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NEW ENGLAND HEALTHCARE INTERNAL AUDITORS INC.

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New CMS 60-Day Rule Revisions:

KEY CHANGES IMPACTING REPORTING AND RETURN OF MEDICARE/MEDICAID OVERPAYMENTS

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Agenda

- What is the 60-Day Overpayment Rule?
  - History
    - Who Created It and When?
    - What is an Overpayment?
    - Why?
    - Who does it apply to?
- Latest Revisions
- Potential Impact on Providers
- Discussion and Questions

What is the 60-Day Rule?

- The 60-Day Rule governs the reporting and returning of overpayments of government funds received by health care providers and organizations.
- 60-Day Rule enacted under Section 6402(a) of the Affordable Care Act in 2010, which established new Section 1128(d) of the Social Security Act.
- Statutory 60-Day Rule codified at 42 U.S.C. 1320a-7k(d).
- 60-Day Rule regulations promulgated (and updated from time to time) by CMS, as discussed further herein.

What is an Overpayment?

- An “overpayment” includes any Medicare or Medicaid funds received by a “person” that the person is not entitled to retain after an applicable reconciliation.

- A “person” under the statutory 60-Day Rule includes a provider of services, supplier, Medicaid managed care organization, Medicare Advantage organization, or PDP sponsor, but does not include Medicare/Medicaid beneficiaries.

Federal False Claims Act

- Federal False Claims Act (FCA) is a longstanding federal civil law implicated whenever a person or entity knowingly submits, or causes to submit, false claims to the government (directly or indirectly). Violators potentially face:
  - Treble damages.
  - Civil per-claim penalties of up to $28k+ per false claim.
- FCA also prohibits concealing or avoiding obligation to repay money/property to government, i.e. a “reverse” false claim.
- No proof of specific intent to defraud required to be liable under the FCA.

- Enforced by the government **and by whistleblowers** (qui tam relators)

What does the 60-Day Rule require?

- Statutory 60-Day Rule requires individual and institutional providers (among other "persons" subject to the law) to report and return an overpayment of Medicare or Medicaid funds no later than:
  i. 60 days of the date on which the overpayment is "identified," or
  ii. the date any corresponding cost report is due, if applicable.

  - The term "identified" is not defined in the statute.

- Statutory 60-Day Rule also requires a person who has received an overpayment to notify the entity to which an overpayment is returned "in writing of the reason for the overpayment."

60-Day Rule – CMS Rulemaking

- Providers had to wait until 2014 (for Medicare Parts C and D) and 2016 (for Medicare Parts A and B) for final rulemaking by CMS that established 60-Day Rule regulations:
  - 42 CFR 422.326 = Medicare Part C Overpayments Regulation
  - 42 CFR 423.360 = Medicare Part D Overpayments Regulation
  - 42 CFR Part 401, Subpart D = Medicare Parts A and B Overpayments Regulations
- This delay in guidance led to litigation regarding applicability of the 60-Day Rule to compliance audits, including in *U.S. ex rel. Kane* (discussed herein).

60-Day Rule – CMS Rulemaking

- 60-Day Rule statute spurred questions and concerns across health care industry regarding when an overpayment was “identified” and thus subject to the strict reporting timeline.

- 2016 Final Rule – CMS indicated that:
  - An overpayment is identified when a provider has, or should have through the exercise of reasonable diligence, determined that the Provider received an overpayment and quantified the amount of the overpayment.
  - Providers are obligated to conduct “reasonable diligence” to identify overpayments received, which includes both proactive and reactive 60-Day Rule compliance activities.
  - 60-Day Rule is subject to a 6-year lookback period (any overpayment identified within six years of the date the overpayment was received must be reported and returned).
  - A timely investigation of potential overpayments cannot exceed 6 months, except in extraordinary circumstances.

60-Day Rule – CMS Rulemaking

- CMS further instructed in 2016 Final Rule that:
  - "Overpayment" is the difference between the amount paid and the amount that should have been paid for an applicable claim.
    - For providers that submit cost reports, that the 60-Day Rule is only implicated where a cost report error results in an increase in reimbursement.
- When does the 60-Day Rule time period begin?
  - When a provider completes "reasonable diligence" efforts; or
  - When the provider received "credible information" of a potential overpayment if the provider then fails to conduct reasonable diligence efforts.

