)(10) – Added by the ACA

How Did We Get Here? 2009 FCA Expansion

- 2009: FERA expands federal FCA liability to include, among other things, retention of overpayments
- 31 U.S.C. §3729(a)(1)(G)
  - "Any person who … knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government or **knowingly conceals** or **knowingly and improperly avoids or decreases** an **obligation** to pay or transmit money or property to the Government…." (emphases added)
- "Obligation" (31 U.S.C. §3729(b)(3))
  - "an **established duty**, whether or not fixed, **arising from** an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from **statute** or regulation, **or from the retention of any overpayment**…." (emphases added)

How Did We Get Here? 2009 FCA Expansion

- FERA also changed the definition of "claim" in 31 U.S.C. §3729(b)(2) so that it:
- "(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—
- (i) is presented to an officer, employee, or agent of the United States; or
- (ii) is made 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, and if the United States Government—
  - (I) provides or has provided any portion of the money or property requested or demanded; or
  - (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and
- (B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property[.]"

How Did We Get Here? 2009 FCA Expansion

- FERA left undefined several critical terms
- "Improperly"
  - Committee Report states: "The Committee does not intend this language to create liability for a simple retention of an overpayment that is permitted by a statutory or regulatory process for reconciliation provided that the receipt of the overpayment is not based on any willful act of a recipient to increase the payments from the Government when the recipient is not entitled to such Government money or property."
- "Established duty … arising from"
- "Overpayment"

How Did We Get Here? PPACA 60-Day Rule Provisions

- PPACA Section 6402(a) (42 U.S.C. § 1320a-7k(d))

(d) Reporting and returning of overpayments

(1) In general. If a person has received an **overpayment**, the person shall—

(A) **report and return** the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and

(B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

(2) Deadline for reporting and returning overpayments. An overpayment must be reported and returned under paragraph (1) by the later of–

(A) the date which is 60 days after the date on which the overpayment was **identified**; or

(B) the date any **corresponding cost report** is due, if applicable.

How Did We Get Here? PPACA 60-Day Rule Provisions

(3) Enforcement. Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an **obligation** (as defined in section 3729(b)(3) of Title 31) for purposes of section 3729 of such title.

(4) Definitions. In this subsection:

(A) Knowing and knowingly. The terms "knowing" and "knowingly" have the meaning given those terms in section 3729(b) of Title 31.

(B) Overpayment. The term "overpayment" means any funds that a person receives or retains under subchapter XVIII or XIX of this chapter to which the person, after **applicable reconciliation**, is not entitled under such subchapter.

(C) Person

(i) In general. The term "person" means a provider of services, supplier, medicaid managed care organization (as defined in section 1396b(m)(1)(A) of this title), Medicare Advantage organization (as defined in section 1395w-28(a)(1) of this title), or PDP sponsor (as defined in section 1395w-151(a)(13) of this title).

(ii) Exclusion. Such term does not include a beneficiary.

How Did We Get Here? PPACA CMP Provisions

- PPACA Section 6402(d) amends the Federal CMP statute
- New 42 U.S.C. § 1320a-7a(a)(10) exposes CMP liability to any person "that **knows** of an **overpayment** (as defined in paragraph (4) of [42 U.S.C. § 1320a-7k(d)]) and does not report and return the overpayment in accordance with such section."
- Penalties: up to $10,000 for each item or service, plus an assessment of up to three times the amount claimed for each such item or service
- Also potential exclusion from participation in federal health care programs, including Medicare and Medicaid

Medicare vs. Medicaid

- The difference between Medicare and Medicaid overpayments -- federal focus on recovering from the state which, in turn, is expected to recover from the provider. *See* "Review of Medicaid Credit Balances at Baystate Franklin Med. Ctr. for the Period Ending June 30, 2006" (Report Number A-01-07-00002) (July 11, 2007) (reviewing federal and state roles in recovering Medicaid provider overpayments).
- Medicaid Integrity Program

2012 NPRM

- On February 16, 2012, CMS published a notice of proposed rulemaking ("NPRM") regarding the obligation to report and return Medicare and Medicaid overpayments (77 Fed. Reg. 9179).
- NPRM would implement §6402(a) of the ACA - 42 U.S.C. §1320a-7k(d)) – but only for purposes of Medicare Parts A and B
- CMS has not yet issued the final rule

Open Questions From 2012 NPRM

- Is the statute self-implementing – to what extent?
- Definition of overpayment –
  - is the term "applicable reconciliation" restricted to interim payments identified by cost report providers?
- 60 day deadline
  - "identify"? – reckless disregard or deliberate ignorance – introduction of knowledge
  - "with all deliberate speed"? – OK to go beyond 60 days?

