



EDUCATIONAL RESOURCES

THE “60-DAY” RULE

The Affordable Care Act’s Obligation to Report & Repay Overpayments

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INTRODUCTION

- Prior to enactment of the Affordable Care Act, when a DMEPOS supplier determined that Medicare should not have paid certain past claims, then it was common for the supplier:
 - (i) not to voluntarily refund the claims, but
 - (ii) to correct the problem from a “go forward” standpoint.
- This type of “go and sin no more” response, while questionable before enactment of the Affordable Care Act (ACA), is clearly not adequate since passage of the ACA



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- Section 6402 of the Affordable Care Act states that any provider or supplier that receives an overpayment must:
 - (i) report to CMS
 - (ii) provide written notice of the reason for the overpayment
- The overpayment must be reported and returned no later than 60 days after it is identified. Failure to do so may result in civil monetary penalties under the Federal False Claims Act.
- In its final rule, CMS provided guidance regarding the obligations of providers and suppliers to report and repay overpayments.

THE “60-DAY” RULE

- The final rule addressed the “lookback period.”
 - This is the time period for which a DMEPOS supplier must examine patient files for overpayment obligations. CMS originally proposed a 10-year lookback period; however, the final rule shortened the lookback period to six years.
- The final rule stated, as a general rule, a supplier will have six months to investigate possible overpayments before the 60-day clock starts running.
 - Compare this to the proposed rule which said that the investigation should be conducted with “all deliberate speed.”

THE “60-DAY” RULE

- The final rule addressed what it means to “identify an overpayment.”
 - According to the final rule, identification occurs when a supplier “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.”
- The word “quantified” is significant. In including “quantified,” CMS responded to commentators who argued that an overpayment must be quantified before it can be reported and repaid.

THE “60-DAY” RULE

- According to the final rule:
 - “We agree and have revised the language ... to clarify that part of identification is quantifying the amount, which requires a reasonably diligent investigation.”
- The “reasonable diligence” requirement differs from the proposed rule which stated that identification occurs when a supplier “has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment.”

THE “60-DAY” RULE

- Under the final rule, a DMEPOS supplier will have identified an overpayment if:
 - (i) the supplier conclusively knows about it or
 - (ii) the supplier would have known about it by acting with “reasonable diligence”
- Although the term “reasonable diligence” gives flexibility to CMS, CMS is unlikely to punish a good faith compliance effort.

THE “60-DAY” RULE

- As stated in a court ruling involving the 60-day rule:
 - “[E]nforcement actions aimed at well-intentioned health care providers working with reasonable haste to address erroneous overpayments ... would be unlikely to succeed.”
- It is important to note that the 60-day rule requires “proactive compliance activities ... to monitor for the receipt of overpayments.” Said another way, the DMEPOS supplier must be proactive, not reactive.
- Lastly, the final rule stated that it is “certainly advisable” for suppliers to create a paper trail that serves as evidence of reasonable diligence.



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RESPONSE BY DMEPOS SUPPLIERS

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- Stripping all of the legalese away, for the DMEPOS supplier, this means:
 - The supplier must be proactive not reactive. It is not an option for the supplier to “bury its head in the sand.”
 - There may be various reasons why a supplier should not have received payment for a claim. For example:
 - (i) the supplier incorrectly used a modifier
 - (ii) the supplier’s documentation is deficient and cannot be rehabilitated
 - (iii) the claim results from actions that violate the federal anti-kickback statute, the Stark physician self-referral statute, the beneficiary inducement statute, or the telephone solicitation statute
 - If a claim should not have been paid to the supplier, then it is likely that a person knows about it. That person might be a mid-level employee in the billing department, an intake person, or a sales rep.

