

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FIRST COAST SERVICE OPTIONS, INC.,
PAID PROVIDERS FOR HYPERBARIC
OXYGEN THERAPY SERVICES THAT
DID NOT COMPLY WITH
MEDICARE REQUIREMENTS**

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Office of Inspector General

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Report in Brief

Date: December 2018

Report No. A-04-16-06196

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



Why OIG Did This Review

Hyperbaric oxygen therapy (HBO therapy) involves giving a patient high concentrations of oxygen within a pressurized chamber in which the patient intermittently breathes in 100-percent oxygen. A prior Office of Inspector General review identified issues with Medicare payments for HBO therapy. More recently, a review by a Centers for Medicare & Medicaid Services (CMS) contractor found that claims for HBO therapy services were denied because of a lack of medical documentation. From 2015 through 2018, CMS conducted a prior authorization demonstration program for non-emergent HBO therapy to test its effectiveness.

For this review, we focused on one Medicare administrative contractor, First Coast Service Options, Inc. (First Coast), because it paid the second largest amount for HBO outpatient therapy services in 2013 and 2014.

Our objective was to determine whether First Coast paid providers for HBO therapy services that complied with Medicare requirements.

How OIG Did This Review

Our review covered 46,857 outpatient claims totaling \$44.3 million for CMS Jurisdiction N that contained HBO therapy services provided to Medicare beneficiaries during calendar years 2012 through 2015. We selected for review a statistical sample of 120 of these claims, submitted by 48 providers.

First Coast Service Options, Inc., Paid Providers for Hyperbaric Oxygen Therapy Services That Did Not Comply With Medicare Requirements

What OIG Found

First Coast paid 48 providers for HBO therapy services that did not comply with Medicare requirements. Of the 120 sampled outpatient claims totaling \$415,513, First Coast made payments for HBO therapy in accordance with Medicare requirements for 5 claims. However, First Coast made payments for HBO therapy services that did not comply with Medicare requirements for 110 claims, resulting in overpayments totaling \$351,970. We treated five claims as non-errors because one was canceled and the Recovery Audit Contractor indicated that the other four were under review by another entity.

First Coast made payments for HBO therapy that did not always comply with Medicare requirements because it had limited policies and procedures in place to ensure that it made correct payments. During the audit period, First Coast did not have effective automated Medicare Part A prepayment edits in its claim processing system to monitor HBO therapy coverage. Based on our sample results, we estimate that First Coast overpaid providers in Jurisdiction N \$39.7 million during the audit period for HBO therapy that did not comply with Medicare requirements.

What OIG Recommends and First Coast Comments

We made the following recommendations to First Coast: (1) recover the appropriate portion of the \$351,970 in Medicare overpayments; (2) notify the providers responsible for the 46,737 nonsampled claims with potential overpayments estimated at \$39.3 million so that those providers can investigate and return any identified overpayments; (3) identify and recover any improper payments for HBO therapy services made after the audit period, and (4) work with CMS to the extent possible in developing more effective automated HBO therapy prepayment edits in the claim processing system, which would result in millions of dollars in future cost savings.

First Coast concurred with three of our recommendations and partially concurred with the fourth. In addition, First Coast questioned language in our draft report stating that First Coast did not have automated Medicare Part A prepayment edits in its claims processing system to monitor HBO therapy. We revised our report language to say that Medicare Part A prepayment edits were active in First Coast's claims processing system but those edits were *not effective* in the prevention of improper payments for HBO therapies.

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INTRODUCTION

WHY WE DID THIS REVIEW

Hyperbaric oxygen therapy (HBO therapy) involves giving a patient high concentrations of oxygen within a pressurized chamber in which the patient intermittently breathes in 100-percent oxygen. A prior Office of Inspector General (OIG) review on HBO therapy expressed concerns that (1) Medicare beneficiaries received treatments for noncovered conditions, (2) medical documentation did not adequately support treatments, and (3) Medicare beneficiaries received more treatments than were considered medically necessary.¹

