



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



June 12, 2012

TO: Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: /Gloria L. Jarmon/
Deputy Inspector General for Audit Services

SUBJECT: Pos-T-Vac Medical Did Not Meet Medicare Documentation Requirements for
Over Half of Sampled Claims for Male Vacuum Erection Systems
(A-07-11-05016)

Attached, for your information, is an advance copy of our final report on our review of Medicare claims submitted by the durable medical equipment supplier Pos-T-Vac Medical. We will issue this report to Pos-T-Vac Medical within 5 business days.

If you have any questions or comments about this report, please do not hesitate to contact me, or your staff may contact Brian P. Ritchie, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at Brian.Ritchie@oig.hhs.gov or Patrick J. Cogley, Regional Inspector General for Audit Services, Region VII, at (816) 426-3591 or through email at Patrick.Cogley@oig.hhs.gov. Please refer to report number A-07-11-05016.

Attachment



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL



OFFICE OF AUDIT SERVICES, REGION VII
601 EAST 12TH STREET, ROOM 0429
KANSAS CITY, MO 64106

June 14, 2012

Report Number: A-07-11-05016

Mr. Ed Stewart
Owner
Pos-T-Vac Medical
1701 North 14th Avenue
Dodge City, KS 67801

Dear Mr. Stewart:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Pos-T-Vac Medical Did Not Meet Medicare Documentation Requirements for Over Half of Sampled Claims for Male Vacuum Erection Systems*. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me at (816) 426-3591, or contact Scott Englund, Audit Manager, at (573) 893-8338, extension 27, or through email at Scott.Englund@oig.hhs.gov. Please refer to report number A-07-11-05016 in all correspondence.

Sincerely,

/Patrick J. Cogley/
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Ms. Nanette Foster Reilly
Consortium Administrator
Consortium for Financial Management & Fee for Service Operations
Centers for Medicare & Medicaid Services
601 East 12th Street, Room 355
Kansas City, MO 64106

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**POS-T-VAC MEDICAL DID NOT MEET
MEDICARE DOCUMENTATION
REQUIREMENTS FOR OVER HALF OF
SAMPLED CLAIMS FOR MALE
VACUUM ERECTION SYSTEMS**



Daniel R. Levinson
Inspector General

June 2012
A-07-11-05016

Office of Inspector General

<http://oig.hhs.gov>

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Notices

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Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Pursuant to sections 1832(a)(1), 1861(s)(6), (s)(8), and (s)(9), and 1861(n) of the Social Security Act, Medicare Part B provides for the coverage of durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS). The Centers for Medicare & Medicaid Services (CMS) contracts with four DME Medicare administrative contractors to process and pay Medicare Part B claims.

Federal guidelines define DMEPOS as equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, is generally not useful to a person in the absence of illness or injury, and is appropriate for use in a patient's home. The non-surgical systems known as male vacuum erection systems (VES), used in the treatment of erectile dysfunction, are DME and as such may be claimed and paid under Medicare.

To be paid for a Medicare DME claim, the supplier must maintain (1) proof-of-delivery documents, (2) documentation of the patient's medical condition to substantiate the necessity for the items ordered, and (3) a signed, detailed written physician's order.

Pos-T-Vac Medical (Pos-T-Vac), based in Dodge City, Kansas, manufactures and supplies VES for the treatment of erectile dysfunction.

OBJECTIVE

Our objective was to determine whether Pos-T-Vac's paid claims for VES were supported by the required documentation.

SUMMARY OF FINDINGS

Pos-T-Vac's paid claims for VES were not always supported by the required documentation. For the 100 DME claims that we sampled (and Pos-T-Vac submitted for payment), our review showed that 49 claims were supported in accordance with Medicare DME documentation requirements. However, the remaining 51 claims totaling \$18,007 did not comply with Medicare DME documentation requirements. Specifically, we identified the following deficiencies. (Two claims were missing more than one piece of required documentation.)

