A New Trend – OIG Mandated Six-Year Lookback Audits and Voluntary Refunds

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Background

- February 12, 2016, CMS issues its final rule that implemented Section 6402 of the Affordable Care Act.
- These rules were effective March 14, 2016.
- 1128J(d) of the Social Security Act.
- 42 CFR Section 401.305 – Requirements for reporting and returning of overpayments.

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Key Provisions

- Meaning of "Identification"
  - 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.
- Lookback Period
  - Reduced from 10 years to 6 years in the final rule.
- How to report and return overpayments.
  - Suppliers must use an applicable claims adjustment, credit balance, self-reported refund, or another appropriate process to satisfy the obligation to report and return overpayments.
  - Must be done in 60 days of identification.

Key Provisions

- Identification of overpayments through the exercise of reasonable due diligence.
  - Proactive compliance activities.
  - Investigative activities in response to credible information about potential overpayments.
    - This includes, per CMS, overpayments identified by contractors, including RACs and UPICs.
- 6 months is a benchmark for investigation
- 60 days to refund
- 6-year lookback period
- No minimum monetary threshold

OIG Report

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

MOST MEDICARE CLAIMS FOR REPLACEMENT POSITIVE AIRWAY PRESSURE DEVICE SUPPLIES DID NOT COMPLY WITH MEDICARE REQUIREMENTS

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Daniel R. Levinson
Inspector General

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What OIG found

- Out of 110 claims in the sample, 86 claims did not meet Medicare requirements.
- Total overpayment in the sample: $13,414
- Extrapolated overpayment: $631.3 million
- "These overpayments occurred because CMS oversight of replacement PAP supplies were not sufficient to ensure that suppliers complied with Medicare requirements or to prevent payment of claims that did not meet those requirements."

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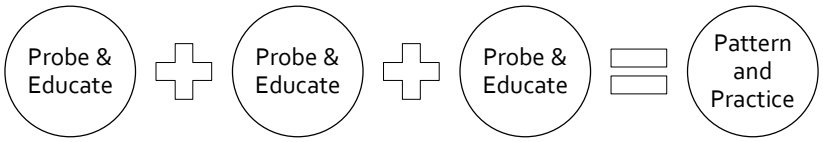
What OIG recommended

- Instruct Medicare contractors to recover the portion of the overpayments of $13,414 associated with the 86 sample claims that are within the 4-year reopening period.
- Work with Medicare contactors to establish periodic reviews of claims for PAP supplies.
  - Increased volume of TPE and SMRC for PAP supplies.
- Take remedial action for suppliers that contractors find consistently bill claims that do not meet requirements.

Revocation Risks

- CMS issued a NEW Final Rule for safeguards to reduce Medicare fraud – December 3, 2014.
  - Under authority of the ACA, CMS can and will deny or revoke enrollment of entities and individuals that pose a program integrity risk to Medicare for the following:
    - "… providers and suppliers that have a **pattern and practice of billing for services that do not meet Medicare requirements**. This is intended to address providers and suppliers that regularly submit improper claims in such a way that it poses a risk to the Medicare program."
- In the preamble to 42 CFR 424.535(a)(8), CMS established the proposition that 3 or more non-compliant Medicare claims constitutes a pattern of abuse.

Proving a pattern or practice



What OIG recommended

- Instruct the Medicare contractors to notify the 82 suppliers associated with the 86 denied claims to "exercise reasonable due diligence to investigate and return any identified overpayments, in accordance with the 60 day rule, and to identify and track any returned overpayments as having been made in accordance with this recommendation."

Contractor Instructions

- As required by 42 CFR 401.305, a provider/supplier who has received an overpayment must report and return within 60 days after having identified the overpayment.
- This requirement applies to overpayments identified within 6 years of the date the overpayment was received.
- Please review the claims you have submitted related to replacement PAP device supplies to determine if overpayments exist within the 6-year lookback period.

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Contractor Instructions

- Provide a written description of:
  A. How each self-assessment was conducted.
  B. The universe, sample size, and service dates of the claims identified and reviewed in the self-assessments.
  C. The statistically valid sampling and extrapolation methodology used to identify the universe and samples.
  D. If extrapolation/sampling was not used, details of how you completed the self-assessment, including a statement that you individually reviewed the entire universe of those claims it identified for review.
  E. Include details that allow extrapolation/sampling to be replicated.

