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

June 2018
A-04-17-04056

Office of Inspector General

https://oig.hhs.gov

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Report in Brief
Date: June 2018
Report No. A-04-17-04056

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Most Medicare Claims for Replacement Positive Airway Pressure Device Supplies Did Not Comply With Medicare Requirements

Why OIG Did This Review

Previous OIG reviews found that Medicare allows replacement of positive airway pressure (PAP) device supplies more frequently than what is reasonable and necessary and that durable medical equipment (DME) suppliers often do not have the documentation required to support the need for replacement supplies.

During our audit period, the Centers for Medicare & Medicaid Services (CMS) contracted with four Medicare contractors to process and pay supplier claims for DME. The contractors' responsibilities also included responding to supplier inquiries, educating suppliers about billing requirements, and reviewing DME claims.

Our objective was to determine whether Medicare claims that DME suppliers submitted for replacement PAP device supplies complied with Medicare requirements.

How OIG Did This Review

We selected a statistical sample of 110 claims for replacement PAP device supplies that Medicare paid in 2014 and 2015. We reviewed supporting documentation from the supplier to determine whether that documentation complied with Medicare requirements.

What OIG Found

Most Medicare claims that DME suppliers submitted for replacement PAP device supplies did not comply with Medicare requirements. Of the 110 claims in our sample, 24 complied with Medicare requirements; however, 86 claims with payments totaling $13,414 did not. On the basis of our sample results, we estimated that Medicare made overpayments of almost $631.3 million for replacement PAP device supply claims that did not meet Medicare requirements.

These overpayments occurred because CMS oversight of replacement PAP device supplies was not sufficient to ensure that suppliers complied with Medicare requirements or to prevent payment of claims that did not meet those requirements. Without periodic reviews of claims for replacement supplies, Medicare contractors were unable to identify suppliers that consistently billed claims that did not meet Medicare requirements or to take remedial action.

What OIG Recommends and CMS Comments

We recommend that CMS recover the portion of the overpayments of $13,414 associated with the 86 sample claims that are within the 4-year reopening period. We also make several recommendations for CMS to work more closely with the four Medicare contractors, which could have saved Medicare an estimated $631.3 million over a 2-year period.

In written comments on our draft report, CMS concurred with our recommendations and described actions that it planned to take to address them.

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INTRODUCTION

WHY WE DID THIS REVIEW

Medicare covers replacement supplies for positive airway pressure (PAP) devices only when suppliers document that the supplies remain reasonable and necessary. Previous Office of Inspector General (OIG) reviews[1] found that Medicare allowed replacement of PAP device supplies more frequently than what was reasonable and necessary and that durable medical equipment suppliers[2] (suppliers) often did not have the documentation required to support the need for replacement supplies.

OBJECTIVE

Our objective was to determine whether Medicare claims that suppliers submitted for replacement PAP device supplies complied with Medicare requirements.

BACKGROUND

Medicare Program

Title XVIII of the Social Security Act (the Act) established the Medicare Program, which provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. Part B of Medicare provides supplementary medical insurance for medical and other health services and supplies when they are medically necessary, including the coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The Centers for Medicare & Medicaid Services (CMS) administers the program.

During our audit period, CMS contracted with four Medicare contractors to process and pay supplier claims for DMEPOS provided to Medicare beneficiaries who reside in the contractors' respective geographical jurisdictions. The contractors' responsibilities also included responding to supplier inquiries, educating suppliers about billing requirements, and reviewing DMEPOS claims.