More recently, a review by a Centers for Medicare & Medicaid Services (CMS) contractor found that claims for HBO therapy services were denied because of a lack of medical documentation to support that the services were medically reasonable and necessary.² From 2015 through 2018, CMS conducted a prior authorization demonstration program for non-emergent HBO therapy in Illinois, Michigan, and New Jersey.³ The program did not create additional documentation requirements but required the documentation to be submitted earlier in the claim payment process for certain covered conditions. CMS is using this program to test whether prior authorization reduces expenditures, while maintaining or improving quality of care, and ensures HBO therapy services provided are in compliance with Medicare requirements. The results of this pilot have not yet been made public. For this review, we focused on one Medicare administrative contractor (MAC), First Coast Service Options, Inc. (First Coast), because, of all MACs, it paid the second largest amount for HBO outpatient therapy services in 2013 and 2014. During the same time period, Wisconsin Physician Services paid the most for HBO outpatient therapy services, but has already been audited by the OIG.⁴

¹ Office of Evaluation and Inspections, *Hyperbaric Oxygen Therapy: Its Use and Appropriateness* (OEI-06-99-00090), October 2000. Available online at <https://oig.hhs.gov/oei/reports/oei-06-99-00090.pdf>.

² The CMS contractor reviewed a random sample of 2,000 claims containing HBO therapy services with dates of service from April 1, 2012, through March 31, 2013. See Valerie Larson-Lohr, MSN, APRN, "Understanding the Post-Payment Review Process," *Today's Wound Clinic*, volume 9, issue 8, dated October 19, 2015. Accessed at <http://www.todayswoundclinic.com/articles/understanding-post-payment-review-process> on November 8, 2017.

³ The CMS prior authorization demonstration program for non-emergent HBO therapy ended on February 28, 2018, based on date of service.

⁴ Office of Audit Services, *Wisconsin Physicians Service Paid Providers for Hyperbaric Oxygen Therapy Services That Did Not Comply With Medicare Requirements* (A-01-15-00515), February 2018. Available online at <https://oig.hhs.gov/oas/reports/region1/11500515.pdf>.

OBJECTIVE

Our objective was to determine whether First Coast paid providers for HBO therapy services that complied with Medicare requirements during calendar years (CYs) 2012 through 2015.

BACKGROUND

Hyperbaric Oxygen Therapy

HBO therapy is typically performed as an outpatient procedure. Patients may receive HBO therapy in a monoplace chamber or a multiplace chamber. A monoplace chamber is designed for a single patient. The entire chamber fills with oxygen during the treatment. A multiplace chamber is designed for several patients to receive treatment at the same time. In a multiplace chamber (Figure 1), patients are immersed in oxygen and also receive it through facemasks or hoods placed on their heads. Risks associated with HBO therapy include barotrauma to the ears due to changes in pressure, lung collapse, changes in vision, oxygen poisoning, and claustrophobia.

Figure 1: Multiplace Chamber



Source: National Oceanic and Atmospheric Administration and the Monterey Bay National Marine Sanctuary (<https://montereybay.noaa.gov/new/2013/hyperbaric.html>).

Medicare Coverage of Hyperbaric Oxygen Therapy

Medicare Part B covers hospital outpatient services including HBO therapy. CMS administers the Medicare program. CMS issues National Coverage Determinations (NCDs) that indicate whether a particular service is covered under Title XVIII of the Social Security Act (the Act) § 1869(f)(1)(B). NCD 20.29 allows Medicare coverage for HBO therapy.

NCD 20.29 states, “For purposes of coverage under Medicare, HBO therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure.” Medicare reimbursement for HBO therapy is limited to that administered in a chamber and only for 15 conditions, including diabetic wounds of the lower extremities and chronic refractory osteomyelitis (chronic bone infections). (See Appendix B for a complete list of covered conditions.)

For diabetic wounds of lower extremities to be covered by Medicare, documentation in the patient’s records must support that the patient has (1) type I or type II diabetes and has a lower extremity wound that is due to diabetes, (2) a wound classified as Wagner grade III or higher,⁵ and (3) failed an adequate course of standard wound therapy. HBO therapy is covered as adjunctive therapy for diabetic wounds of lower extremities only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care (NCD 20.29). The documentation for patients with chronic refractory osteomyelitis must support that the condition was unresponsive to both conventional medical and surgical management.