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Timelines

- Contractors gave suppliers 180 days (6 months) to conduct the review and then 60 days to return the overpayment.
- 240 days total (8 months)

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Outcomes

- vHG was engaged through supplier's counsel to perform sampling design, auditing, and extrapolations.
- Overpayments ranged from $0 - $1,236,712.52
- Costs ranged from $815 - $40,700
  - Average cost was $12,500
  - Legal fees ranged from $7,000 - $15,000 with an average cost of $12,000

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Process

- Appealed claim to MAC Redeterminations and QIC, if necessary.
- Identify scope
- Claims data universe
- Sample sizes
- Audit components
  - Order
  - Proof of delivery
  - Refill request
  - Continued need
- Analysis of findings
  - Is there a loss to the government?
- Identify overpayment
- Extrapolation
- Summary report
- Submit to MAC

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Contractor Response

1. **Description of the Review Population (Universe) -** Provide an explanation of the methodology used to develop the population and the basis for this determination.
2. **Electronic listing of the Universe -** The body of data (usually claim lines) that is initially obtained from your data source.
3. **Electronic spreadsheet of the Sampling Frame -** List the sampling frame, which is the totality of the sampling units from which the sample was selected.
   - The MAC must receive the entire listing even if claims of other government or private payers were included in the universe.

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Contractor Response

4. **Sample size considerations** – Indicate how an estimate of the size for the sample was conducted.
5. **Random numbers** – Name the random number generator (RNG) used, such as RAT-STATS or SAS RANUNI. Either provide the RNG output in electronic format or indicate the seed number so that the generation of the random numbers can be replicated and applied against the frame to obtain the sample.
6. **Sample Findings/Overpayment Spreadsheet** - Send an electronic listing of the claims in the sample with the results of the review for each. (If the sampling unit is a claim with services per claim line, provide the overpayment per line prior to totaling per claim even if the overpayment is $0.)

Contractor Response

7. **Estimation Methodology -** Provide the RAT-STATS results or if RAT-STATS was not used for the extrapolation, provide the formulas used to obtain the results along with the calculations.
   - Include point estimate, standard error, and precision percent of your extrapolation.
8. **OIG Involvement –** Provide a copy of any related OIG CIA and/or Self-Disclosure Protocol submitted to and approved by the OIG as well and name and contact of OIG representative handling your case.

Impact

- Since 2016, this language has showed up in nearly every report of overpayments that has impacted:
  - Hospitals and health systems
  - Inpatient/outpatient therapy
  - Chiropractic services
  - X-Ray
  - Durable medical equipment
  - Emergent and non-emergent ambulance transports
  - Labs
  - Hospice
  - Home health

Impact

- Orthotics
- Hyperbaric oxygen services
- Radiation therapy
- Long-term care
- Dialysis providers
- Inhalation medications
- Ambulatory surgical procedures
- Behavioral health

Medicaid Lookbacks

- Some states are now sending notices to providers requiring them to perform self-audits for specified time periods.
- In one instance, the outcome we got was very different from the outcome they got and things are at a standstill.
- National Association of Medicaid Program Integrity (NAMPI) featured speakers on this topic and there was a good deal of interest.

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OIG Work Plan

- Part B medications
- Hospice
- Speech language pathology
- Urine drug testing
- Sleep studies
- Facet joint procedures
- Clinical diagnostic test labs
- ESRD-related billing by physicians
- Skilled nursing facilities
- Podiatry
- Physician home visits
- Chronic care management

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OIG Work Plan

- Hospital and health systems
- Home health
- Critical care E/M services
- Post-operative services
- Hospice
- Outpatient cardiac and pulmonary rehab
- Durable medical equipment and orthotics
- Bariatric surgeries
- Portable X-ray
- Psychotherapy
- Inpatient psychiatric

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Recent UPIC Audit

- Reviewed 20 claims for prosthetic components
- Denied all 20 claims
- Identified an actual overpayment of $178,814.29
- Currently in the appeal process

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UPIC Language

Action Needed - Self-Assessment/Voluntary Refund

- The rate of error identified in this small sampling of claims is significant; therefore, it is likely that you have been overpaid by Medicare on other claims or services not identified in this letter or its attachments.
- If so, you are obligated to refund the program. After reviewing the education provided herein, AdvanceMed recommends that you conduct a self-assessment in order to identify any additional overpayments your practice or facility has received as a result of the actions which are the subject of this letter.
- Additionally, CMS published a final rule regarding overpayments in the Federal Register on February 12, 2016, to provide clarity and consistency in the reporting and returning of self-identified overpayments: https://www.gpo.gov/fdsys/pkg/FR-2016-02-12/pdf/2016-02789.pdf.