RESPONSE BY DMEPOS SUPPLIERS

- An employee who knows that a claim should not have been paid is a potential “whistleblower”
 - If the supplier engages in “reasonable diligence,” discovers claims that should not have been paid, and reports and repays them, then (depending on the timing involved) the whistleblower will likely not be able to proceed with a whistleblower (or “qui tam”) lawsuit
 - If a supplier knows that it should not have been paid for certain claims or if the supplier “buries its head in the sand” and does not exercise “reasonable diligence” to determine if some claims should not have been paid, then the supplier is incurring potential liability under the False Claims Act
- If claims result from violations of one of the federal statutes referenced above, then the supplier will have failed to comply with Supplier Standard #1, which can place the supplier’s PTAN in jeopardy

RESPONSE BY DMEPOS SUPPLIERS

- All of this boils down to the fact that the DMEPOS supplier needs to:
 - (i) have a robust compliance program,
 - (ii) conduct internal audits, and
 - (iii) have an outside auditor come in periodically to conduct audits.
- In implementing a “robust compliance program,” the supplier should:
 - (i) examine its document retention,
 - (ii) examine how claims are submitted,
 - (iii) determine if any of its operations violate the anti-fraud laws referenced above, and
 - (iv) provide regular training to employees.



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KANE V. HEALTHFIRST, INC., ET AL

KANE V. HEALTHFIRST, INC., ET AL.

- On August 3, 2015, a district court in New York issued the first opinion in the country addressing this issue.
- In *Kane v. Healthfirst, Inc., et al.*, the court denied the hospital defendants' motion to dismiss the case after finding that the government had stated a claim against the hospitals under the False Claims Act.
- The hospitals in this case are several affiliated hospitals in New York that erroneously billed New York Medicaid as a secondary payor due to a software glitch.
- The hospitals assigned an employee to investigate the potential software problem in 2011 and it was that employee (Kane) who later brought a qui tam suit against the hospitals alleging violations of the False Claims Act.

KANE V. HEALTHFIRST, INC., ET AL.

- Kane sent an email to certain hospital executives in February 2011 detailing a list of 900 claims totaling over \$1 million that were potentially improperly billed.
- The hospitals started making some repayments of those claims after receiving Kane's email but did not repay the majority of those claims until 2013 after being served with a Civil Investigative Demand from the U.S. Department of Justice.
- Kane filed a *qui tam* complaint under seal in 2011, and the government chose to intervene in the case in 2014.

KANE V. HEALTHFIRST, INC., ET AL.

- At issue in this opinion was a motion to dismiss the case filed by the defendant hospitals.
- The hospitals argued that they had not identified the overpayments at the time of Kane's email in 2011 because the email was only a list of potentially erroneous payments which were not classified as overpayments with any certainty.
- Thus, the defendants argued that the potential overpayments were not "identified" in the email.
- The government's argument, which the court ultimately accepted, is that overpayments are identified when "a person is put on notice that a certain claim may have been overpaid."

KANE V. HEALTHFIRST, INC., ET AL.

- The court arrived at this conclusion after a long analysis of a number of items including the plain meaning of the words at issue, legislative history, and the potential ramifications of adopting each party's proposed definition.
- The court noted that its decision imposed a demanding standard on providers and suppliers.
- Ultimately, in adopting the government's position on the definition of "identified," the court determined that the defendant hospitals were not entitled to have the case dismissed and that the parties would have to proceed with litigation.

KANE V. HEALTHFIRST, INC., ET AL.

- The Kane case was settled.
- New York City-based Mount Sinai Health System agreed to pay \$3 million to resolve the allegations against it.
- Approximately \$1.8 million of the settlement went to the state of New York and approximately \$1.2 million went to the federal government.
- Whistleblower Robert P. Kane, who was allegedly fired after reporting the overpayments, received roughly \$350,000.
- Mount Sinai's payout is more than triple the nearly \$850,000 that its hospitals took two years to repay after learning about inadvertent double-billing of Medicaid.



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ACTIONS BY NORIDIAN AND CGS

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- The risk of violating the “60-Day Rule” and, hence, the risk of violating the False Claims Act has recently been ratcheted up.
- In June 2018, the OIG released a report entitled *Most Medicare Claims for Replacement Positive Airway Pressure Device Supplies Did Not Comply With Medicare Requirements* (“Report”).
- The Report findings were a result of previous OIG work that found that Medicare allowed replacement of positive airway pressure (“PAP”) device supplies more frequently than what is reasonable and necessary and that DME suppliers often do not have the documentation required to support the need for replacement supplies.