First Coast issued the Local Coverage Determination (LCD)⁶ L28887 on December 30, 2013, with an effective date until September 30, 2015.⁷ The LCD contains covered conditions relating to NCD 20.29. The LCD also contains noncovered conditions that should not be reimbursed by Medicare, documentation maintenance requirements for HBO claims, and ICD-9 diagnosis codes that should be billed for rendering the HBO service under the covered conditions.

⁵ The Wagner grading system is a commonly used measurement system for diabetic foot ulcers. There are grades I through V with grade V wounds being the most severe. Wagner grade III wounds are lesions that have penetrated to tendon, bone, or joint and there is an abscess, osteomyelitis, pyarthrosis (infectious arthritis), plantar space abscess, or infection of the tendon and tendon sheaths.

⁶ Section 1869(f)(2)(B) of the Act defines LCDs as determinations by a fiscal intermediary or a carrier regarding whether a particular item or service is covered on an intermediary- or carrier-wide basis. LCDs specify under what clinical circumstances an item or service is reasonable and necessary. They contain information to assist providers in submitting correct claims for payment and to provide guidance to the public and medical community within their jurisdictions. First Coast published LCDs L28887 and L36504 for HBO services. LCD 36504 did not become effective until April 11, 2016.

⁷ First Coast issued an earlier version of LCD L28887 with an effective date of February 16, 2009.

Medicare Requirements for Outpatient Claims and Payments

Medicare payments may not be made for items and services that are not “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act § 1862(a)(1)(A)). In addition, the Act precludes payment to any provider of services or other person unless there has been furnished such information as may be necessary to determine the amounts due such provider or other person (section 1833(e)). During CYs 2012, 2013, and 2014, hospitals billed Medicare for outpatient HBO therapy services using Healthcare Common Procedure Coding System (HCPCS) code C1300, hyperbaric oxygen under pressure, full body chamber, one unit for each 30-minute interval. Effective January 1, 2015, HCPCS code C1300 was discontinued and replaced with HCPCS code G0277.

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 amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (60-day rule).⁸

First Coast Service Options, Inc.

A MAC is a private health care insurer that CMS has awarded a geographic jurisdiction to process Medicare Part A and Part B medical claims for Medicare fee-for-service (FFS) beneficiaries. First Coast is the MAC for Jurisdiction N,⁹ which includes Parts A and B claims for the State of Florida and the territories of Puerto Rico and the United States Virgin Islands.¹⁰ We excluded Puerto Rico and the United States Virgin Islands from our review.

HOW WE CONDUCTED THIS REVIEW

Our review covered 46,857 outpatient claims totaling \$44,348,527 for 70 providers in Jurisdiction N that had scheduled payment dates during CYs 2013, 2014, 2015, and 2016 and contained HBO therapy services provided to Medicare beneficiaries during CYs 2012 through

⁸ 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).

⁹ On February 11, 2014, First Coast was awarded a CMS contract for the administration of Medicare Part A and Part B FFS claims in Jurisdiction N, previously Jurisdiction 9.

¹⁰ First Coast also services providers in Georgia, Illinois, Kansas, North Carolina, Tennessee, and Texas whose corporate headquarters are located in Florida. These providers are part of First Coast’s Jurisdiction N national workload and were included in our review.

2015.¹¹ We selected a statistical sample of 120 of these claims, submitted by 48 providers, for review. Our medical review contractor subsequently reviewed the medical records associated with the sampled claims for compliance 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 the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, and Appendix D contains our sample results and estimates.

FINDINGS

Of the 120 sampled outpatient claims totaling \$415,513,¹² First Coast made payments for HBO therapy in accordance with Medicare requirements for 5 claims. However, First Coast made payments for HBO therapy that did not comply with Medicare requirements for 110 claims (92 percent), resulting in overpayments for HBO therapy totaling \$351,970.¹³ We did not review the remaining five claims because one was canceled and the Recovery Audit Contractors (RAC) indicated that the other four were under review by another entity.

