What's the Future of the CMS 60-Day Repayment Rule?

Can Negligence Really Trigger False Claims Act Exposure?

AHLA Physicians and Hospitals Law Institute
February 2018

Andrew Ruskin
Morgan Lewis & Bockius
(202) 739-5960
andrew.ruskin@morganlewis.com

Barbara Rowland
Post & Schell, P.C.
(202) 661-6945
browland@postschell.com

Agenda

- History/background of 60-Day Repayment Rule
- Meaning of “Overpayment” & “Identification”
- Guidance on “Credible Information”
- Cost reporting issues and interpretation of “applicable reconciliation”
- Reporting and returning overpayments
- Conducting an internal audit
- Responding to external audits
- Intersection of the 60-Day Repayment Rule and the FCA
  - Medicaid 60-Day Rule
- Implications of the United Healthcare Insurance Company’s suit against CMS

History and Background of 60-Day Repayment Rule

History and Background

- 1128B(a)(3) of the Social Security Act

Whoever . . .having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized . . . [shall face criminal penalties]

History and Background *(cont.)*

- OIG Compliance Program Guidance
  - Requires reporting within 60 days of "credible evidence" of a violation of criminal, civil, or administrative law

- CMS issued two proposed rules on repayment obligations, but never finalized
  - Would have required reporting and returning overpayments within 60 days of identification

History and Background *(cont.)*

- ACA enacted Section 1128J(d) (42 U.S.C. § 1320a-7k(d))
  - Must "report and return" overpayment and notify government of the reason for the overpayment
  - Must make repayment:
    - within "60 days after the date on which the overpayment was identified;" or
    - at time of cost report filing (if applicable)
  - Overpayments may require "reconciliation" before due

History and Background *(cont.)*

- ACA intersection with False Claims Act
  - Congress specified that overpayments to Medicaid & Medicare, if not returned w/i 60 days, would become subject to FCA fraud damages and penalties
  - "Any overpayment retained by a person after the deadline for reporting and returning the overpayment… is an obligation under the False Claims Act."
- False Claims Act is a civil statute oft-described as the government's "most effective tool" to combat fraud, waste, and abuse of government funds
- Generally, FCA prohibits false claims involving government funds or property

History and Background *(cont.)*

- Part A/B (Physicians and Hospitals)
  - Proposed rule published on Feb. 16, 2012
  - Final rule published on Feb. 12, 2016
- Part C/D (Medicare Advantage plans and Drug Benefits)
  - Proposed rule published on Jan. 10, 2014
  - Final Rule published on May 23, 2014
- Medicaid
  - No rule published
  - Limited FCA case law development

Meaning of “Overpayment”

Meaning of "Overpayment"

- Defined as "any funds that a person has received or retained under title XVIII of the Act to which the person, after applicable reconciliation, is not entitled under such title."
- Overpayments include (in CMS's view):
  - Payments tainted by AKS violations
  - Payments without documentation support
  - Medicare secondary payments
- No right to offset underpayments
- No *de minimus* exception

Meaning of “Identification”

Meaning of Identification

- Part A/B provider has "identified" an overpayment when it "has, or should have, through the exercise of reasonable diligence, determined that [it] has received an overpayment and quantified the amount of the overpayment"

- Same definition for Part C/D providers except no "quantification" period because CMS, not providers, quantify provider payments

Meaning of Identification

- What should “identified” mean in practice?
  - When you first learn of a potential overpayment, such as through a compliance hotline?
  - When you verify that a billing error has occurred?
  - Should have become aware of the billing error through proactive compliance reviews?

- All of the above?

Guidance on "Credible Information"

Guidance on "Credible Information"

- Responding to "credible information" is a subset of "reasonable diligence," which includes proactive monitoring and reactive investigating
- "Credible information" is not the same as "identification" – it is what triggers the duty to investigate
- "Credible information" includes information that supports a reasonable belief that an overpayment may have been received

Guidance on "Credible Information" *(cont.)*

- Acting on "credible information"
  - Providers have 6 months from receipt of credible information to investigate and decide if in fact they have an overpayment or not
  - Providers that receive credible information but do not have proactive measures to monitor for such credible information, and therefore do not know that they have credible information, have liability 60 days after receipt
  - "Credible information" is credible information, no matter who in the organization receives it

