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CMS 60-Day Rule: Reporting and Refunding Overpayments, Enforcement, Compliance, Self-Disclosure

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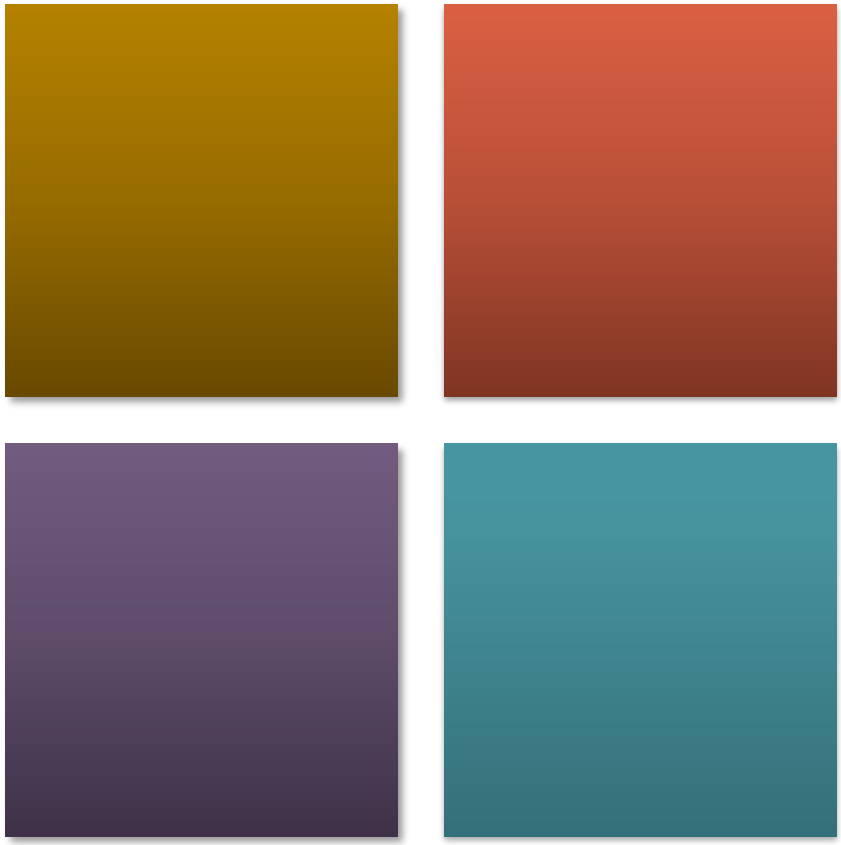

Strafford Webinar

September 13, 2018

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Agenda

1. Background on 60-Day Rule
2. Key Aspects of the 60-Day Rule
3. Compliance Safeguards
4. Discussion/Examples

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Background on the 60-Day Rule

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ACA Statutory Requirement

- On March 23, 2010, Section 1128J(d) of the Social Security Act was passed, setting forth the statutory 60-Day overpayment requirement.
- The Statute requires a person who has received an overpayment:
  - to report and return the overpayment to the government agency/contractor and
  - to notify the agency/contractor in writing of the reason(s) why the overpayment was returned.

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ACA Statutory Requirement

- Further, the Statute set the 60-Day rule stating that the overpayment must be reported and returned by the later of:
  - the date which is 60 days after the date on which the overpayment was identified, or
  - the date any corresponding cost report is due, if applicable.
- Overpayments retained after the deadline for reporting and returning an overpayment become an "obligation" under the federal False Claims Act, subject to treble damages, per claim penalties and CMPs.

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Scope of the ACA Statutory Requirement

- The Statute applies broadly:
  - Medicare Part A
  - Medicare Part B
  - Medicare Advantage/Part C
  - Medicare Part D
  - Medicaid FFS
  - Medicaid Managed Care

Overpayment Regulations

- On May 23, 2014, CMS published the Medicare Parts C and D Final Rule.
- **On February 12, 2016, CMS published the Medicare Parts A and B Final Rule, which we will discuss today.**
- No final rule has been published that addresses Medicaid requirements.