“Identification” of an Overpayment

Reminder:

- Under the 2016 final rule, a person has identified an overpayment when the person has or should have, *through the exercise of reasonable diligence*, determined that the person has received an overpayment and quantified the amount of the overpayment.

- CMS declined to adopt a “scienter” standard consistent with the FCA, as had been suggested by stakeholders

Lookback Period Applies to Investigation of Overpayment

- When examining whether an overpayment has occurred and whether a pattern of overpayments may exist, the investigation should cover a period **6 years** from "the date the person identifies the overpayment."
- Key to this aspect is whether the "identification" or initial discovery of an overpayment yields reasonable suspicion that a pattern or historical recurrence may have taken place.

60-Day Rule – Proactive and Reactive Compliance Efforts

- 60-Day Rule obligates providers to conduct proactive and reactive compliance efforts to identify overpayments, including in the event a provider receives credible information of a potential overpayment.
  - Proactive compliance measures may include periodic internal audits, probe sample claims reviews, and utilization/volume monitoring for outliers; and
  - Reactive compliance efforts may include targeted audits or probes into specific errors, reviews of providers or claims/services identified by payors or regulators as outliers, or an internal investigation in the event of a complaint.

“Credible Information” of Potential Overpayments

- What constitutes “credible information” of a potential overpayment?
  - Information supporting a reasonable belief that an overpayment may have been received, including (without limitation):
    - Results of a contractor or government claims audit;
    - Discovery of at least one overpaid claim (which could spur an obligation to exercise reasonable diligence to determine if there are additional overpayments tied to the same issue);
    - Unusually high profits from a practice/provider relative to work effort; or
    - Allegations of improper conduct.

How Do You Return an Overpayment?

- CMS confirmed that overpayments can be returned in a variety of ways, including:
  - Claims adjustments
  - Credit balances
  - Self-reported refund processes
  - Other appropriate processes to report and return overpayments
- CMS: No minimum threshold for returning overpayments.
- Reminder: Must include the “reason” for the overpayment!

60-Day Rule – What about Medicaid?

- To date, CMS has still not issued any regulations addressing Medicaid overpayments.
- However, CMS has emphasized in its Medicare overpayments rules that the statutory 60-Day Rule applies to the Medicaid program.
- Notably, the definition of a "person" subject to the statutory 60-Day Rule includes "Medicaid managed care organizations."
- The *U.S. ex rel. Kane* case actually arose from a dispute regarding alleged Medicaid overpayments.

U.S. ex. rel Kane Overpayments Litigation

- 1st publicly unsealed whistleblower case under the statutory 60-Day Rule (filed in 2011).
- Involved the New York Medicaid program, and allegations that a health system provider inadvertently "balance billed" Medicaid as a secondary payor for certain managed care claims, in violation of Medicaid billing rules.
  - The duplicate claims were submitted allegedly due to a software error.
- The relator – a former employee – was tasked with identifying all affected claims, created a spreadsheet containing 890 claims, 444 of which had been impermissibly submitted to, and reimbursed by, New York's Medicaid program.
  - The amount of the alleged overpayment exceeded $800k.
- Case settled in 2016 (a few months following the issuance by CMS of its Final Rule establishing a definition of when overpayments were "identified").
  - Defendants paid $1,180,000 to the federal government and $1,770,000 to the State of New York.

Court Case Prompts Scrutiny of Reasonable Diligence Standard and Changes

- In 2018, *United Healthcare Insurance Co v. Azar* case resulted in a Federal District Court finding that "reasonable diligence" standard in the 2014 Parts C & D 60-day rule was invalid because it "improperly imposed FCA liability for mere negligence," which conflicted with FCA's knowledge standard.
  - Court noted that the FCA has a specifically-defined knowledge standard that does not encompass negligence.
- In 2021, the DC Circuit reversed the District Court, but on other grounds (CMS did not challenge the District Court's holding as to the negligence standard).
- This prompted CMS to revisit its 60-Day Rule regulations in 2022 and finalize changes in 2024.