First Coast made payments for HBO therapy that did not always comply with Medicare requirements because First Coast had limited policies and procedures in place to ensure it made correct payments. During the audit period, First Coast did not have effective automated Medicare Part A prepayment edits in its claims processing system to monitor HBO therapy coverage. Based on our sample results, we estimated that First Coast overpaid providers in Jurisdiction N \$39.7 million during the audit period for HBO therapy that did not comply with Medicare requirements.

PAYMENTS FOR HYPERBARIC OXYGEN THERAPY THAT WAS NOT MEDICALLY NECESSARY

Medicare payments may not be made for items and services that are not “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act § 1862(a)(1)(A)). In addition, the Act precludes payment to

¹¹ These outpatient claims contained services and items other than HBO therapy services. We limited our review to the Part A HBO therapy services on the claim.

¹² The total paid amount for the 120 sampled outpatient claims includes payment for all services and items on the claim.

¹³ The overpayment amounts in the findings only include payments for HBO HCPCS codes C1300 and G0277.

any provider of services or other person without information necessary to determine the amount due the provider (section 1833(e)).

For 110 of 120 sampled outpatient claims, First Coast paid providers for HBO therapy services that were not medically reasonable or necessary, resulting in overpayments for HBO therapy totaling \$351,970.¹⁴ Specifically, the medical records submitted for review did not support that the HBO therapy provided met the requirements in NCD 20.29. We determined that the medical records did not always support that HBO therapy was provided as treatment for a covered condition. Additionally, the medical records did not always support that HBO therapy was provided only after standard or conventional treatment failed for applicable conditions.

Example 1: Medicare Payment for HBO Therapy Without Failing Conventional Treatment

A Medicare beneficiary underwent seven HBO therapy sessions as of 4/25/2014, for treatment of osteomyelitis. HBO therapy for osteomyelitis can be a Medicare-covered condition when it is chronic refractory osteomyelitis and has been unresponsive to conventional medical and surgical treatment. The medical records indicated that HBO therapy treatment began before the conventional treatment had been completed. The hospital billed \$1,949 for these six HBO therapy sessions.

Example 2: Medicare Payment for HBO Therapy That Was Not Medically Necessary

A Medicare beneficiary underwent 35 HBO therapy sessions as of 11/30/2013, for treatment of a failed flap¹⁵ procedure, which is a covered condition. However, there was no evidence that the beneficiary ever received a flap procedure. She had surgery that resulted in a wound that became infected and did not heal, but there was no evidence that she ever received a flap. The hospital billed \$7,604 for 24 of these HBO sessions.

Example 3: Medicare Payment for HBO Therapy With Insufficient Documentation

A Medicare beneficiary underwent 58 HBO therapy sessions as of 10/11/2013, for treatment of a diabetic ulcer, which can be a covered condition when at least 30 days of standard wound care therapy are provided, with no measurable signs of healing, prior to HBO therapy. However, the medical records did not contain sufficient documentation to support that there were at least 30 days of standard

¹⁴ If the medical reviewers determined that the HBO therapy billed was not medically reasonable or necessary, they did not review the claim to determine whether the HBO therapy service(s) was coded and billed correctly.

¹⁵ A skin flap is healthy skin and tissue that is partly detached and moved to cover a nearby wound.

wound care therapy provided prior to HBO therapy. The hospital billed \$2,535 for eight of these HBO sessions.

CAUSES OF IMPROPER PAYMENTS FOR HYPERBARIC OXYGEN THERAPY

First Coast made payments for HBO therapy that did not always comply with Medicare requirements because it did not have effective automated Medicare Part A prepayment edits in its claims processing system to monitor HBO therapy coverage. As a result, we estimated that First Coast overpaid providers in Jurisdiction N \$39.7 million during the audit period for HBO therapy that did not comply with Medicare requirements. Furthermore, Medicare beneficiaries may have received excessive or inappropriate treatments that were potentially ineffective, exposing them to unnecessary risks and discomfort.