- For 50 claims, Pos-T-Vac did not maintain proof of delivery in its files.
- For two claims, Pos-T-Vac did not maintain sufficient documentation of the patients' medical condition to substantiate the necessity for the items ordered.
- For one claim, the physician's written order in Pos-T-Vac's files lacked the signature of the treating physician.

Based on the results of our sample, we estimated that unsupported Pos-T-Vac paid claims for VES resulted in overpayments totaling \$4,217,800 during the period January 1, 2008, through December 31, 2009. Pos-T-Vac submitted unsupported claims because it lacked adequate internal controls to ensure that it collected and maintained the required documentation.

RECOMMENDATIONS

We recommend that Pos-T-Vac:

- refund \$4,217,800 to the Federal Government for unallowable DME claims and
- develop and implement policies and procedures to help ensure that it collects and maintains the required documentation.

AUDITEE COMMENTS

In written comments on our draft report, Pos-T-Vac did not concur with most of our findings. Pos-T-Vac concurred with our finding on the two claims for which Pos-T-Vac did not maintain sufficient documentation of the patients' medical condition to substantiate the necessity for the items ordered. Pos-T-Vac also concurred with our finding on the claim in which the physician's written order lacked the treating physician's signature.

However, Pos-T-Vac did not concur with our first finding on proof of delivery and with the questioned costs associated with that finding. Specifically, Pos-T-Vac disagreed with our finding on the 48 claims for which Pos-T-Vac did not maintain proof of delivery as required by 42 CFR § 424.57(c)(12) and the provisions of CMS's *Medicare Program Integrity Manual*.

Pos-T-Vac's comments are in Appendix C. We excluded 76 pages of attachments to those comments because they contain personally identifiable information. We are providing the attachments in their entirety to CMS.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing Pos-T-Vac's comments, we maintain that our findings and recommendations are valid. Federal requirements mandate that Medicare DME suppliers maintain proof of delivery. The information that Pos-T-Vac provided to supplement its comments did not represent sufficient and/or appropriate evidence for supporting a conclusion that the items had actually been delivered to beneficiaries.

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INTRODUCTION

BACKGROUND

Medicare Coverage of Durable Medical Equipment

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Pursuant to sections 1832(a)(1), 1861(s)(6), (s)(8), and (s)(9), and 1861(n) of the Act, Medicare Part B provides for the coverage of durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS). Section 1862(a)(1)(A) of the Act requires that, to be paid by Medicare, a service or an item be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

As a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS contracted with four durable medical equipment Medicare administrative contractors (DME MAC) to process and pay Medicare Part B claims for DMEPOS. Further, CMS contracts with Zone Program Integrity Contractors (ZPIC) to fulfill program integrity functions for the Medicare program.¹

National coverage determinations describe the circumstances for Medicare coverage nationwide for specific medical service procedures or devices, including DMEPOS, and generally outline the conditions under which a service or device is considered covered. The *Medicare National Coverage Determinations Manual*, Pub. No. 100-03, chapter 1, part 4, section 280.1, defines DME as equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, is generally not useful to a person in the absence of illness or injury, and is appropriate for use in a patient's home. Medicare contractors develop local coverage determinations (LCD) for some covered DMEPOS items. The non-surgical systems known as male vacuum erection systems (VES), used in the treatment of erectile dysfunction, are DME and as such may be claimed and paid under Medicare.

Medicare Durable Medical Equipment Documentation Requirements

Although there are no LCDs for VES, Medicare DME documentation requirements apply. To be paid for a Medicare DME claim, including VES, the supplier must maintain (1) proof-of-delivery documents, (2) documentation from the patient's medical records to substantiate the necessity for the items ordered, and (3) a signed, detailed written physician's order.

¹ Section 202 of the Health Insurance Portability and Accountability Act of 1996 added section 1893 to the Act, establishing the Medicare Integrity Program and authorizing CMS to contract with entities to fulfill program integrity functions for the Medicare program. Each ZPIC is assigned to one or more of seven geographical zones nationwide. The majority of the claims we reviewed for this audit were made on behalf of beneficiaries in Zones 2 and 5.