Positive Airway Pressure Device Supplies

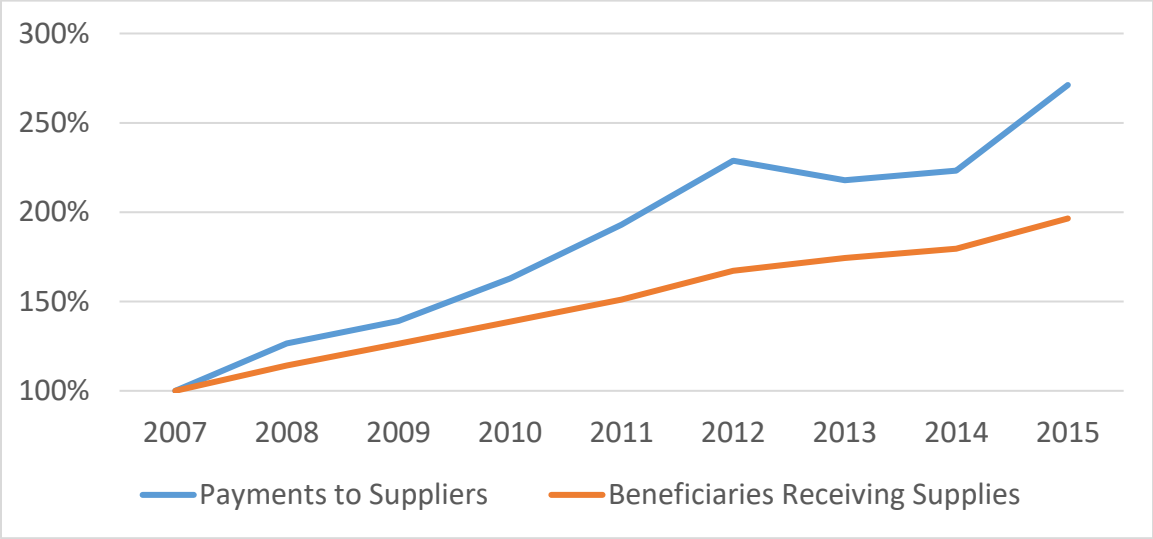
PAP devices include continuous positive airway pressure and respiratory assist devices. These devices are DMEPOS that apply air pressure to the patient's nose, mouth, or both, to treat conditions such as sleep apnea, severe chronic obstructive pulmonary disease, and hypoventilation syndrome. PAP devices use a variety of supplies such as masks, tubing,

[1] Appendix B contains a list of related OIG reports.

[2] A "supplier" is an entity or individual, including a physician or a Part A provider, that sells or rents items covered by Part B to Medicare beneficiaries.

cushions, headgear, and filters, which frequently require replacement. Over time, these supplies degrade and must be replaced for the device to continue to function effectively. For example, tubing may crack and cushions may tear with regular use. Medicare payments for PAP device supplies increased 271 percent from approximately $194 million in 2007 to $526 million in 2015. The number of beneficiaries receiving PAP device supplies also increased 196 percent from approximately 774,000 in 2007 to 1.52 million in 2015. See the figure below.

Figure: Medicare Payments for and Number of Beneficiaries Receiving PAP Device Supplies (as a Percent of 2007 Values)



Medicare Requirements for Positive Airway Pressure Device Supplies

Under the general provisions of the Act, supplies are only covered by Medicare when they are reasonable and necessary (§ 1862(a)(1)(A)). Medicare contractors may define what items or services are covered in their jurisdictions by issuing local coverage determinations (LCDs), which specify what items are reasonable and necessary. The LCDs issued by the four Medicare contractors[3] were identical throughout our audit period.

OIG believes that this audit report constitutes credible information of potential overpayments. Providers who receive notification of these potential overpayments must (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any overpayment

[3] *LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea* (L33718) and *LCD for Respiratory Assist Devices (L33800)* for Medicare contractor Jurisdictions A, B, C, and D. Available online at https://localcoverage.cms.gov/mcd_archive/. Before October 1, 2015, the Medicare contractors had separate but identical LCDs for PAP devices (i.e., L11528, L27230, L11518, and L171 for PAP devices for the treatment of obstructive sleep apnea and L11504, L27228, L5023, and L11493 for respiratory assist devices in Medicare contractor Jurisdictions A, B, C, and D, respectively).

amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (60-day rule).[4]

HOW WE CONDUCTED THIS REVIEW

We identified 7,279,625 claims for replacement PAP device supplies with payments totaling $847,462,971 during calendar years (CYs) 2014 and 2015. We excluded PAP device supplies that were delivered on the same day as a new PAP device to focus on replacement supplies. From this amount, we selected a stratified random sample of 110 claims for replacement PAP device supplies with payments totaling $16,872. For each claim in our sample, we reviewed supporting documentation from the supplier to determine whether that documentation complied with Medicare requirements.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains our audit scope and methodology, and Appendix C contains the details of our sample design and methodology.

FINDINGS

Most Medicare claims that suppliers submitted for replacement PAP device supplies did not comply with Medicare requirements. Of the 110 claims in our sample, 24 complied with Medicare requirements. However, 86 claims with payments totaling $13,414 did not. Table 1 lists the errors in those 86 claims. On the basis of our sample results, we estimated that Medicare made overpayments of $631,272,181 for replacement PAP device supply claims that did not meet Medicare requirements.