2024: New Standard for an “Identified Overpayment”

- A person has “identified” an overpayment when an entity or individual “knowingly receives or retains an overpayment” by (1) having actual knowledge of the overpayment or (2) acting in deliberate ignorance or reckless disregard of the overpayment.
- As an important clarification on the “quantification” issue, CMS clarified that the 60-day clock starts immediately upon identifying an overpayment, regardless of whether the precise overpayment amount has been quantified at the time of identification. Absent a legitimate suspension of the deadline, the precise amount of the overpayment must be calculated in the 60-day time frame.
  - CMS: “In cases where a provider or supplier is actively investigating a potential overpayment, the 60-day period for reporting and returning the overpayment begins when the provider or supplier has actual knowledge of the overpayment.”

What About a Single Overpayment?

- As a reminder, the 60-Day Rule obligates health care organizations to undertake proactive and reactive compliance efforts to identify and return overpayments.
- Longstanding question/issue – does discovery of a single overpayment trigger an obligation to conduct an investigation?
  - CMS (in 2024): YES – "where a single overpayment is found and other related overpayments are suspected, the provider or supplier should investigate and calculate the aggregate overpayment prior to its return."

180-Day Suspension

- As an attempt to address the concerns of providers regarding the necessary amount of time required to investigate, calculate and return overpayments, the 2024 final rule allows for the suspension of the 60-day deadline for up to 180 days for the purpose of conducting a “timely, good faith investigation” to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment.
- This appears to have been intended to formalize the review practices that grew out of six-month language in the 2016 rule.

Illustration of How this Suspension Works

- Day 1: person identifies an overpayment arising from failure to properly document the medical record to support coding.
- Upon initial investigation, reason to believe this error may have been a common practice, so there may be more claims.
- Based on initial identification, 60-day timeline starts to return the overpayment.
- However, based on this belief that a pattern of more claims may exist, the 60-day deadline can be suspended up to 180 days to conduct a good faith investigation.
    - If a good faith investigation is not conducted, the overpayments are due on Day 60.
    - If the investigation is conducted, 60-day clock continues once the investigation concludes. Max time = 240 days.

There is a Catch – NO EXTENSIONS

- No additional time beyond the 240 days total, and no extensions allowed.
- Utilization of the 180-day suspension must be justified; subject to review by CMS or the courts.
- Good practice to document the investigatory steps and basis for any claimed suspension of the return clock.

Implications to Health Care Providers

- It is imperative to have robust systems that clearly document the processes and procedures for auditing, identifying, and tracking possible overpayments.
- The clarification regarding the “knowledge” standard is positive because it potentially raises the threshold for liability.
  - However, it remains ambiguous as to what specifically is required to establish liability / scienter in a reverse false claims act case.
- The removal of the “quantification” requirement also removes a valid “excuse” for delay in the overpayment process. Quantification, by itself, cannot justify a good faith investigation or the 180-day suspension.

Implications to Health Care Providers

- Using the suspension should be done sparingly and only when actual, documented justification exists.
- There is a question of whether 180 days is actually enough to truly conduct a proper investigation, given the complexity of audits and required coordination of providers, compliance department, legal department, and other clinical professionals.
- Remember that there are “eyes” in every institution and the failure of providers to properly monitor this process and ensure employee compliance with these requirements could result in an increase of whistleblower lawsuits.

Takeaways for Health Care Organizations

- **60-Day Rule** Heightens Compliance Risk of Inactivity
  - If providers have "credible information" of potential overpayments, they have an obligation to conduct compliance activities.
  - Cannot rely on the "ostrich defense" strategy.
- "Reverse" FCA Liability in connection with the 60-Day Rule is a significant new "arrow in the quiver" for relators and government/regulators.
- 60-Day Rule also heightens the risk posed by routine errors (e.g., software errors) that can quickly turn into significant potential exposure.

Takeaways for Health Care Organizations

- Organizations are well advised to document proactive and reactive compliance activities as part of compliance plans.
- Organizations must have systems in place to consistently support compliance decision making (e.g., as to the bases for initiating an investigation, or a suspension in the event of an investigation)
- Organizations must take governmental, regulator, and payor notices concerning reimbursements and potential overpayments seriously, and address them promptly.