Pos-T-Vac Medical

Pos-T-Vac Medical (Pos-T-Vac), based in Dodge City, Kansas, manufactures and supplies VES for the treatment of erectile dysfunction.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Pos-T-Vac's paid claims for VES were supported by the required documentation.

Scope

We reviewed a total of \$10,160,035 in DME claims that Pos-T-Vac submitted for VES and that the DME MAC paid during the period January 1, 2008, through December 31, 2009.

Our review focused on whether Pos-T-Vac met Medicare documentation requirements for VES. We did not conduct a medical review to determine whether the services were medically necessary.

We did not review the overall internal control structure of Pos-T-Vac. We limited our review of internal controls to those related to our audit objective.

We conducted our fieldwork in March 2011 at Pos-T-Vac's office in Dodge City, Kansas.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and DME MAC guidance;
- reviewed Pos-T-Vac's policies and procedures for submitting claims for VES;
- interviewed staff at Pos-T-Vac to gain an understanding of its process for billing DME claims for VES;
- discussed with staff at AdvanceMed² the allowability of claims that lacked proof-of-delivery documentation;
- obtained electronic paid claims data for Pos-T-Vac during the period January 1, 2008, through December 31, 2009;

² AdvanceMed is the ZPIC for Medicare DMEPOS in Zones 2 and 5.

- selected a simple random sample of 100 paid claims from the 28,088 paid claims during the period January 1, 2008, through December 31, 2009;
- obtained and reviewed the supporting documentation for each claim that we sampled to determine the allowability of the claim; and
- discussed the results of our review with Pos-T-Vac officials on April 21, 2011.

See Appendix A for our sample design and methodology and Appendix B for our sample results and estimates.

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 objective.

FINDINGS AND RECOMMENDATIONS

Pos-T-Vac's paid claims for VES were not always supported by the required documentation. For the 100 DME claims that we sampled (and Pos-T-Vac submitted for payment), our review showed that 49 claims were supported in accordance with Medicare DME documentation requirements. However, the remaining 51 claims totaling \$18,007 did not comply with Medicare DME documentation requirements. Specifically, we identified the following deficiencies.

- For 50 claims, Pos-T-Vac did not maintain proof of delivery in its files.
- For two claims, Pos-T-Vac did not maintain sufficient documentation of the patients' medical condition to substantiate the necessity for the items ordered.
- For one claim, the physician's written order in Pos-T-Vac's files lacked the signature of the treating physician.³

Based on the results of our sample, we estimated that unsupported Pos-T-Vac paid claims for VES resulted in overpayments totaling \$4,217,800 during the period January 1, 2008, through December 31, 2009. Pos-T-Vac submitted unsupported claims because it lacked adequate internal controls to ensure that it collected and maintained the required documentation.

³ Two claims were missing more than one piece of required documentation.

INSUFFICIENT MEDICARE DURABLE MEDICAL EQUIPMENT DOCUMENTATION

Federal Requirements and Guidelines

Proof of Delivery

Section 1833(e) of the Act provides that no payment shall be made to a provider of services under Part B unless there is furnished such information as may be necessary to determine the amount due. Pursuant to 42 CFR § 424.57(c)(12), a supplier “[m]ust be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery.”

Chapter 4, section 4.26, of CMS’s *Medicare Program Integrity Manual*, Pub. No. 100-08 (the manual), provides that:

Suppliers are required to maintain proof of delivery documentation in their files. Documentation must be maintained in the supplier’s files for 7 years.

Proof of delivery is required in order to verify that the beneficiary received the DMEPOS Proof of delivery must be made available to the DME MAC upon request. For any services, which do not have proof of delivery from the supplier, such claimed items and services will be denied and overpayments recovered.

Further, chapter 4, section 4.26.1, of the manual provides examples of proof of delivery if a supplier delivers directly to the beneficiary (or designee) or uses a shipping service or mail order. The manual states: “An example of proof of delivery to a beneficiary [or the designee] is having a signed delivery slip If the supplier utilizes a shipping service or mail order, an example of proof of delivery would include the service’s tracking slip”

Medical Condition

Chapter 5, section 5.8, of the manual states: “The supplier should ... obtain as much documentation from the patient’s medical record as they determine they need to assure themselves that coverage criteria for an item have been met.”