[4] The Act § 1128J(d); 42 CFR part 401 subpart D; 42 CFR §§ 401.305(a)(2) and (f); and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

Table 1: Errors in Sampled Items

Description of Error	Number of Errors[5]
Physicians' orders were not in accordance with LCDs	53
Replacement supplies were not reasonable or necessary	
Supplier did not have a proper request for replacement supplies	50
Supplier did not document continued need for PAP device therapy and supplies	22
Supplier dispensed more supplies than allowed	1
Supplier had no proof of delivery	36
Supplier did not respond to our requests for documentation	3

These overpayments occurred because CMS oversight of replacement PAP device supplies was not sufficient to ensure that suppliers complied with Medicare requirements or to prevent payment of claims that did not meet those requirements. Although Medicare contractors review claims for PAP devices, they do not conduct periodic reviews of claims for replacement PAP device supplies. The contractors relied on their LCDs and other published guidance[6] to ensure that suppliers met Medicare requirements. However, without periodically reviewing claims for replacement supplies, Medicare contractors were unable to identify suppliers that consistently billed claims that did not meet Medicare requirements or to take remedial action.

MOST CLAIMS DID NOT COMPLY WITH MEDICARE REQUIREMENTS

Of the 110 sample claims, 86 did not comply with Medicare requirements. Of the 86 claims, 57 contained more than 1 error.

Physicians' Orders Were Not in Accordance With Local Coverage Determination Requirements

The LCDs for PAP devices state that an order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Suppliers may dispense supplies based on a verbal or written dispensing order, but the supplier must obtain a detailed written order before submitting a claim. The detailed written order must contain several elements, such as the beneficiary's and physician's names, the date of the order, a detailed description of the items to be dispensed, the quantity to be dispensed, the frequency of use, and the number of refills. The supplier must obtain a new order when there is a change in supplier, supplies, frequency or quantity of use, or length of need.

[5] The total exceeds 86 because 57 sample items contained more than 1 error.

[6] The other published guidance included supplier educational materials and newsletters that explained the Medicare coverage requirements.

For 53 claims in our sample, the physicians' orders were not in accordance with the LCDs because (1) the written order did not contain at least one of the required elements, (2) the supplier did not obtain a detailed written order before billing Medicare, (3) the order did not contain at least one of the supplies on the claim, or (4) the supplier did not obtain a new order after a change of supplier.

These orders often contained multiple supplies that were contradictory, such as more than one type of mask; did not indicate which specific supplies the physician was ordering; or were missing the frequency or duration of use.

Replacement Supplies Were Not Reasonable or Necessary

Supplier Did Not Have a Proper Request for Replacement Supplies

The LCDs for PAP devices state that suppliers must ensure that replacement supplies are reasonable and necessary by documenting a request for new supplies from the beneficiary.[7] Specifically, the request must contain the date of the request, the description of each item requested, and the functional condition of the items being replaced in sufficient detail to demonstrate why they need to be replaced. Suppliers must assess whether the beneficiary's current supplies remain functional and provide replacement only when those supplies are no longer able to function. Additionally, to confirm any changes or modifications to the order, the supplier's contact with the beneficiary must occur no more than 14 days before filling the order for new supplies.

For 50 claims in our sample, the supplier did not have a proper request for replacement supplies. Specifically, (1) there was no evidence that the beneficiary had requested the supplies, (2) the supplier did not determine the functional condition of the beneficiary's current supplies before sending replacement supplies, or (3) the supplier's contact with the beneficiary occurred more than 14 days before sending replacement supplies.

Supplier Did Not Document Continued Need for Positive Airway Pressure Device Therapy and Supplies

The LCDs for PAP devices state that suppliers must be able to justify the beneficiary's continued medical need for and use of PAP device therapy by obtaining documentation from the beneficiary's medical record, such as a recent order by the treating physician for replacement supplies or documentation showing usage of the PAP device and supplies. The documentation must be dated within the 12 months preceding the delivery of replacement supplies.

For 22 claims in our sample, the supplier could not provide recent evidence that the beneficiary continued to need PAP device therapy and replacement PAP device supplies. In one case, the

[7] A beneficiary may designate a caregiver or other person to request new supplies and accept supply deliveries on the beneficiary's behalf.

supplier went more than 6 years without obtaining evidence of the beneficiary's continued need for PAP device supplies.

Supplier Dispensed More Supplies Than Allowed

The LCDs for PAP devices state that, regardless of utilization, suppliers must not dispense more than a 3-month quantity of supplies at a time.

For one claim in our sample, the supplier dispensed more than 3 months of supplies. The beneficiary's physician ordered one disposable filter per month; however, the supplier delivered six filters, a 6-month quantity, to the beneficiary.

