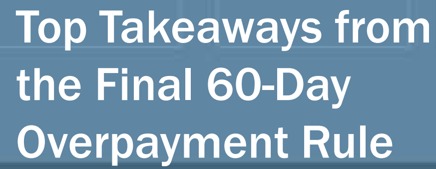

February 17, 2016

©2016 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60654 • 312.832.4500

Lawrence Vernaglia, JD, MPH

Chair, Health Care Industry Team

Foley & Lardner LLP

111 Huntington Avenue

Boston, MA 02199

617-342-4079

lvernaglia@foley.com

Heidi A. Sorensen, Esq.

Foley & Lardner LLP

3000 K Street, N.W.,

Suite 600

Washington, D.C. 20007

202-672-5596

hsorensen@foley.com

©2016 Foley & Lardner LLP

©2010 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60654 • 312.832.4500

Top Takeaways

- Six-year Look Back Period
- What does it mean to identify an overpayment?
  - Reasonable Diligence
  - Quantification
  - Six-month Period
- Refund Processes
- Underpayments
- What else did CMS say?

©2016 Foley & Lardner LLP

Statutory and Regulatory History

- March 23, 2010: ACA Section 6402(d) sets forth statutory requirement
- February 13, 2012: CMS Proposed Rule, 77 Fed. Reg. 9179-9187
- May 23, 2014: CMS Final Rule on Parts C & D Medicare Advantage and Prescription Drug Plan sponsors, 79 Fed. Reg. 29844-29844
- February 12, 2016: CMS Final Rule on *Medicare* overpayments, 81 Fed. Reg. 7654-7684 (Effective March 14, 2016)
- No final federal rule for Medicaid overpayments yet, but some state Medicaid programs have addressed themselves

©2016 Foley & Lardner LLP

©2010 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60654 • 312.832.4500

Why did it take six years to publish a Final Rule?

- February 17, 2015 Federal Register, CMS cited "exceptional circumstances" to delay by another year.
  - "complexity of the rule and scope of comments";
  - "significant policy and operational issues that need to be resolved in order to address all of the issues raised by the comments….".
  - CMS goal was a Final Rule that "provides clear requirements for persons to report and return Medicare overpayments."

©2016 Foley & Lardner LLP

What did the 2010 ACA require?

''(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.

©2016 Foley & Lardner LLP

©2010 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60654 • 312.832.4500

What did the 2010 ACA require?

''(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, United States Code) 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, United States Code.

''(B) OVERPAYMENT.—The term ''overpayment'' means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.

''(C) PERSON.—

''(i) IN GENERAL.—The term 'person' means a provider of services, supplier, Medicaid managed care organization (as defined in section 1903(m)(1)(A)), Medicare Advantage organization (as defined in section 1859(a)(1)), or PDP sponsor (as defined in section 1860D–41(a)(13)).

''(ii) EXCLUSION.—Such term does not include a beneficiary.

©2016 Foley & Lardner LLP

Scope of the 2010 ACA Requirements

- The Statute applies broadly:
  - Providers
  - Suppliers
  - Medicare Part D Plan Sponsors
  - Medicaid MCOs
  - Medicare Advantage organizations

©2016 Foley & Lardner LLP

©2010 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60654 • 312.832.4500

Enforcement Mechanisms from the 2010 ACA

1. **Civil Monetary Penalties Law**
   - Failing to report and return known overpayment within 60 days/or when cost report due (such failure is also subject to potential FCA liability)
     S.S.A. Sec. 1128A(a); 42 U.S.C. 1320a–a(a) (N.B., does show up on on-line SSA/USC)

2. **False Claims Act "obligation"**
   - ACA § 6402(a): Express duty to refund and report Medicare and Medicaid overpayments
   - By *the later* of 60 days after overpayment "identified" or the date cost report is due
   - Failure to report and return is an "obligation" for the purpose of FCA
     S.S.A. Sec. 1128J(d); 42 U.S.C. 1320a-7k(d)

3. **(Medicare and) Medicaid Program Exclusion**
   S.S.A. Sec. 1128A.; 42 U.S.C. §1320a-7a and S.S.A. Sec. 1902(a); 42 U.S.C. 1396a(a)

©2016 Foley & Lardner LLP

TOP TAKEAWAYS

©2016 Foley & Lardner LLP

©2010 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60654 • 312.832.4500

Six Year Look Back Period

- Proposed Rule had required ten years (the "outer limit of the False Claims Act statute of limitations")
- Note that the six-year look back period is:
  - Not retroactive
  - Not effective until March 14, 2016
  - Six years counted back from identification
- Six years is consistent with:
  - CMPL Statute of limitations
  - Basic statute of limitations under FCA
- But longer than current reopening period and longer than period CMS has required providers to review under SRDP for Stark.