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Questions Addressed by Final Rule

- Confusion regarding the requirements, scope and impact of the ACA Statutory Requirement –
  - What does "identification" mean?
    - Does the clock start when you get the hotline call?
    - Do you have to audit the issue, calculate the repayment and repay within 60 days?
  - How far back do you have to go?
    - RACs go back 3 years; FCA goes back either 6 or 10 years; CMS has gone back 4 years for reopenings (absent fraud or similar fault)

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FCA Case from Overpayment – *U.S. ex rel. Malie v. First Coast Cardiovascular*

- Overpayment Issue –
  - According to complaint and settlement, provider "allowed" the accrual of overpayments owed to government healthcare programs.
  - When provider became aware of the obligation to return the overpayments, it failed to return the overpayments to the affected government health care programs with 60 days.
- Overpayments related to credit balances
- Provider settled for $448,821.58 on $175,000 in overpayments
- Case LESSONS: (1) Providers must be proactive in investigating potential overpayments; (2) Investigate and address (repay, etc.) credit balances and (3) Any identified overpayments must be timely repaid.

Key Aspects of the 60-Day Rule

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Key Aspects of the 60-Day Rule

- 6-Year Look Back Period
  - Amended reopening period
- What does it mean to "identify" an overpayment?
  - Reasonable diligence
  - Quantification
  - 6-month period
- Refund Processes
- How are underpayments treated (if at all)?

Six-Year Lookback Period

- Under the Final 60-Day Rule, there is a 6-year lookback period for Part A and B.
  - (The Proposed Rule had required 10 years (the outer limit of the False Claims Act statute of limitations).)
- Note that the 6-year lookback period is:
  - Not retroactive
  - Became effective March 14, 2016
  - Six years counted back from identification of overpayment

Six-Year Lookback Period (cont.)

- Six years is consistent with:
  - CMPL statute of limitations
  - Basic statute of limitations under FCA
- But longer than current 4-year reopening period and longer than period CMS had required providers to review under SRDP for Stark Law.
- There is a duty to go back beyond 3-year RAC recoveries or other government recoveries if less than the 6-year time period.

Amended Reopening Period

- The Final 60-Day Rule -
  - amended the reopening period to permit providers and suppliers to request reopening for up to 6 years in order to report and return overpayments
  - did not expand the authority of contractors to reopen paid claims not subject to voluntary disclosure
  - did not amend or eliminate the authority to reopen claims without temporal limitation for "fraud or similar fault"

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What does it mean to "identify" an overpayment?

- Not defined in the ACA
- Not just actual knowledge
- Final Rule removed the Proposed Rule's specific reference to the reckless disregard and deliberate ignorance standards

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What does it mean to "identify" an overpayment? (cont.)

- Providers have an obligation to exercise "reasonable diligence" through "timely, good faith investigation of credible information"
- Determining whether information is sufficiently credible to merit an investigation is fact-specific

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What does it mean to "identify" an overpayment? (cont.)

- CMS makes clear that identification requires both proactive and reactive auditing of billing.
- Merely auditing based on compliance hotline calls or issues raised by staff is insufficient.
- Even if an overpayment is the result of a mistake, not fraud and abuse, the provider still has an obligation to report and return the overpayment under the ACA and Final Rule.

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What does it mean to "identify" an overpayment? (cont.)

- Under the Final 60-Day Rule, an overpayment is not "identified" until the amount of refund has been "quantified"
- 60-Day clock does not start running until after the reasonable diligence period has concluded, which may take "at most 6 months from receipt of credible information, absent extraordinary circumstances"
- That means an 8-month period:
  - 6 months for timely investigation; plus
  - 60 days for reporting and returning of the overpayment

What does it mean to "identify" an overpayment? (cont.)

- "Extraordinary circumstances" include:
  - Complex internal investigations
  - Stark Law issues (under CMS Voluntary Self-Referral Disclosure Protocol)
- OIG disclosures under SDP can be completed in two steps: initial disclosure followed within 90 days by internal investigation and self-assessment
  - OIG SDP two-step process, when appropriate, is well-suited to complex internal investigations

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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.

Who is responsible for identifying/refunding overpayments?