Supplier Had No Proof of Delivery

The LCDs for PAP devices state that suppliers must maintain evidence that supplies were delivered to the beneficiary. The proof of delivery must include the beneficiary's name and delivery address, a description of the items delivered, the quantity delivered, and the date of delivery. In addition, the proof of delivery must contain the beneficiary's signature for items delivered directly to the beneficiary and complete tracking information from the supplier to the beneficiary for items delivered via a shipping or delivery service.

For 36 claims in our sample, the supplier could not provide evidence that the supplies were delivered to the beneficiary. Most often the suppliers' delivery documentation did not contain all of the applicable required elements, such as the shipping service's package identification information and confirmation of delivery.

Supplier Did Not Respond to Our Requests for Documentation

Section 1833(e) of the Act precludes payment to any provider of services or other person who does not provide information necessary to determine the amount due the provider. Further, the LCDs state that documentation to demonstrate compliance with those requirements must be available upon request.

For three claims in our sample, the supplier did not provide any documentation to support the claims. We contacted the supplier multiple times and requested documentation to support the claims; however, the supplier did not respond to any of our requests.

MEDICARE OVERSIGHT OF REPLACEMENT POSITIVE AIRWAY PRESSURE DEVICE SUPPLIES WAS NOT SUFFICIENT

Medicare oversight of PAP device replacement supplies was not sufficient to ensure that suppliers complied with Medicare requirements or to prevent payment of claims that did not meet those requirements. The contractors' efforts to prevent overpayments related to PAP devices focused on ensuring that claims for the device itself met Medicare requirements

instead of on the replacement supplies for the device. For example, the contractors had claim processing edits that initiated random reviews of PAP device claims; however, the contractors had no such edits to initiate reviews of claims for replacement supplies. Officials from one of the two[8] contractors stated that they had not performed any reviews of claims for PAP device supplies because the payments for individual replacement supply claims were small in relation to other DMEPOS claims. Rather, the contractors relied on their LCDs and other published guidance to ensure that claims met Medicare requirements.

Without periodic reviews of claims for replacement supplies, Medicare contractors were unable to identify suppliers that consistently billed claims that did not meet Medicare requirements or to take remedial action.

ESTIMATE OF OVERPAYMENTS

Based on our sample results, we estimated that Medicare made overpayments of $631,272,181 for replacement PAP device supply claims that did not meet Medicare requirements.

RECOMMENDATIONS

We recommend that CMS:

- instruct the 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;[9]

- work with Medicare contractors to establish periodic reviews of claims for replacement PAP device supplies and take remedial action for suppliers that the contractors find consistently bill claims that do not meet Medicare requirements, which could have saved Medicare an estimated $631,272,181 over a 2-year period; and

- instruct the Medicare contractors to notify 82 suppliers, associated with 86 claims with potential overpayments of $13,414, to exercise reasonable diligence to investigate and return any identified overpayments, in accordance with the 60-day rule, and to identify

[8] At the time of our audit, two Medicare contractors processed supplier durable medical equipment claims. Each contractor processed claims in two of the four geographical jurisdictions.

[9] OIG audit recommendations do not represent final determinations by the Medicare Program but are recommendations to action officials within the Department of Health and Human Services. Action officials at CMS, acting through a Medicare contractor or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with its policies and procedures. If a disallowance is taken, providers have the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). The Medicare Parts A and B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a decision by the Office of Hearings and Appeals. If a provider exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

and track any returned overpayments as having been made in accordance with this recommendation.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our recommendations and described actions that it planned to take to address them. CMS's comments are included in their entirety as Appendix E.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 7,297,625 Medicare claims for replacement PAP device supplies,[10] totaling $847,462,971, paid to suppliers during CYs 2014 and 2015. We excluded PAP device supplies that were delivered on the same day as a new PAP device to focus on replacement supplies. We selected a stratified random sample of 110 claims for PAP device supplies with payments totaling $16,872.

We did not review the overall internal control structure of CMS or the Medicare contractors. Rather, we limited our internal control review to the objective of our audit.

We conducted our audit from October 2016 to June 2017.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal requirements and Medicare contractor guidance;
- interviewed CMS officials to identify any existing reviews of claims for replacement PAP device supplies;
- interviewed officials from the Medicare contractors to gain an understanding of their claim processing and payment procedures, system edits, ongoing monitoring, and LCDs for PAP devices;
- used the CMS National Claims History File to identify claims for replacement PAP device supplies paid in CYs 2014 and 2015;
- selected a stratified random sample of 110 claims totaling $16,872 (see Appendix C);
- reviewed available data from CMS's Common Working File for the sampled line items to validate information from the National Claims History and determine whether any of the sampled claims had been canceled or adjusted;
- obtained and reviewed documentation from suppliers for the sample claims to determine whether the claims met Medicare documentation requirements;

[10] For the purposes of our audit, PAP replacement supplies included items billed using Healthcare Common Procedure Coding System (HCPCS) codes A4604, A7027–A7039, and A7046.