Chapter 5, section 5.7, of the manual provides additional guidelines regarding requirements for documentation. Section 5.7 of the manual states:

For any DMEPOS item to be covered by Medicare, the patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable) [T]he DME MACs ... or ZPICs may request this information in selected cases. If the DME [MACs] ... or ZPICs do not receive the information when requested or if the information in the patient’s medical record does not adequately support the medical necessity for the item, then on assigned claims the supplier is liable for the dollar amount involved

unless a properly executed advance beneficiary notice (ABN) of possible denial has been obtained.

Physician's Order

Chapter 5, section 5.2.1, of the manual requires that the DME supplier obtain an order from the treating physician before dispensing DMEPOS to a beneficiary. Chapter 5, section 5.2.3, of the manual provides that a “supplier must have a detailed written order before submitting a claim If the claim is for an item for which an order is required by statute ..., the claim will be denied as not meeting the benefit category.... For all other items ... if the supplier does not have an order that has been both signed and dated by the treating physician before billing the Medicare program, the item will be denied as not reasonable and necessary.”

Insufficient Documentation

For 50 of the 100 claims that we sampled, Pos-T-Vac did not maintain proof of delivery as required by 42 CFR § 424.57(c)(12) and the manual provisions. As a result, Pos-T-Vac was unable to provide proof of delivery upon request. According to Federal requirements, if a supplier does not have proof of delivery for an item, the item must be denied and overpayments recovered.

After we made Pos-T-Vac aware of this finding, Pos-T-Vac sent to those 50 beneficiaries statements that it referred to as “affidavits.” Each statement contained language affirming receipt of the item for which Pos-T-Vac had received Medicare payment. Twenty-two of the fifty beneficiaries returned the statements, each of which contained an unwitnessed beneficiary signature.⁴ However, the 22 statements do not warrant a high degree of confidence as proof of delivery because they contain: (1) handwritten dates of delivery that were almost 2 years before the date the beneficiaries signed the statements, and (2) instructions implying that the beneficiaries had to sign them. Thus, the signed statements are not sufficient to verify that the beneficiaries received the items.

Because Pos-T-Vac did not maintain proof of delivery as required by 42 CFR § 424.57(c)(12) and the manual provisions and because the signed statements were not sufficient to verify that the beneficiary actually received the items, the items must be denied and overpayments must be recovered. Officials of the ZPIC with whom we consulted agreed that all 50 claims not supported by proof of delivery should be denied for lack of proof-of-delivery documentation, including the 22 claims whose delivery was supported by signed statements obtained almost 2 years after the claimed items had been delivered.

For 2 of the 100 claims that we sampled, Pos-T-Vac did not maintain sufficient documentation of the patients' medical condition to substantiate the necessity for the items ordered. For these two claims, the treating physicians' written orders were the only documentation that Pos-T-Vac

⁴ None of the signed statements is an affidavit. An affidavit is a formal sworn statement of fact, signed by its author, and witnessed by a taker of oaths, such as a notary public, who swears to the authenticity of the affiant's signature.

maintained. After we made Pos-T-Vac aware of this finding, Pos-T-Vac requested medical records from the treating physicians' offices that would support the medical necessity of these two claims. However, no medical records were provided. Consequently, the supplier (Pos-T-Vac) is liable for the dollar amounts of the two claims. Additionally, for 1 of the 100 claims that we sampled, Pos-T-Vac submitted a claim with a physician's written order that lacked the treating physician's signature. Therefore, according to the manual provisions, the item must be denied as not reasonable and necessary.

Pos-T-Vac submitted unsupported claims because it lacked adequate internal controls to ensure that it collected and maintained the required documentation. Specifically, Pos-T-Vac did not have a policy in place that defined proof of delivery and other Medicare DME documentation requirements, nor did it have adequate procedures in place to ensure that it met these documentation requirements.