Open Questions From 2012 NPRM

- What is the effect of the mandatory repayment provisions on appeal rights and waiver of liability?
- Look-back period
  - 10 years
  - Amendments to reopening rules
- Use of MAC-required form vs. electronic claims credit
- Beneficiary copayment refunds?

2014 Final Rule – Parts C & D

- On May 23, 2014, the Secretary published a final rule concerning application of the 60-day rule to Medicare Parts C and D programs. 79 Fed. Reg. 29,844 *et seq*. (May 23, 2014).
- To date, rulemaking has not been initiated to implement the 60-day rule as it relates to state Medicaid programs.

2014 Final Rule – Parts C & D

Definitions under 42 C.F.R. §422.326 (Part C) (*see also* §423.360 (Part D)):

- (c) *Identified overpayment*. The MA organization has identified an overpayment when the MA organization has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment.
- (f) *Look-back period*. An MA organization must report and return any overpayment identified for the 6 most recent completed payment years.

Questions under Part C

- Are overpayments to "downstream" providers in Medicare Advantage and Medicaid Managed Care Plans subject to the 60 day rule statute?
  - Definition of "person" in the 60 day rule statute
  - Definition of "claim" in FCA added by FERA
- The focus of the final rule for MAO and PDP sponsor overpayments is on MAO and PDP sponsor obligations and silent with regard to provider and supplier obligations arising from plan payments.

Questions under Part C

- If so, do contractual provisions always control?
  - Applicability of "applicable reconciliation"
  - Effect of Federal and State coverage and payment provisions
  - To whom are overpayment refunds made?
  - Contractor performance

Questions under Parts A & B

- How far to go back for purposes of calculating the amount of an overpayment?
  - Effect of administrative finality
  - Effect of extension of the time period from three years to five years (six years total) over which the "without fault" provisions in 42 U.S.C. §1395gg(b) apply (§638 of the American Taxpayer Relief Act of 2012)
  - Statute of limitation vs. elements of cause of action
  - 10-year look-back period in NPRM

Questions under Parts A & B

- What is an not an overpayment under 60 day rule or not an obligation under FCA?
  - COP violations?
  - COC violations?
  - Does answer change if there is substantial non-compliance?
  - Other regulations that don't appear to be conditions of payment
  - Netting-out underpayments?

Questions under Parts A & B

- How far to go back for purposes of calculating the amount of an overpayment?
  - 10-year look-back period in Part A/B NPRM but suggests that cost report issues are subject to administrative finality.
  - The final rule for MAOs and PDP sponsors includes a 6-year look-back period. It is unclear if this difference reflects the government's attempt to account for differences between provider and plan overpayments or, perhaps, is a result of comments criticizing the 10-year lookback in the 2012 proposed rule.

Questions under Parts A & B

- When will an overpayment be deemed to be "identified"?
- What is the meaning of "after applicable reconciliation"?
- What is the effect of the mandatory repayment provisions on appeal rights and waiver of liability?
- To what extent is administrative finality available as a defense?

Questions under Parts A & B

- Is there FCA liability if there is no overpayment under the 60 day rule statute?
- If there is an overpayment, does the failure to report and refund timely, which is an "obligation" under 1320a-7k(d)(3), automatically result in FCA liability?

How Far Back Do You Go

- 1-1-14 hospital system finds and fixes a computer glitch in its non-hospital services affiliate
- Data collection is done and repayment is made 3-1-14
- How far back is the repayment to go?
  - 3-1-10?
  - 1-1-10?
  - Go back 6 years?

How Far Back Do You Go

- 1-1-13 hospital system finds a computer glitch in its non-hospital services affiliate that has been in the system for 8 years
- Consultant hired and issues report on 3-1-13 – OK
- 1-1-14 new CFO says not OK and fixes the problem
- Data collection is done and repayment is made 3-1-14
- How far back is the repayment to go?
  - 3-1-10? 1-1-10?
  - 3-1-09? 1-1-09?
  - 6 years?

Audit Issues – Sampling Issues

- Hospital department does E&M review of claims 1-1-14 – 2-20-14 affiliated physician practice
- 100 claims reviewed – claims pulled subjectively by staff
- 50 contain errors
- 50 claims refunded
- Any duty to do further auditing?
- Change facts – the 50 claim statistically valid probe audit – Any duty to do further auditing?

Drinker Biddle

Medicare & Medicaid Repayments and Disclosures

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First Enforcement of 60-Day Rule

- *U.S. ex rel. Kane v. Healthfirst, Inc*., No. 11-2325 (S.D.N.Y.) – USA and NY intervene.
- Test case?
- Medicaid managed care company sent erroneous electronic remittances that triggered hospitals to erroneously submit claims to secondary payors, including Medicaid. Hospitals blameless.
- NY Comptroller discovered and advised hospitals of certain improperly submitted claims.
- Persisted from early 2009 until late 2010.