RECOMMENDATIONS

We recommend that First Coast:

- recover the portion of the \$351,970 in Medicare overpayments from the 48 providers for the 110 incorrectly billed claims that are within the 4-year reopening period;
- notify the 70 providers responsible for the remaining 46,737 nonsampled claims with potential overpayments estimated at \$39.3 million so that those providers can exercise reasonable diligence to investigate and return any identified overpayments, in accordance with the 60-day rule, and identify and track any returned overpayments as having been made in accordance with this recommendation;
- identify and recover any improper payments for HBO therapy services made after the audit period; and
- work with CMS to the extent possible in developing more effective automated HBO therapy prepayment edits in the claim processing system, which would result in millions of dollars in future cost savings.

FIRST COAST COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, First Coast concurred with three of our recommendations and partially concurred with the fourth. A summary of First Coast's comments and our responses to those comments are included below.

In addition, First Coast questioned language in our draft report stating that First Coast did not have automated Medicare Part A prepayment edits in its claims processing system to monitor HBO therapy. First Coast stated that, based on CMS guidance at the time, edits were in place for Medicare Part A and Part B claims during our audit period, and it provided a detailed description of those edits. We revised our report language to say that Medicare Part A prepayment edits were active in First Coast's claims processing system but those edits were *not effective* in the prevention of improper payments for HBO therapies. Because our audit scope did not include Medicare Part B claims, no similar revisions were needed to address First Coast's point that edits were in place for those types of claims.

First Coast's comments are included in their entirety as Appendix E.

RECOMMENDATIONS TO RETURN OVERPAYMENTS RECEIVED DURING OUR AUDIT PERIOD

First Coast Comments

Regarding our first recommendation, First Coast concurred and stated that it will proceed with recovery of overpayments subsequent to OIG sending claims data. First Coast also concurred with our second recommendation and requested that we provide additional information such as National Provider Identifier (NPI) numbers or Provider Transaction Access Numbers (PTAN) for the associated providers for nonsampled claims. With the NPI/PTAN data, First Coast said that it will notify providers to investigate and return identified overpayments.

OIG Response

We will provide to First Coast all of the claims data for the 120 sampled claims and provider identifier information for the remaining non-sampled claims to assist it in the identification and recovery of overpayments.

RECOMMENDATION TO IDENTIFY AND RETURN OVERPAYMENTS RECEIVED AFTER OUR AUDIT PERIOD

First Coast Comments

Regarding our recommendation that First Coast identify and recover any improper payments for HBO therapy services made after the audit period, First Coast concurred. To ensure proper payment for HBO therapy services and to comply with the CMS Targeted Probe and Educate

(TPE) program, First Coast stated that it intends to perform targeted medical record reviews on providers identified as statistical outliers. In addition, First Coast will provide one-on-one education to those providers to prevent or reduce the possibility of further improper claim submission. Additionally, First Coast will refer to CMS for further action those providers who do not become compliant after 3 rounds of education.

OIG Response

The inclusion of HBO therapies in the TPE program, as dictated by CMS's Change Request (CR) 10249, does not adequately address our recommendation. We understand that the payments cannot be recovered without medical review and that the medical review is now directed by CR 10249. However, limiting medical review to those providers that are statistically aberrant, while our audit showed that 110 of 120 (92 percent) of the claims resulted in overpayments, will not decrease the unallowable HBO therapy payments made throughout the system. Therefore, we believe our third recommendation is proper.

RECOMMENDATION TO DEVELOP MORE EFFECTIVE EDITS

First Coast Comments

Regarding our recommendation that First Coast work with CMS to develop automated HBO therapy prepayment edits in the claim processing system, First Coast partially concurred. First Coast stated that the "hard coded system logic" is already in place as a result of the NCD for HBO Therapy. Because of claims processing system limitations, additional edits can't be put into place at this time. However, First Coast said that it will perform targeted medical record reviews on providers identified as statistical outliers and provide one-on-one education to prevent or reduce the possibility of further improper claims submissions. First Coast stated that it will refer to CMS for further action those providers who do not become compliant after 3 rounds of education.