Guidance on "Credible Information" *(cont.)*

- Acting on "credible information" *(cont.)*
  - CMS's view is that even a *single claim* that has been overpaid can be "credible information" that requires further investigation
  - CMS's further view is that extrapolation is *always* appropriate, no matter what the error rate from a probe sample
- CMS acknowledges, however, that it is only concerned with 60 Day Repayment Rule implementation and is not describing whether FCA liability is triggered

Cost Reporting Issues and Interpretation of “Applicable Reconciliation”

Cost Reporting Issues and Interpretation of "Applicable Reconciliation"

- "Applicable reconciliation" is the filing of the cost report (for reimbursement matters calculated through the cost report)
  - CMS declined to use cost report settlement as the trigger for reconciliation
- Issues identified after the initial submission must be disclosed through the filing of an amended cost report
- Exceptions are the SSI fraction and outlier recalculations, where reconciliation occurs at cost report settlement

Cost Reporting Issues and Interpretation of "Applicable Reconciliation" *(cont.)*

- Issues subject to "applicable reconciliation" include:
  - DSH
  - GME
  - Bad debt
  - Organ transplant
- What about SCH status? Provider-based status?

Reporting and Returning Overpayments

Reporting and Returning Overpayments Timetable

- Part A/B – 6 months to investigate PLUS 60 days to report and return = 8 months
- Part C/D – 60 days after identifying (or should have identified) erroneous risk adjustment data
- Medicaid – 60 days after identifying although term not defined by CMS

Reporting and Returning Overpayments Timetable

- Lookback periods
  - Part A/B – providers must report and return overpayments identified within 6 years of when overpayment received
  - Part C/D – Medicare Advantage and Part D sponsors must report and return overpayments they identify within 6 most recent payment years (for which there has been a reconciliation)
  - Medicaid – not specified, but 6 years is likely; state law may have separate lookback period

Reporting and Returning Overpayments

- Practice tips
  - Train all employees on “chain of command” should concern about erroneous data arise
  - Use competent compliance, finance, and legal support to conduct review and interact with CMS
  - Consider early disclosure to CMS and keep CMS informed of status of review
  - Document your actions and maintain those records to demonstrate your good faith
  - Schedule out a timeline of when certain events must occur and follow-through

Conducting an Internal Audit

Conducting an Internal Audit

- Proactive and reactive reviews are necessary
- Proactive reviews are not necessarily based on “credible information”
  - Work Plans should establish what is the basis for a review and expressly state where an entry is not based on credible information

Conducting an Internal Audit *(cont.)*

- Sources for proactive review work plan entries can include:
  - OIG Work Plan
  - New policies
  - Auditing corrections to prior instances of non-compliance
  - Other stakeholders within the organization
  - Reviewing and assessing LCDs and MLN Matters

Conducting an Internal Audit *(cont.)*

- Sources of "credible information" triggering a reactive review
  - Hotline calls
  - Allegations of misconduct
    - Falsification of medical records
    - Potential AKS/Stark violations
  - Uncovering evidence that conditions of payment had not been met
  - Unexplained pattern of, or increase in, payment denials
  - PEPPER reports, etc.
  - CMS would include unexplained increases in payment
  - External audits (but only in some cases)

Conducting an Internal Audit *(cont.)*

- Determining the Audit Scope
  - The scope will determine the size of the universe, as well as the potential exposure
  - Question is how the uncovered item (or work plan item) creates some form of "reasonable belief"
  - For example, if a hospital learns that some of its PT services were medically unnecessary, does it need to do an audit of all of its PT services? Suggestions for trying to focus on the potential problem include:
    - Determining if the services were all furnished by the same therapist
    - Determining whether only a small number of procedures are involved
    - Determining if only a certain patient type is affected
    - Determining if the problem existed only during a certain timeframe

Conducting an Internal Audit *(cont.)*

- Structuring the Audit
  - Probe audit vs. statistically valid random sample
    - How much knowledge does the auditor already have? Is it no longer appropriate to do a mere probe audit?
  - Determining the unit
    - Is it a claim? Is it contracts where FMV issues are questioned? For medical necessity of a series of services, is the patient the unit?
  - The structure of the audit must reflect the nature of the information that formed the "reasonable belief" of an issue and generate reliable results