EFFECT OF UNALLOWABLE CLAIMS

Of the 100 claims in our sample, 51 did not comply with the Medicare DME documentation requirements. Based on the results of our sample, we estimated that unsupported Pos-T-Vac paid claims for VES resulted in overpayments totaling \$4,217,800.

RECOMMENDATIONS

We recommend that Pos-T-Vac:

- refund \$4,217,800 to the Federal Government for unallowable DME claims and
- develop and implement policies and procedures to help ensure that it collects and maintains the required documentation.

AUDITEE COMMENTS

In written comments on our draft report, Pos-T-Vac did not concur with most of our findings. Pos-T-Vac concurred with our finding on the two claims for which Pos-T-Vac did not maintain sufficient documentation of the patients' medical condition to substantiate the necessity for the items ordered. Pos-T-Vac also concurred with our finding on the claim in which the physician's written order lacked the treating physician's signature. Pos-T-Vac stated that it had reviewed these three claims in question and implemented procedures to ensure that these types of errors would not occur in the future.

However, Pos-T-Vac did not concur with our first finding on proof of delivery and with the questioned costs associated with that finding. Specifically, Pos-T-Vac disagreed with our finding on the 48 claims for which Pos-T-Vac did not maintain proof of delivery as required by 42 CFR § 424.57(c)(12) and the manual provisions. Pos-T-Vac stated:

Pos-T-Vac Medical did, in fact, deliver these items to the beneficiaries via United Parcel Service (UPS). Specifically, my client [i.e., Pos-T-Vac] was enrolled in

the Quantam View Tracking Program with UPS which allows them to obtain tracking confirmation electronically. Unfortunately, they were unaware that the confirmations of delivery forms are only available for 18 months. As a result, they are unable to provide these. However, the system does account for all deliveries and we have provided electronic copies of two reports generated by UPS Based on this information, it can be concluded that the equipment was delivered to the beneficiaries.⁵

Pos-T-Vac also cited a portion of the *DME MAC Supplier Manual* for each jurisdiction describing examples of acceptable proof of delivery documentation. Pos-T-Vac stated that the combination of a copy of its invoice and the corresponding delivery confirmation information provided by UPS constituted sufficient documentation to show that the equipment was delivered and met the Federal requirements for proof of delivery. Pos-T-Vac also described corrective actions, including (1) creating a new position for file verification to ensure that claims being submitted would contain the appropriate documentation and (2) implementing internal policies to ensure accuracy of documentation. Pos-T-Vac added that it planned to add the UPS tracking number to its invoices for the 48 claims and has implemented this change for all new claims going forward. Pos-T-Vac stated that this change would allow the invoice and delivery confirmation to be cross-referenced.

Pos-T-Vac's comments are in Appendix C. We excluded 76 pages of attachments to those comments because they contain personally identifiable information. We are providing the attachments in their entirety to CMS.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing Pos-T-Vac's comments, we maintain that our findings and recommendations are valid. Federal requirements mandate that Medicare DME suppliers maintain proof of delivery in their files and provide proof of delivery upon request. Pos-T-Vac utilizes UPS to deliver items to the beneficiaries. UPS provides a delivery confirmation to Pos-T-Vac for each shipment as proof of delivery, usually in the form of an email, containing the date delivered and the signature of the receiver. However, during our audit, Pos-T-Vac could not provide proof of delivery for 48 of the 100 sample items as required. Pos-T-Vac did not routinely maintain proof of delivery documentation in its files for all equipment it provided to Medicare beneficiaries, and UPS routinely purges its delivery confirmation information in its system after 18 months. Consequently, to supplement its comments on our draft report, Pos-T-Vac provided additional electronic reports as delivery confirmation information. Pos-T-Vac asserted that the combination of a copy of its invoice and the corresponding delivery confirmation information constituted proof of delivery in accordance with Federal requirements. However, upon reviewing these additional electronic reports, we could not conclude that they constituted sufficient and/or appropriate evidence because we could not validate the data, which were incomplete and contained irregularities.

⁵ Pos-T-Vac retained the services of a consulting firm, The van Halem Group, LLC, which prepared the auditee comments. For this reason, the written comments occasionally refer to Pos-T-Vac as "my client."