OIG Response

We continue to believe that more restrictive pre-payment edits would be the best solution for addressing the 92 percent overpayment rate in HBO therapy claims. First Coast's hard coded system logic did not prevent the HBO Therapy overpayments in our audit. Targeting HBO providers is not an effective strategy, when nearly all Hyperbaric claims are found to be in error.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered 46,857 outpatient claims totaling \$44,348,527 that had scheduled claim payment dates during CYs 2013, 2014, 2015, and 2016 and contained services for HBO therapy provided to beneficiaries during CYs 2012 through 2015. Our review was limited to outpatient claims that contained HBO therapy services paid to First Coast Jurisdiction N providers.

We limited our review of internal controls to gaining an understanding of the policies and procedures First Coast had in place during our audit period for reimbursing providers for HBO therapy services.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- held discussions with CMS officials to gain an understanding of the Medicare requirements for HBO therapy;
- extracted outpatient claims that contained HBO therapy services from CMS's National Claims History file for CYs 2012 through 2015;
- identified a sampling frame of 46,857 outpatient claims that had scheduled claim payment dates during CYs 2013, 2014, 2015, and 2016 totaling \$44,348,527;
- selected a statistical sample of 120 outpatient claims for review;
- sent a letter to each provider associated with the claims in our sample to request all medical records associated with the HBO therapy services contained in the 115 sampled outpatient claims;¹⁶
- used an independent medical review contractor to determine whether the HBO therapy services contained on 115 outpatient claims met Medicare requirements as billed;
- identified the portion of the total claim payments for the sampled outpatient claims that was overpaid by First Coast for HBO therapy services that did not meet Medicare requirements;

¹⁶ We did not request documentation to support the remaining five sampled claims because one was canceled and the RAC indicated that the other four were under review by other entities.

- estimated the total amount of Medicare overpayments made to providers for HBO therapy services that did not meet Medicare requirements; and
- discussed the results of our review with First Coast 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: MEDICARE COVERAGE OF HYPERBARIC OXYGEN THERAPY

Medicare reimbursement for HBO therapy will be limited to that which is administered in a chamber (including a one-person unit) and is limited to the following conditions:¹⁷

- acute carbon monoxide intoxication (acute carbon monoxide poisoning);
- decompression illness (bubbles in blood or tissue caused by rapid decrease in atmospheric pressure);
- gas embolism (gas bubbles in the blood that obstruct circulation);
- gas gangrene (rapidly progressing tissue death resulting from a bacterial infection);
- acute traumatic peripheral ischemia (caused by an injury that blocks blood flow to an extremity);
- crush injuries and suturing of severed limbs;
- progressive necrotizing infections (necrotizing fasciitis) (serious infections of tissue);
- acute peripheral arterial insufficiency (lack of oxygen and nutrients to tissue);
- preparation and preservation of compromised skin grafts (failing skin graft caused by insufficient oxygen supply to tissue);
- chronic refractory osteomyelitis (chronic bone infections) unresponsive to conventional medical and surgical management;
- osteoradionecrosis (bone death from radiation therapy);
- soft tissue radionecrosis (soft tissue death);
- cyanide poisoning;
- actinomycosis (infection of soft tissue), only as an adjunct to conventional therapy when the disease is refractory to antibiotics and surgical treatment; and

¹⁷ NCD 20.29.

- diabetic wounds of the lower extremities (sores or ulcers on legs and feet caused by diabetes) in patients who meet the following three criteria:
 - patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes,
 - patient has a wound classified as Wagner grade III or higher, and
 - patient has failed an adequate course of standard wound therapy.

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

TARGET POPULATION

The target population consisted of Medicare outpatient claims with HCPCS codes C1300 or G0277¹⁸ that were processed and paid by First Coast to Jurisdiction N providers, had total claim paid amounts greater than \$0, and were for HBO therapy services with dates of service during CYs 2012–2015.

SAMPLING FRAME

We obtained databases of Medicare outpatient claims that contained services for HBO therapy provided to beneficiaries during CYs 2010 through 2015. For our review, we analyzed the claim data and then selected First Coast Jurisdiction N processed claims with HCPCS codes C1300 or G0277, dates of service in CYs 2012 through 2015, and claim payment amounts greater than zero. We determined that First Coast processed 59,690 paid outpatient claims for C1300 and G0277 HBO therapy services, with a total paid amount of \$58,042,240. We then removed the following claims:

- 400 claims with providers under OIG investigation,
- 2,236 claims in which the total revenue center payment amount for HCPCS codes C1300 or G0277 per claim was less than \$200,
- 214 claims that were corrected by an adjustment,
- 293 claims that matched claim data in the RAC Data Warehouse,
- 9,680 claims that had CY 2012 payment dates, and
- 10 claims that did not have Medicare as the primary payer.