- used the results of the sample to estimate the total Medicare overpayment for replacement PAP device supplies for our audit period (see Appendix D); and

- discussed the results of our review with CMS officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Replacement Schedules for Medicare Continuous Positive Airway Pressure Supplies	OEI-07-12-00250	6/24/2013
Medical Services of America Did Not Always Have Required Documentation on File to Support Its Medicare Claims	A-04-11-04010	12/5/2012
Claim Modifier Did Not Prevent Medicare From Paying Millions in Unallowable Claims for Selected Durable Medical Equipment	A-04-10-04004	4/5/2012

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

TARGET POPULATION

The target population consisted of Medicare claims for replacement PAP device supplies paid from January 1, 2014, through December 31, 2015.

SAMPLING FRAME

The sampling frame consisted of 7,279,625 Medicare claims for replacement PAP device supplies with a total paid amount of $847,462,971. We excluded claims that were covered by previous recovery audits or were for PAP supplies that were delivered on the same day as a new PAP device.

SAMPLE UNIT

The sample unit was a claim.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample design (Table 2):

Table 2: Sample Design

Stratum	Payment Range	Sample Item Count	Total Payments	Sample Size
1	< $90	3,447,781	$141,027,721	30
2	≥ $90 and < $195	2,567,702	365,938,479	41
3	≥ $195 and < $1,497	1,264,142	340,496,770	39
Total[11]		**7,279,625**	**$847,462,971**	**110**

SOURCE OF RANDOM NUMBERS

We generated the random numbers using the OIG, Office of Audit Services (OIG/OAS) statistical software.

METHOD OF SELECTING SAMPLE ITEMS

For each stratum, we consecutively numbered the claims in the sampling frame. After generating the random numbers, we selected the corresponding frame items.

[11] Differences in total calculations are due to rounding.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of Medicare overpayments.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample Results

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Improper Payments	Value of Improper Payments
1	3,447,781	$141,027,721	30	$1,258	23	$986
2	2,567,702	365,938,479	41	5,751	29	3,810
3	1,264,142	340,496,770	39	9,862	34	8,617
Total[12]	**7,279,625**	**$847,462,971**	**110**	**$16,872**	**86**	**$13,414**

Table 4: Estimated Value of Improper Payments
(Limits Calculated for a 90-Percent Confidence Interval)

Point Estimate	$631,272,181
Lower Limit	568,377,526
Upper Limit	694,166,836

[12] Differences in total calculations are due to rounding.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

APR 12 2018

DATE:

TO: Daniel R. Levinson
Inspector General

FROM: Seema Verma SV.
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Most Medicare Claims for Replacement Positive Airway Pressure Device Supplies Did Not Comply With Medicare Requirements (A-04-17-04056)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

CMS is committed to providing Medicare beneficiaries with high quality health care while protecting taxpayer dollars by preventing improper payments. CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including automated system edits within the claims processing system, and conducting prepayment and postpayment reviews. Additionally, CMS has taken action to prevent improper Medicare payments by educating health care providers on proper billing. CMS educates health care providers on avoiding Medicare billing errors through various channels including the Medicare Learning Network, weekly electronic newsletters, and quarterly compliance newsletters.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation
The OIG recommends that CMS instruct the 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.

CMS Response
CMS concurs with this recommendation. CMS will instruct its Medicare contractors to recover the identified overpayments consistent with the agency's policies and procedures.

OIG Recommendation
The OIG recommends that CMS work with Medicare contractors to establish periodic reviews of claims for replacement PAP device supplies and take remedial action for suppliers that the contractors find consistently bill claims that do not meet Medicare requirements, which could have saved Medicare an estimated $631,272,181 over a 2-year period.

CMS Response

CMS concurs with this recommendation. CMS will work with its Medicare contractors to establish periodic reviews of claims for replacement PAP device supplies. Additionally, CMS will take action, as appropriate, for suppliers that the contractors find consistently bill claims that do not meet Medicare requirements.

OIG Recommendation

The OIG recommends that CMS instruct the Medicare contractors to notify 82 suppliers, associated with 86 claims with potential overpayments of $13,414, to exercise reasonable 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.

CMS Response

CMS concurs with this recommendation. CMS will instruct its Medicare contractors to notify the 82 suppliers of OIG's audit and the potential overpayment. CMS will track any returned overpayments made in accordance with this recommendation and the 60-day rule.