Generally accepted government auditing standards (GAGAS) require that auditors obtain sufficient, appropriate evidence to provide a reasonable basis for their findings and conclusions. These standards state that the concept of sufficient, appropriate evidence is integral to an audit. We reviewed the information that Pos-T-Vac provided as part of its written comments on our draft report to determine whether it was sufficient and appropriate in the context of our audit findings and conclusions.

GAGAS standard 6.60 states:

Appropriateness is the measure of the quality of evidence that encompasses the relevance, validity, and reliability of evidence used for addressing the audit objectives and supporting findings and conclusions.

- a. Relevance refers to the extent to which evidence has a logical relationship with, and importance to, the issue being addressed.
- b. Validity refers to the extent to which evidence is a meaningful or reasonable basis for measuring what is being evaluated. In other words, validity refers to the extent to which evidence represents what it is purported to represent.
- c. Reliability refers to the consistency of results when information is measured or tested and includes the concepts of being verifiable or supported.

GAGAS standard 6.65 states: “When auditors use information provided by officials of the audited entity as part of their evidence, they should determine what the officials of the audited entity or other auditors did to obtain assurance over the reliability of the information.”

Additionally, GAGAS standard 6.66 states: “Auditors should assess the sufficiency and appropriateness of computer-processed information regardless of whether this information is provided to auditors or auditors independently extract it The assessment of the sufficiency and appropriateness of computer-processed information includes considerations regarding the completeness and accuracy of the data for the intended purposes.”

Finally, GAGAS standard 6.71 states:

When assessing the sufficiency and appropriateness of evidence, auditors should evaluate the expected significance of evidence to the audit objectives, findings, and conclusions, available corroborating evidence, and the level of audit risk. The steps to assess evidence may depend on the nature of the evidence, how the evidence is used in the audit or report, and the audit objectives.

- a. Evidence is sufficient and appropriate when it provides a reasonable basis for supporting the findings or conclusions within the context of the audit objectives.

- b. Evidence is not sufficient or not appropriate when (1) using the evidence carries an unacceptably high risk that it could lead the auditor to reach an incorrect or improper conclusion, (2) the evidence has significant limitations, given the audit objectives and intended use of the evidence, or (3) the evidence does not provide an adequate basis for addressing the audit objectives or supporting the findings and conclusions. Auditors should not use such evidence as support for findings and conclusions.

To substantiate that delivery had occurred for the items in question, Pos-T-Vac provided electronic reports that it referred to as “corresponding delivery confirmation information.” According to Pos-T-Vac, these reports were provided by UPS. These electronic reports included emails and two Microsoft Excel spreadsheets. The UPS emails, sent by the senior account manager in the UPS sales department, stated that the data came from the UPS data warehouse and had been verified from shipping and billing manifests sent from the Pos-T-Vac UPS Worldship shipping system.⁶ The UPS official also said that the “stop complete” column of one of the spreadsheets provided by UPS had the dates of delivery of the items in question.⁷

Although Pos-T-Vac said that it had provided us with proof of delivery documentation for the 48 questioned claims, we determined that the data were incomplete because the spreadsheets did not provide any information for 5 of the 48 claims. Moreover, the data that were provided in the spreadsheets exhibited irregularities that caused us to question the validity and reliability of the information that they contained. Specifically, we found:

1. One of the two spreadsheets that was said to have been prepared by UPS appeared to have been prepared by the Pos-T-Vac consultant. This was indicated by the “property” tab in Microsoft Excel.
2. The file names of the two spreadsheets that Pos-T-Vac said UPS had prepared had been changed. Specifically, we noted that the file names of the spreadsheets in the email string from UPS and forwarded to Pos-T-Vac were different than the file names of the spreadsheets Pos-T-Vac forwarded to us. Therefore, we know that the file names were modified. We do not know whether the data within the spreadsheets were also modified.
3. For 14 of the items, there were 2 or more dates in the “stop complete” column, which indicated that on more than one occasion, a driver either attempted delivery or made delivery of a particular item. Because the source documentation is not available for testing those dates, we do not know whether the dates in these 14 instances represent

⁶ The information provided by Pos-T-Vac did not include an explanation of how the data were entered into the Excel spreadsheet (i.e., entered manually into the spreadsheet by the UPS official or electronically transferred from the data warehouse into the Excel spreadsheet). There would be substantially more risk that the data were inaccurate if it were manually entered.