- An entity to which a provider or supplier has assigned benefits is responsible for identification of overpayments
- However, that responsibility does not mean that the person who reassigned his/her benefits does not ALSO have responsibility
- Person who reassigned has responsibility for a fact-specific determination of the reassignor's knowledge of the circumstances leading to the overpayment

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Examples of Credible Information

- Even if an overpayment is the result of a mistake, not fraud and abuse, the provider still has an obligation to report and return the overpayment under the Final Rule
- Whether a hotline complaint constitutes "credible information" is a factual determination
- Results of a contractor or government audit are "credible information" that require the provider to conduct reasonable inquiry to confirm or contest the results
- Unusually high profits/revenue in relation to hours worked or RVUs associated with the work could constitute credible information

Notification & Refund Processes

- Final Rule allows for different refund processes beyond the MAC voluntary refund process.
- Providers can use any appropriate process to return overpayments:
  - Claims adjustments
  - Credit Balances
  - Voluntary offset
  - OIG Self-Disclosure Protocol
  - CMS Self-Referral Disclosure Protocol

Notification & Refund Processes (cont.)

- CMS specifically stated that it did not want providers to return only a subset of claims identified as overpayments and did want providers to extrapolate the full amount of the overpayment:
  - Do not refund based on specific claims from a probe sample
  - In most cases, extrapolation can be done in a timely manner consistent with the rule's identification requirements

Notification & Refund Process (cont.)

- Having individuals claims in appeal process does not suspend the 60-Day clock.
- If a contractor identifies the overpayment and notifies the provider that it will correct, then there is no need to affirmatively report, even if that process takes time.
- CMS stated that it will "consider" creating a standardized notification form.
  - CMS has not created this form, but Medicare Administrative Contractors (MACs) have revised their forms.

Notification & Refund Process (cont.)

- You can NOT refund with caveats. In other words, you can NOT refund, stating:
  - "Contested"
  - "With Reservation"
- You also can NOT, as a practical matter, change your mind or "unring the bell" once you have disclosed an overpayment so take the time on the front end to get it right
  - While CMS does suggest reopening for correction of a mistake is possible, CMS does not expect it to be a frequent occurrence.
- CMS stated that including one refund coversheet, attaching a spreadsheet with the appropriate data, is acceptable.

Underpayments

- CMS stated that underpayments were "outside the 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

What Else Did CMS Say?

- No *de minimis* threshold
- Show your work! (Statistical sampling methodology)
- Applicable reconciliation
- AKS issues
- Tolling
- Appeals
- Administrative Burden

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No *De Minimis* Threshold

- *De minimis* standard would be susceptible to abuse
- All potential overpayments should be investigated - there should not be a cost/benefit analysis of whether to commit resources to investigate a potential overpayment
- However, CMS will consider a minimum monetary threshold for cost report-related overpayments only in separate future guidance or rulemaking

Statistical Sampling Methodology

- Expect decision whether to do extrapolation to be scrutinized closely. Consider whether to explain decision as part of initial disclosure.
  - "After finding a single overpaid claim, we believe it is appropriate to inquire further to determine whether there are more overpayments on the same issue before reporting and returning the single overpaid claim."

Statistical Sampling Methodology (cont.)

- Sampling and extrapolation methodology must be explained in disclosure (if used).
- Sources of guidance:
  - OIG Self Disclosure Protocol
  - CMS Program Integrity Manual, Ch. 8.4, Use of Statistical Sampling for Overpayment Estimation
  - Outside statistical expert

Applicable Reconciliation

- Final Rule made no changes to definition of applicable reconciliation in Proposed Rule
- Applicable reconciliation occurs when a cost report is filed (subject to two limited exceptions addressing DSH and outliers)
- Industry request for broader interpretation was rebuffed

AKS Issues

- Final Rule reiterates guidance from Proposed Rule that:
  - A provider or supplier who is not a party to a kickback arrangement is unlikely to identify overpayment, and there is no duty to report or repay
  - However, if that provider or supplier does have sufficient knowledge, it should report and repay
- CMS will refer to OIG for appropriate action and suspend repayment obligation until resolved
- Enforcement focus on holding perpetrators of arrangement accountable

AKS Issues (cont.)

- Only parties to kickback are required to repay overpayment received by the innocent provider or supplier (except in extraordinary circumstances)
- Example: Hospital unaware that device manufacturer paid kickback to physician to induce physician on hospital medical staff to use particular device.