60-Day Rule – Enforcement/Litigation Examples

- 2015: $6.88 Million Settlement (plus CIA) with DOJ by the Pediatric Services of America to resolve FCA allegations arising from alleged failure to report and return overpayments from Medicare and Medicaid
  - First of its kind settlement as it concerned the provider's alleged failure to "investigate credit balances on its books to determine whether they resulted from overpayments."
  - DOJ: federal health care program participants "required to actively investigate whether they have received overpayments and, if so, promptly return the overpayments."
  - Case originated with 2 whistleblowers.
- *2016 Kane* Case Settlement.
- 2017: DOJ reached $450k settlement with physician practice for allegedly retaining $175k in potential overpayments in violation of 60-Day Rule (overpayments arose from alleged improper retention of credit balances from federal payors).

60-Day Rule – Enforcement/Litigation Examples

- 2018: DOJ-PA enters into $12.5M settlement with health system and CEO arising out of alleged improper unbundling (via improper use of Modifier 59) of claims to “artificially inflate reimbursements.”
  - DOJ claimed that improper billing practices resulted in millions of dollars of overpayments to the defendant.
- 2024: Gentiva (f/k/a Kindred) entered into $19.4M FCA settlement to resolve allegations of knowing retention of overpayments (and submission of false claims) for hospice services.

60-Day Rule – Enforcement/Litigation Examples

- 2025: DOJ-NY announces $5M settlement (plus CIA) with non-profit provider of services for developmentally/intellectually disabled individuals in NY for “improperly avoiding the return of overpayments” received from Medicaid.
  - Overpayments arose from alleged failure to properly document services rendered in accordance with requirements of the New York State Office for People With Developmental Disabilities.

- 2025: DOJ-CT announces $427k settlement with pain management practice and its owner and notes that, even after notice of improper modifier use and assessment of an overpayment in 2019, the alleged improper practice continued for 4 additional years.

60-Day Rule – Enforcement/Litigation Examples

- Ongoing: DOJ and UnitedHealth Group are engaged in litigation over DOJ allegations of improper retention of overpayments under Medicare Advantage program.
  - Case initiated in 2011 by whistleblower, with DOJ joining in 2017.
  - 2025 Special Master Ruling: “Mere possibility of an overpayment” not enough for DOJ to carry its burden.
  - As of April 2025, DOJ was pushing back on the Special Master’s conclusions.

2025 Enforcement Priorities

U.S. Department of Justice

Criminal Division

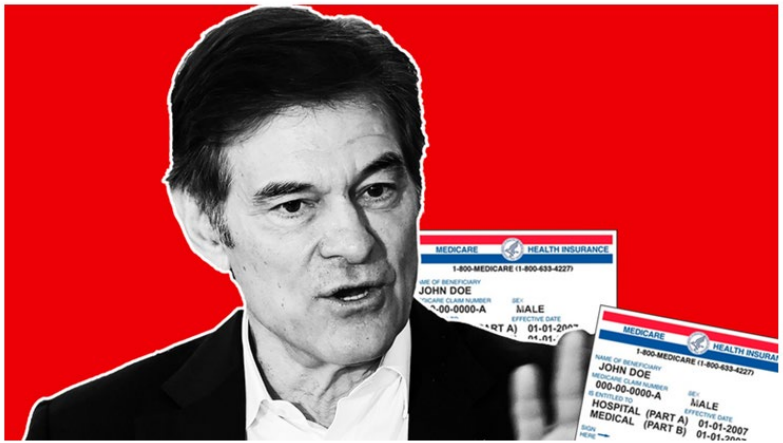
Office of the Assistant Attorney General *Washington, D.C. 20530*

- DOJ Criminal Division Memo (5/12/25):
  - "White-collar crime [] poses a significant threat to U.S. interests"
  - "Criminal Division will prioritize investigating and prosecuting white-collar crimes in the following high-impact areas:
    1. Waste, fraud, and abuse, including health care fraud and federal program and procurement fraud that harm the public fisc;"

2025 Enforcement Priorities

ALERT Up-to-the-minute breaking news

Wednesday, May 21, 2025



POLICY

CMS to crack down on Medicare Advantage overpayment

QUESTIONS?

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