⁷ In its comments, Pos-T-Vac asserted that the data also included information identifying the individual who signed for each package. However, we concluded that the data did not include that information.

dates of attempted delivery or of actual delivery. Ultimately, the information provided by Pos-T-Vac did not differentiate between an attempted delivery and a completed delivery.

4. The information provided by Pos-T-Vac appeared to show that 2 of the 48 items were delivered to Pos-T-Vac's address. Such entries would indicate that the two items were not accepted by the beneficiaries and had been returned to Pos-T-Vac. If this were the case, the claims should have been adjusted. We reviewed the associated claims in the Medicare claims processing system, but found that there had been no adjustments to reflect these apparent returns. Without the original delivery confirmation documentation, we cannot determine whether or not these items were delivered to the beneficiaries or returned to Pos-T-Vac.

In light of these irregularities and the lack of original source delivery documentation against which to validate the data, we maintain, in accordance with GAGAS, that the electronic reports provided as part of Pos-T-Vac's comments did not represent sufficient and/or appropriate evidence for supporting a conclusion that the items had actually been delivered to beneficiaries.

APPENDIXES

APPENDIX A: SAMPLING METHODOLOGY

POPULATION

The population consisted of Medicare durable medical equipment (DME) claims that were submitted by Pos-T-Vac Medical for male vacuum erection systems and paid during the period January 1, 2008, through December 31, 2009.

SAMPLING FRAME

The sampling frame contained 28,088 paid claims totaling \$10,160,035.

SAMPLE UNIT

The sampling unit is a paid Pos-T-Vac Medical DME claim.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

We selected a sample of 100 units (paid claims).

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the Office of Inspector General, Office of Audit Services (OAS) statistical software.

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the sampling frame. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate the amount of overpayments.

APPENDIX B: SAMPLE RESULTS AND ESTIMATES

Sample Results

Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Unallowable Services	Value of Unallowable Services
28,088	\$10,160,035	100	\$35,986	51	\$18,007

Estimated Value of Unallowable Services (Limits Calculated for a 90-Percent Confidence Interval)

Point Estimate	\$5,057,919
Lower Limit	\$4,217,800
Upper Limit	\$5,898,037

APPENDIX C: AUDITEE COMMENTS



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February 7, 2012

Mr. Scott Englund
Audit Manager
Office of Audit Services, Region VII
601 East 12th Street, Room 0429
Kansas City, MO 64106

Re: Report Number: A-07-11-05016
Pos-T-Vas Medical ["Pos-T-Vac"]

Dear Mr. Englund:

This letter is in response to the above-referenced report dated January 10, 2012 sent to my client, Pos-T-Vac [see Exhibit 1]. The van Halem Group is a Medicare consulting firm that has been retained by Pos-T-Vac to assure compliance with federal laws, regulations, and policies associated with their Medicare business. As a result of this draft report, we have reviewed the related files and would like to provide the following response on behalf of our client.

Out of 100 claims reviewed, your office found that 50 claims did not include appropriate proof of delivery, 2 claims did not maintain sufficient documentation of the patient's medical condition to substantiate the necessity of the items ordered, and 1 claim did not have a physician signature on the order. We were provided the specific claims data and present the following response.

In the instance in which the claim was denied because the order was missing a signature¹ and the two instances in which the claims were denied for no clinical documentation², we have reviewed the files and concur with these findings. The missing signature was an error on the part of my client. Regarding the documentation, it is important to note that while suppliers must be able to provide documentation which supports the items they bill are reasonable and necessary, they are not required to maintain this documentation in their files. It is only upon request that it must be provided. In these instances, Pos-T-Vac was unable to obtain the documentation from the ordering physician. Pos-T-Vac has implemented procedures to assure that these types of errors do not occur in the future. We will continue to communicate with the ordering physicians to educate them on the documentation requirements and obtain appropriate documentation on the front end as much as possible. We will continue conducting quality assurance reviews as part of our accreditation standards to identify and correct errors such as the missing signature. While we continue to strive for perfection, we think it's important to note that these errors account for only 3% of the sample population.