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Tolling

- Final Rule specifies that the use of the CMS Self-Referral Disclosure Protocol (SRDP) and the OIG Self-Disclosure Protocol (SDP) toll the period of time to identify and return overpayment
- Final Rule also specifies that disclosures to DOJ or the Medicaid Fraud Control Unit (MFCU) do not toll period of time to identify and return overpayment

Appeals

- Responsibility to identify, report, and return overpayments is independent of contractors' overpayment determinations
- Fact-specific
  - Contractor overpayment determination may constitute credible evidence
  - Provider may appeal contractor overpayment determination and decide it is premature to initiate investigation of identical or similar conduct until after determination on appeal

Appeals (cont.)

- Final Rule declined to create explicit appeal rights for self-identified overpayments
  - Existing appeal rights for revised initial determinations of specific claims retained
- No appeal rights for self-identified overpayments that do not involve identification and adjustments of individual claims

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Administrative Burden

- CMS's view of the burden on providers may be unrealistic:
  - Proposed rule: CMS stated that providers would return on average 3-5 overpayments per year and that it would take approximately 2-1/2 hours to research, identify, report and return an overpayment.
  - Final rule: In response to comments from the industry, CMS raised estimate to 6 hours.
- While 6 hours may be realistic for a small overpayment that does not involve statistical sampling, this is not realistic for many overpayment refunds.

Administrative Burden (cont.)

- CMS's view of who needs to be involved in the overpayments refund process may also be unrealistic:
  - Industry commented that legal and compliance professionals may need to be involved in refunds
  - CMS stated that legal and compliance professionals would only need to be involved in the "rarest of circumstances, such as potential fraud or certain investigations of the physician self-referral law."

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Compliance Safeguards

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Overpayment Policy

- Review your existing overpayment policy (or develop one if you do not yet have one)
- Revise to incorporate the key aspects of the Final 60-Day Rule (applicable to Medicare Parts A & B) that we will be discussing today

Overpayment Policy (cont.)

- Sample policies may be found:
  - On HCCA website
  - Through ACC Health Law Section
  - Websites of some providers that make their compliance policies publicly available
- But only use policies revised since Feb. 12, 2016, when the Final Rule was published

Document Retention Policies

- Review your document retention policies (or develop them if you do not yet have them)
- Many existing document retention policies are based upon either:
  - Reopening rules (4 years)
  - Medicare hospital CoP (5 years)
  - FCA statute of limitations (6/10 years)
- Revise to cover the 60-Day Rule's 6-year look-back period if not already covered by existing policies

Document Retention Policies (cont.)

- In response to industry comments, in 60-Day Rule commentary, CMS noted 5-year retention requirement for medical records from hospital conditions of participation is a minimum and industry standard is already 6 - 7 years
- CMS acknowledged that paper records are not necessary to validate claims under the lookback period and scanned or electronic records are sufficient

Internal Audits

- Evaluate your processes for conducting internal audits
  - It is helpful to have written guidelines or policies to ensure internal audits are thorough and meet certain basic requirements
- Revise to incorporate the process, timing, and reporting expectations we discuss today

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Training

- Employees involved in the process of identifying and refunding overpayments should receive updated/supplemental training on the 60-Day Rule and its impact on overpayment policies. These employees include:
  - Accounting Department
  - Audit Department
  - Compliance Department
  - Legal Department
- Certain employees should receive updated/supplemental training on any changes to document retention policies:
  - Records Department
  - IT Staff

Training (cont.)

- Certain employees should receive updated/supplemental training on changes to your internal investigation processes
  - Compliance Department
  - Legal Department
  - Audit Department
- Incorporate a high level overview of the requirement to return identified overpayments and the Final Rule into your annual employee compliance training
  - Final Rule states that the organization is responsible if employee or agent at any level has knowledge of an overpayment

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Discussion/Examples

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Discussion

- Examples
  - OIG subpoena dies on the vine
  - RAC audits for last 3 years
  - Medicaid claims issue
  - One facility in national chain finds overpayments
  - Credit Balances
- Questions
  - What obligation is there to identify and refund/notify?
  - What time frame?
  - Other considerations or unique circumstances?

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Questions?

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