Conducting an Internal Audit *(cont.)*

- Audits should be based on a policy, which can include:
  - Key definitions, such as “credible information,” “reasonable diligence,” and “overpayment”
  - Which payers the policy applies to
  - Who in the organization can conduct the audit
  - When a statistical sampling is to be used
  - What constitutes an acceptable error rate
  - How to effectuate repayment, including timelines
  - When to conduct the audit under privilege or otherwise consult Legal regarding the structure of the audit
  - Corrective actions and reaudits
  - Applicable stakeholders within the organization

Conducting an Internal Audit *(cont.)*

- Once a policy is finalized, there must be competent training.
  - Individuals within the organization must know when to report.
  - It is also critical that individuals learn that words have meaning. Words like “identification” and “overpayment” should only be used once the policy processes have been followed and an official determination has been rendered.

Responding to External Audits

Responding to External Audits

- CMS expressly states that contractor audit findings (including cost report adjustments) are "credible information"
  - OIG routinely states that auditees must comply with the 60 Day repayment rule based on audit report findings
- CMS states that must go beyond original audit scope once have audit findings
- CMS acknowledges that, if a denial is appealed, it would be premature to perform more diligence

Responding to External Audits *(cont.)*

- Questions to ask when deciding whether an audit has led to "credible information"
  - Is the provider appealing or protesting the determination?
  - Is the issue one like medical necessity, where the findings are likely unique to the patients reviewed?
  - What level of authority is the auditor basing the finding on? Regulation? Manual?
  - Has the law or interpretation recently changed?
  - Have other auditors looked at the same records and determined that the provider billed appropriately?
- If there is "credible information," then make sure the scope of the follow-on review is well-defined.

Intersection of the 60-Day Repayment Rule and the FCA

FCA Basics: What is Prohibited Claims and Obligations

- 31 U.S.C. § 3729(a)(1)(A) & (B): presenting or causing to be presented a false claim to government or making or using a false record or statement material to a false claim
- 31 U.S.C. § 3729(a)(1)(G): using false record or statement to reduce or avoid an obligation to the government, or improperly avoiding or reducing an obligation to pay or transmit money to the government
  - An obligation is an established duty, whether or not fixed, arising from the retention of any overpayment

FCA Basics: What is Knowledge

- Knowing of submission of false claim:
  - Actual knowledge of the relevant information
  - Reckless disregard of the truth or falsity of the information
  - Deliberate ignorance of the truth or falsity of the information
- Specific intent is not required
- But innocent mistake or negligence is not enough

Medicaid 60-Day Rule

- CMS has not promulgated a rule applicable to Medicaid providers
- In the context of a False Claims Act case, one court has ruled that for Medicaid claims the 60-day clock starts to run after the provider receives *notice of a potential overpayment*
  - *United States ex rel. Kane v. Continuum Health Partners*, 120 F. Supp. 3d 370 (S.D.N.Y. 2015)

Continuum Case – Background

- Continuum hospital system billed Medicaid as secondary payor even though its MCO received fixed payments for services provided
- New York State Comptroller raised the issue with Continuum
- Continuum assigned relator to team conducting billing review
  - Relator sent management an email attaching spreadsheet of more than 900 potential billing errors, noting further analysis was needed to confirm the accuracy of the findings
  - Four days after sending the spreadsheet to management, relator was terminated
- 60 days after sending the spreadsheet (notice?), relator filed an FCA case
- Continuum did nothing with potential errors until DOJ investigated

Continuum Case – Analysis

- Continuum moved to dismiss arguing DOJ failed to state a claim because notice of relator's spreadsheet with potential errors was not the same as Continuum "identifying" overpayments
- Court disagreed
  - Overpayment is identified when a provider is put on "notice" of a potential overpayment, rather than when the error is conclusively established
  - "Identified" definition is same as FCA "knowledge," *i.e.*, actual knowledge, reckless disregard, and willful blindness
  - Continuum alleged to have been willfully blind to the spreadsheet's potential errors because it took no action to investigate further until DOJ appeared

Continuum Case – Analysis

- Court looked to FCA amendment legislative history and Part A/B proposed rule and Part C/D Final Rule for guidance
  - Although CMS rules had no legal effect on Medicaid and no judicial deference required, court observed its holding was "at least consistent with" CMS rules
- Court acknowledged the "unforgiving" timeline for providers and noted that for diligent providers, law enforcement unlikely to pursue FCA claims for refunds past 60 days