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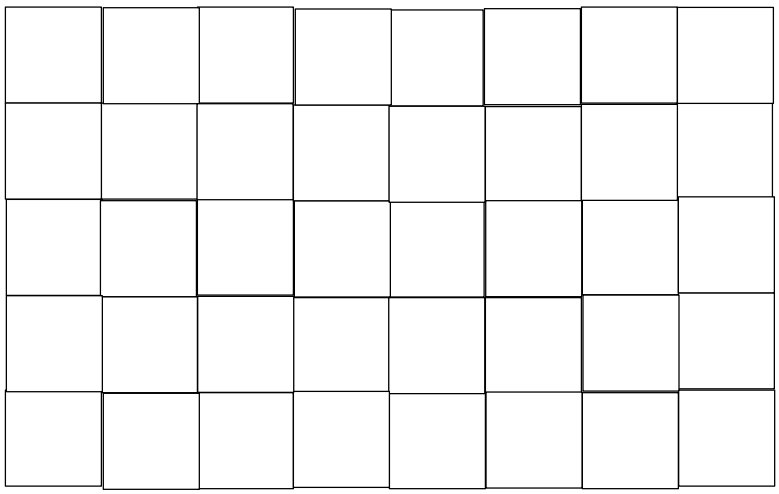
What do you see?



A pattern is developing

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Federal Register

- CMS-6037-F
- Requirements in this rule are meant to:
  - Ensure compliance with applicable statutes
  - Promote the furnishing of high-quality care
  - Protect the Medicare Trust Fund against fraud and improper payments

Legal Implications

- Section 6402 of the Affordable Care Act states that any provider or supplier that receives an overpayment must
  - (i) report to CMS and
  - (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 previously published Final Rule, CMS provided guidance regarding the obligations of providers and suppliers to report and repay overpayments.

Legal Implications

- The Final Rule addressed the "lookback period." This is the time period for which a DME supplier must examine its patient files for overpayment obligations. CMS originally proposed a 10-year lookback period. However, the Final Rule shortened the lookback period to 6 years.
- The Final Rule stated that, as a general rule, a supplier will have 6 months to investigate possible overpayments before the 60-day clock starts running. Compare this to the initial Proposed Rule which said that the investigation should be conducted with "all deliberate speed."

Legal Implications

- 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."

Legal Implications

- 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.
- Assume that
  - the supplier ignores the letter, the supplier does not respond, and the contractor audits the claims described in the letter; or
  - 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
  - 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.

Legal Implications

- 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.

Some things to consider…

- If claim appealed successfully, you do not have to perform lookback .
- Consider scope of review as suppliers are being advised they have *flexibility.*
- Conduct an advised risk assessment with your counsel.
- Are you covered under a Corporate Integrity Agreement?

Bottom line…

- This is important. Suppliers must respond.
- Try to identify claim(s) and denial reasons.
- Discuss parameters of the review with your counsel.
- Suppliers need to either review 100% of their claims going back 6 years or identify a Statistically Valid Random Sample (SVRS).

Bottom line…

- Suppliers should consider engaging experts:
  - Health care attorney
  - Statistician
  - Third-party reviewers
- If a supplier uses a statistician and/or third-party reviewer, then the supplier should strongly consider having its health care attorney hire the consultant/reviewer so that the findings fall under the attorney-client privilege.

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What do we anticipate

- This requirement will most likely be in every OIG report moving forward.
- UPIC audits now appear to be following suit.
- Contractors were instructed to "identify and track any returned overpayments as having been made in accordance with this recommendation."
- This will likely be provided to the OIG.

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What will happen next?

- CMS and contractors are not likely to pursue any other action against suppliers who respond reasonably.
- There may have been suppliers who chose not to respond.
- If contractor provides information back to OIG, it would be likely that they target those who did not respond or did not respond reasonably.
  - No one knows their definition of "reasonable."
- For right now, it is a wait and see situation.

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What can be done now?

- Do not wait for this to happen. You must be proactive in this environment.
- If you are not continuously and strictly scrutinizing claims, a 6-year look-back audit could have a devastating impact.
  - Imagine what your claims looked like 6 years ago.
- Many of the errors we identified in our reviews would have been errors we would have corrected many years ago, but the suppliers didn't realize they were erroneous.
  - Blanket orders
  - Delivery confirmation
  - Refill requests

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What if this happens to me?

- Recommendations
  - Engage counsel
  - If you engage a third party, such as a statistician or independent review organization, do so through counsel as well for privilege (due to potential false claim implications)
  - Immediately appeal claim denial
  - Clearly and succinctly determine the scope of the review
  - Adhere to timelines specified, but if you cannot, then notify the contractor

Lessons Learned

- While employees are good intentioned, you must trust AND verify.
- Many in senior positions were trusting their employees were doing things the correct way. But, in fact, they were not, and no one was monitoring the claims on a regular, on-going basis.
- Problems discovered quickly can be fixed quickly with minimal impact. Problems ignored or unnoticed lead to significant issues.
  - Quarterly auditing at a minimum with follow-up education and training and benchmarking of issues, employees, etc.

Questions

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