The remaining 48 claims [see attached list] were denied solely for lacking proof of delivery and we respectfully do not concur with these findings. Pos-T-Vac Medical did, in fact, deliver these items to the beneficiaries via United Parcel Service (UPS). Specifically, my client was enrolled in the Quantam View Tracking Program with UPS which allows them to obtain tracking confirmation electronically. Unfortunately, they were unaware that the confirmations of delivery forms are only

¹ Office of Inspector General Note - The deleted text has been
² redacted because it is personally identifiable information.



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available for 18 months. As a result, they are unable to provide these. However, the system does account for all deliveries and we have provided electronic copies of two reports generated by UPS [see attached disk]. The first file³ is a spreadsheet which includes the tracking number, name of the individual it was sent to, the address it was delivered to, by whom the packaged was signed for, and other data provided by UPS. For authenticity purposes, all data provided has been included in the spreadsheet. The second file⁴ is a searchable spreadsheet with the corresponding tracking numbers and date and time of delivery [per UPS, this is the "Stop Complete Time" column on the spreadsheet]. As part of our response to the draft report, we are also providing additional clarification from UPS confirming that the information is all that can be provided at this time but the data is accurate [see Exhibit 2]. Based on this information, it can be concluded that the equipment was delivered to the beneficiaries. Additionally, in these 48 instances, we recommended that Pos-T-Vac add the UPS Tracking number to their invoice and implement this change for all new claims moving forward. This was implemented to assure that the invoice and delivery confirmation can be cross-referenced and is currently the procedure in place.

According to the DME MAC Supplier Manual for each jurisdiction⁵, the following proof of delivery documentation is required:

If you utilize a shipping service or mail order, an example of proof of delivery would include the service's tracking slip and your own shipping invoice. If possible, your records should also include the delivery service's package identification number for the package sent to the beneficiary. The shipping service's tracking slip should reference each individual package, the delivery address, the corresponding package identification number given by the shipping service, and if possible, the date delivered. If you utilize a shipping service or mail order, you must use the shipping date as the date of service on the claim.

In reviewing the files, we determined in each of the 48 instances that my client did provide a copy of their own invoice [see Exhibit 3] documenting the equipment that was provided. The corresponding delivery confirmation information provided by UPS does reference suggested information from the paragraph above. Therefore, we feel we have sufficient documentation to show that the equipment was delivered and meets the Medicare guidelines highlighted above.

In closing, Pos-T-Vas is committed to being in compliance with Medicare laws, regulations, and policies and continues to strive to provide a quality covered product to Medicare beneficiaries. As additional information, we have provided a summary of corrective actions, including a new position for file verification, which has been implemented to assure claims being submitted contain the appropriate documentation as well as internal policies in place to assure accuracy [see Exhibit 4]. In question here is not if these services were delivered, but the format of the proof of delivery. We have provided proof that the packages were delivered which includes the elements requested by Medicare and has been confirmed by the third-party delivery service. As a result, we feel that an extrapolated overpayment of \$4,217,800.00 is not reasonable in this instance. We respectfully ask that this information be considered when issuing your final report.

Sincerely,



Wayne H. van Halem, CFE, AHFI
President
The van Halem Group, LLC

Cc: Ed Stewart, Pos-T-Vac Medical

³ File "UPS Tracking_Pos T Vac_02 06 2012"

⁴ File "UPS Delivery Conf Dates_Pos T Vac_02 06 2012"

⁵ Jurisdiction A DME MAC Supplier Manual, Chapter 10; Jurisdiction B DME MAC Supplier Manual, Chapter 8; Jurisdiction C DME MAC Supplier Manual, Chapter 3; and Jurisdiction D DME MAC Supplier Manual, Chapter 3