ACTIONS BY NORIDIAN AND CGS

- In preparing the report, the OIG selected a statistical sample of 110 claims for replacement PAP device supplies that Medicare paid in 2014 and 2015 and reviewed the supporting documentation from the supplier to determine whether that documentation complied with Medicare requirements.
- Of the 110 claims in the sample, 24 complied with Medicare requirements while 86 claims with payments totaling \$13,414 did not.
- On the basis of the sample results, the OIG estimated that Medicare made payments of \$631,272,181 for replacement PAP device supply claims that did not meet Medicare requirements.

ACTIONS BY NORIDIAN AND CGS

- According to the OIG, errors in these claims included:
 - Physicians' orders were not in accordance with LCDs
 - Replacement supplies were not reasonable or necessary
 - Supplier did not have a proper request for replacement supplies
 - Supplier did not document continued need for PAP device therapy and supplies
 - Supplier dispensed more supplies than allowed
 - Supplier had no proof of delivery
 - Supplier did not respond to requests for documentation

ACTIONS BY NORIDIAN AND CGS

- In the Report, the OIG recommended that, among other steps, the Medicare contractors should notify 82 suppliers associated with the 86 claims containing potential overpayments and instruct the suppliers to exercise reasonable diligence to investigate and return any identified overpayments.
- The OIG further recommended that the contractors inform the suppliers that, in accordance with the “60-Day Rule,” the suppliers should identify and return identified overpayments.
- As a result of the Report, a number of suppliers received notices from Noridian and CGS advising them to “review claims submitted related to replacement PAP device supplies to determine if overpayments exist within the 6-year lookback period.”
- Noridian and CGS are encouraging suppliers to use statistical analysis to determine a valid sample that can be extrapolated into the universe to determine the claims to be reviewed versus a review of all claims billed in the last 6 years.

ACTIONS BY NORIDIAN AND CGS

- Suppliers have 180 days (6 months) to conduct the review and identify any overpayments and, by statute, will have 60 days (2 months) to report and return overpayments.
- In total, suppliers have 240 days from the date of the notification letter to complete the investigation, identify overpayments, and make the necessary arrangements with the MACs to refund.
- What makes the Noridian and CGS letter ominous is that under the “60-Day Rule,” the letter sets up the supplier for potential liability under the False Claims Act.

ACTIONS BY NORIDIAN AND CGS

- Assume that
 - (i) the supplier ignores the letter, the supplier does not respond, and the contractor audits the claims described in the letter; or
 - (ii) the supplier does not audit its files but simply reports to the contractor that the claims are proper, and the contractor audits the claims described in the letter; or
 - (iii) the supplier audits its files, the supplier reports to the contractor that the claims are proper, and the contractor audits the claims described in the letter.

ACTIONS BY NORIDIAN AND CGS

- Assume that in any of these scenarios, the contractor concludes that all or some of the claims are improper.
- There is a risk that the contractor will turn its findings over to the OIG. If this occurs, then there is a risk that the OIG and the Department of Justice will instigate an investigation of the supplier under the False Claims Act.
- The bottom line is that the supplier should take the CGS/Noridian letter seriously.
- The wisest course of action is for the supplier's health care attorney to hire a consultant to conduct the audit.

ACTIONS BY NORIDIAN AND CGS

- An experienced consultant will have the statisticians available to conduct a statistical analysis and determine a valid claims sample.
- The consultant will report to the attorney, and in turn, the attorney will report the findings back to the supplier. This way, the audit results will be protected by the attorney-client privilege.
- By following these steps, the supplier can control how and when to disclose the audit results.
- The supplier should report its findings to the contractor.
- If the audit reveals that some claims should not have been paid, then the supplier should voluntarily repay those claims.



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QUESTIONS?



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THANK YOU

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