First Enforcement of 60-Day Rule

- Software vendor implemented fix in 12/10.
- Kane, an employee in Revenue Cycle Dep't, was tasked by hospital system to investigate.
- 2/5/11 – Kane sends email to multiple executives with spreadsheet identifying 900+ claims, with >$1 million in Medicaid claims.
- 2/11/11 – Kane terminated.
- 4/5/11 – Kane files *qui tam* (60 days after his email)

First Enforcement of 60-Day Rule

- Defendants allegedly "did not nothing further with Kane's analysis or the claims identified therein."
- From 3/11 to 2/12, the NY Comptroller brought additional affected claims to defendants' attention, and defendants reimbursed NY Medicaid in 30 batches.
- Kane's list of 900 claims was allegedly a substantially accurate list.
- Defendants only repaid the final 300 claims after DOJ served a civil investigative demand in June 2012.

First Enforcement of 60-Day Rule

- Government did not intervene against the MCO or against dozens of other hospitals, and relator has voluntarily dismissed claims against them.
- Defendants have informed the Court that they intend to move to dismiss on grounds of no “identification” because Kane’s work was incomplete.

What is an overpayment?

- Express or implied certifications of regulatory compliance
  - Cost reports ("I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations").
  - Provider and supplier enrollment applications (Forms 855A, 855B, 855I and 855S), although these are prospective. ("I agree to abide by the Medicare laws, regulations and program instructions that pply to this provider…. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of Medicare").

What is an overpayment?

- Conditions of participation. *U.S. ex rel Baklid-Kunz v. Halifax Hosp*. (M.D. Fla. July 1, 2014).
- DME supplier standards as conditions of participation. *U.S. ex rel. Williams v. Renal Care Group, Inc*., 696 F.3d 518 (6th Cir. 2012); *U.S. ex rel. Jamison v. McKesson Corp*, 784 F. Supp. 2d 664 (N.D. Miss. 2011).
- Is there an overpayment if there is no written physician order?

What is an overpayment

- No overpayment if provider is "without fault" (a very narrow concept that is unrelated to blameworthiness, and which requires that the provider be unable to determine that it was overpaid based on all information available to it; provider presumed to be aware of all pertinent Medicare instructions and regulations). *See* Medicare Financial Management Manual ch. 3 § 80.
- Examples of provider with fault
  - MAC makes a mathematical or clerical error
  - MAC makes a duplicate payment to provider
- Examples of provider without fault
  - Medicare overpayment is due to beneficiary's exhaustion of benefits which provider could not possibly ascertain from its own records.
  - More than three years before the current calendar year (4 years) (*Id*.)

Overpayments Due to Lack of Medical Necessity

- Medicare will forego recouping overpayments for services that were not "reasonable and necessary" if both the provider and beneficiary reasonably did not know that the service was not covered. 42 U.S.C. 1395pp.
- If the provider or beneficiary, or both, could have or should have known that the claim was not covered, provider can avoid liability if the beneficiary signed an ABN (and beneficiary will become liable). Medicare Claims Processing Manual ch. 30, § 20.

Self-Disclosure Process

- Investigation
  - Privilege or not?
  - Retain consultants under privilege?
  - Extent of document review? Review electronic records?
  - Quantify with internal or external resources?
  - Netting, sampling, and offsetting
- Corrective Action

Disclosure Options

- Disclose and refund to Medicare Administrative Contractor, Medicaid Agency
- Disclose Stark Law only matters to CMS under Self-Referral Disclosure Protocol ("SRDP")
- Disclose to OIG under OIG Self-Disclosure Protocol ("SDP")
- U.S. Attorney's Office
- New York Medicaid Inspector General

Stark Law Disclosure Protocol (SRDP)

- Issued September 2010 under PPACA
- For “potential” or actual Stark Law violations
- Matters that “may also raise liability risks” under Anti-Kickback Statute should be disclosed under OIG’s SDP, and parties should not disclose same conduct to both CMS and OIG.
- As of 10/4, there have been 52 reported settlements and estimated backlog of 350+ disclosures.
- Settlement range: $60 to $584,000 (covering 19 violations).