©2016 Foley & Lardner LLP

What does it mean to "identify" an overpayment?

- Not defined in the ACA
- CMS Final Rule does several important things
- First,
  - Continues to incorporate more than just actual knowledge, but removes specific reference to the reckless disregard and deliberate ignorance standards, which were used under the proposed rule and are used under the FCA and CMPL
  - CMS has "programmatic concern" with "ostrich defense":
    - *i.e.*, Avoiding responsibility to report and return overpayments by avoiding taking action to obtain actual knowledge of an overpayment

©2016 Foley & Lardner LLP

©2010 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60654 • 312.832.4500

What does it mean to “identify” an overpayment?

- Second, incorporated principle (“obligation”) of “reasonable diligence” (“reasonable inquiry” in Proposed Rule).
  - Both “proactive” and “reactive”
  - 60 day clock does not start running until after reasonable diligence has concluded.

©2016 Foley & Lardner LLP

What does it mean to “identify” an overpayment?

- Third, providers have not identified an overpayment until the amount of the refund has been “quantified”
  - Has been significant issue for providers
  - 60 days is often not enough time to quantify (even roughly) an overpayment

©2016 Foley & Lardner LLP

©2010 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60654 • 312.832.4500

What does it mean to “identify” an overpayment?

- Fourth, a timely reasonable diligence investigation may take “at most 6 months from receipt of the credible information, absent extraordinary circumstances”
  - “Extraordinary circumstances” include “unusually complex investigations that the provider or supplier reasonably anticipates will require more than six months to investigate”
  - Stark investigation expressly referenced as “unusually complex”

©2016 Foley & Lardner LLP

What does it mean to “identify” an overpayment?

- Consequently:
  - An overpayment should be reported and returned no later than eight months from the receipt of credible information –
    - Six months of reasonable diligence plus 60 days for reporting and returning

©2016 Foley & Lardner LLP

©2010 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60654 • 312.832.4500

Kane v. Healthfirst, Inc. (Continuum), Case No. 1:11-cv-02325-ER, (S.D.N.Y 2015)

- "[T]he sixty (60) day clock begins ticking when a provider is put on notice of a potential overpayment, rather than the moment when an overpayment is conclusively ascertained."
  - Acknowledged that this interpretation "would impose a stringent—and, in certain cases, potentially unworkable—burden on providers," but found no leeway in the language of the ACA
  - Court mentioned potential for "prosecutorial discretion" when "well-intentioned healthcare providers" address overpayments "with reasonable haste"
- CMS's Final Rule is a rejection of the Kane standard for the Medicare Parts A & B overpayment refund duty.

©2016 Foley & Lardner LLP

Refund Processes

- Providers can use any appropriate process to return overpayments
  - Claims adjustments
  - Credit Balances
  - Voluntary offset
  - OIG Self-Disclosure Protocol
  - CMS Self-Referral Disclosure Protocol
- NOT just existing MAC voluntary refund processes

©2016 Foley & Lardner LLP

©2010 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60654 • 312.832.4500

Underpayments

- “Outside scope” of rulemaking
- CMS declined to extend one-year period to rebill claim
- CMS declined to permit offsets of identified underpayments from identified overpayments
- Underpayments must continue to be resolved under existing reopening rules

©2016 Foley & Lardner LLP

What Else Did CMS Say?

- No *de minimis* threshold
- Explanation of statistical sampling methodology required (if used)
- Clarifications on cost reporting
- AKS issues
- SRDP and OIG SDP toll 60 days, but disclosures to DOJ or MFCU do not.
- Administrative Burden

©2016 Foley & Lardner LLP

©2010 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60654 • 312.832.4500

What to Do Now

- Review and revise your overpayment policy
- Review and revise, if needed, your document retention policies
- Evaluate your processes for conducting internal investigations and update as needed
- Update training in these areas and conduct supplemental training

©2016 Foley & Lardner LLP

Questions?

Lawrence Vernaglia, JD, MPH
Chair, Health Care Industry Team
Foley & Lardner LLP
111 Huntington Avenue
Boston, MA 02199
617-342-4079
lvernaglia@foley.com

Heidi A. Sorensen, Esq.
Foley & Lardner LLP
3000 K Street, N.W.,
Suite 600
Washington, D.C. 20007
202-672-5596
hsorensen@foley.com

©2016 Foley & Lardner LLP

©2010 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60654 • 312.832.4500