Implications of the Unitedhealthcare Insurance Company's Suit Against CMS

Unitedhealthcare (UHC) Litigation

- In January 2016, UHC filed a Complaint for Declaratory and Injunctive Relief against CMS in the U.S. District Court for the District of Columbia
- Two principal issues raised by UHC:
  - Part C/D Final Rule imposes FCA liability for reverse false claims based on a negligence standard neither included in the FCA's knowledge requirement nor contemplated by the ACA's "identified" language
  - The Part C/D Final rule violates the statutory mandate of "actuarial equivalence" between traditional Medicare Fee-For-Service (FFS) plans and Medicare Advantage (MA) plans

UHC Litigation

- Separately, in California, two relators, joined by DOJ, brought FCA cases against UHC entities alleging overpayments arising from risk adjustment data that did not accurately reflect the health risk of patients
  - UHC allegedly conducted retrospective reviews to find diagnosis codes that had not been submitted, but did not delete unsupported diagnostic codes that it discovered during the reviews
  - Overlap with UHC "actuarial equivalence" dispute because CMS could potentially require UHC to delete unsupported diagnostic codes as a proactive compliance measure or otherwise impose FCA overpayment liability
  - Medicare FFS not required to clean up unsupported diagnostic codes because paid on a claims basis

UHC Litigation – Motion to Dismiss

- In the District of Columbia, CMS moved to dismiss the Complaint, arguing that UHC lacked standing and the court lacked subject matter jurisdiction
- District Court denied CMS's motion
  - In ruling on whether UHC had standing to sue, court had to first determine whether UHC had been injured by the rule, which included an analysis of whether the rule imposed a new legal obligation or restated an existing obligation
  - Court found that the rule imposed a new obligation by insisting that MA plans conduct proactive compliance activities under pain of FCA liability provable by negligence alone

UHC Litigation – Summary Judgment

- Negligence as a Basis for FCA Liability
  - UHC:
    - Plain and unambiguous meaning of "identified" as used in the ACA requires actual knowledge
    - Even if "identified" was ambiguous, CMS' interpretation is unreasonable given the ACA's legislative history and the well-established scope of FCA liability
    - CMS pulled a "surprise switcheroo" in violation of the Administrative Procedures Act by publishing a final rule incorporating a negligence standard, when the proposed rule only referenced a recklessness standard

UHC Litigation – Summary Judgment

- Negligence as a Basis for FCA Liability
  - CMS:
    - Focuses entirely on the "reasonable diligence" portion of the rule rather than the "should have identified" language
    - Part C/D Final Rule's use of "reasonable diligence" incorporates pre-existing duty of MA plans to undertake "due diligence" in submitting accurate, complete, and truthful risk adjustment data
    - "Should have been identified" is not a negligence standard, but rather it is a "reckless disregard" or "willful blindness" standard

UHC Litigation – Summary Judgment

- Overpayment Rule Violates Statutory Mandate of Actuarial Equivalence
  - UHC:
    - Statute establishing MA program requires HHS to ensure "actuarial equivalence" between MA and Medicare FFS programs and to use the "same methodology" to calculate the risk scores of MA beneficiaries as it does Medicare FFS beneficiaries
    - Risk scores for MA plans account for unsupported diagnostic codes, thus no need for MA plans to delete them
  - CMS:
    - MA plans have always been responsible for supplying complete and accurate data, including diagnostic codes

UHC Litigation – Why Does It Matter?

- Resists challenge to FCA knowledge standard through CMS "should have known" standard
- Questions whether holding providers responsible under FCA liability for what they "should have known" through "exercise of reasonable diligence"
  - Proactive compliance reviews
    - Who gets to decide what is reasonable?
    - Opportunistic whistleblowers?
- Holds government agencies accountable for their knowledge of providers' technical non-compliances with regulations
  - Consistent with Supreme Court Escobar decision requiring "rigorous" materiality standard for FCA liability

Questions?

Andrew Ruskin
Morgan Lewis & Bockius
(202) 739-5960
andrew.ruskin@morganlewis.com

Barbara Rowland
Post & Schell, P.C.
(202) 661-6945
browland@postschell.com