Stark Law Disclosure Protocol

- Required Elements of a Disclosure
  - Facts surrounding potential/actual violation
  - Legal analysis
  - Remedial action description
  - Why potential/actual violation occurred
  - When discovered
  - What was done to investigate
  - Description of Compliance Program

Stark Law Self-Disclosure Protocol

- Elements of a Disclosure (cont'd)
  - Medicare payments under four-year lookback.
    - Factual disclosure not limited to four years, just financial analysis is.
    - Boxes 76 and 77 from UB-04.
    - Describe assumptions in making the financial analysis.
  - Payments to/from physician during four-year lookback.
  - Certification
  - Can package many violations in a single disclosure

Stark Law Disclosure Protocol - Process

- Submit electronically and include relevant documents
- Immediate electronic confirmation, including confirmation that 60-day rule is suspended.
- Eventually, CMS will ask for more documents or other questions
- Multiple CMS components review (Office of Technical Payment Policy, Office of General Counsel, Financial Management)
- Then, one day, CMS will call and tell you of its compromise. CMS intends for no negotiations, but at that point will be willing to hear about ability-to-pay issues.
- BUT, CMS will refer matters to OIG and DOJ when it feels law enforcement may be appropriate.

Stark Law Disclosure Protocol

- Include discussion of exculpatory factors
  - Evidence of non-willful conduct
  - Involvement of counsel in preparing documents
  - Lack of impact to patients or Medicare
  - Sole community provider
  - Ability to pay
  - Effective response to identified issues
- Mention any other relevant facts
  - E.g., business need to expedite settlement

Stark Law Self-Disclosure Protocol

- Settlements
  - No release of civil penalties or any other laws. Release strictly covers overpayment liability.
  - Handful of referrals to OIG or DOJ
  - Settlement agreements are subject to FOIA. Are the disclosures themselves?

Stark Law Self-Disclosure Protocol - Summary

- You are playing with fire if you do not disclose an identified Stark Law violation under the Self-Disclosure Protocol

OIG Self-Disclosure Protocol

- Premise: To self-disclose and settle matters that could involve liability under the Civil Money Penalties Law or serve as basis for exclusion
- Since 1998, resolved over 800 disclosures, recovered over $300M.
- About 65 SDP settlements per year.
  - 65% relate to excluded individuals; 25% involve billng issues; and 10% are AKS issues.
  - Settlements of $10,000 to $2 million.
- No Stark-Law-only disclosures

OIG Self-Disclosure Protocol

- Benefits
  - Release of CMP and exclusion
  - Typically, no Corporate Integrity Agreement. (Since 2008, only one of 235 settlements have included integrity requirements).
  - Lower damages. As low as 1.5 times the overpayment.
  - Suspends 60-day rule

OIG Self-Disclosure Protocol

- Required elements
  - Factual summary (including names of individuals responsible), statement of laws potentially violated, corrective action
  - Certification
- Other features
  - Must admit that there was a “potential” violation
  - Federal health care program financial impact must be computed and provided within 90 days of initial disclosure
  - OIG commits to resolve within 12 months
  - Six-year lookback

OIG Self-Disclosure Protocol

- April 2013 Guidance on computing damages
  - May audit all claims or a sample of at least 100 claims (which may include the probe sample)
  - No minimum precision required, just at least 100 claims
  - No "netting" of underpayments
  - Use mean point estimate to determine damages. (By contrast, Medicare Manual allows low end of range, for 90th percent confidence interval, for Medicare auditors. OIG also used that standard in recent audits, *see, e.g.*, audit of University of Miami).
  - Full report required on damages calculations

OIG Self-Disclosure Protocol

- Disclosure of employment of, contracting with, excluded persons
  - Disclose reimbursement amount of separately billed services of that person (e.g., pharmacist)
  - Settlement likely based on employment cost adjusted by payor mix for federal programs.
  - Must explain how excluded status was missed and corrective action.
  - Must screen all current employees and contractors against LEIE before making disclosure.

OIG Self-Disclosure Protocol

- Anti-Kickback Statute disclosures
  - April 2013 Guidance lays out pointed questions to answer
  - Settlements will often be at a multiple of the potential unlawful remuneration
  - Minimum settlements of $50,000

OIG Self-Disclosure Protocol

- What is released?
  - CMP Law, exclusion
  - OIG confers with DOJ on settlements.
  - False Claims Act is not released, unless disclosing party requests DOJ participation or DOJ chooses to participate.
  - How about 31 U.S.C. 3730(e)(3)?
- Criminal matters may be disclosed under protocol
- Don't disclose a matter to both OIG and CMS. But, as part of a broader review of physician financial relationships, some may be suitable for the OIG SDP and others for only the Stark Law SRDP.

Will Self-Disclosure Preclude A Qui Tam Action?

- Eliminates the risk of continued False Claims Act violations for failure to refund and disclose overpayments.
- Does not trigger public disclosure bar: U.S. ex rel. Rost v. Pfizer (1st Cir.)
- Does trigger public disclosure bar: U.S. ex rel. Whipple v. Chattanooga-Hamilton Cty. Hosp. Auth. (E.D. Tenn. 2013)
- But an "original source" may litigation a qui tam action even if public disclosure bar is triggered.
- How about 31 U.S.C. 3730(e)(3), which bars qui tam actions where a civil money penalties proceeding is pending?