The resulting sampling frame contained 46,857 outpatient claims, paid in calendar years 2013, 2014, 2015, and 2016, with a total claim paid amount of \$44,348,527.

SAMPLE UNIT

The sample unit was an outpatient claim.

¹⁸ Effective January 1, 2015, HCPCS code C1300 was discontinued and replaced with HCPCS code G0277.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample as follows.

Table 1: Sample Design

Stratum	Claim Payment Range	Number of HBO Therapy Claims	Sample Size	Dollar Value of Claim Payments in the Frame
1	\$204.82 to \$1,117.97	40,017	38	\$14,527,115
2	\$1,117.98 to \$5,449.33	4,539	37	13,675,026
3	\$5,449.34 to \$18,684.60	2,293	37	16,119,142
4	N/A*	8	8	27,245
Totals		46,857	120	\$44,348,527[†]

* Eight claims were assigned to a separate stratum because they lacked necessary diagnosis codes.

† The numbers do not add up to the total because of rounding.

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in the sampling frame for the first three strata. After generating 38 random numbers for stratum 1, 37 for stratum 2, and 37 for stratum 3, we selected the corresponding frame items. We selected all eight claims in stratum 4.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the dollar amount of the improper Medicare payments for outpatient claims paid to providers for HBO therapy services provided during CYs 2012 through 2015. We also used the software to estimate the corresponding lower and upper limits of the two-sided 90-percent confidence interval.

We identified 4 claims within our sample that were being reviewed by another entity. To ensure that our findings do not overlap with recoveries by other entities, we treated these four claims as having no overpayments for the purpose of both our statistical estimate and our sample results.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Results by Stratum

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Value of the Sample	Number of Errors in Sample	Value of Overpayments in the Sample
1	40,017	\$14,527,115	38	\$14,767	34	\$12,726
2	4,539	13,675,026	37	118,348	35	99,233
3	2,293	16,119,142	37	255,152	37	227,821
4	8	27,245	8	27,245	4	12,190
Total	46,857	\$44,348,527*	120	\$415,513*	110	\$351,970
* The numbers do not add up to total because of rounding.						

ESTIMATES

**Table 3: Estimated Value of Cost Savings
(Limits Calculated for a 90-Percent Confidence Interval)**

Point Estimate	\$39,705,963
Lower Limit	37,035,942
Upper Limit	42,375,983

APPENDIX E: AUDITEE COMMENTS



Harvey B. Dikter
President & CEO
First Coast Service Options, Inc.
harvey.dikter@fcso.com

September 6, 2018

Ms. Lori S. Pilcher
Office of Audit Services, Region IV
61 Forsyth Street, SW, Suite 3T41
Atlanta, GA 30303

Reference: A-04-16-06196

Dear Ms. Pilcher

First Coast is questioning the verbiage within the OIG report in the 'What OIG Found Section': "during the audit period FCSO did not have automated Medicare Part A prepayment edits in its claims processing system to monitor HBO therapy."

For Part A based on CR 8109, the hard-coded diagnosis editing (Reason Codes 59087/59088) was coded in the system on 04/01/13 for dates of service on or after 10/01/14. However, with CR 8799 the implementation date was delayed till 10/01/15. Therefore, there was hard-coded diagnosis editing in the system between the time the old HBO LCD was retired (09/30/15) and the new HBO LCD was implemented (04/11/16).

For Part B based on CR 8109, the hard-coded diagnosis editing (Edit 021L) was coded in the system on 03/26/13 for dates of service on or after 10/01/14. However, with CR 8799 the implementation date was delayed till 10/01/15. Therefore, there was hard-coded diagnosis editing in the system between the time the old HBO LCD was retired (09/30/15) and the new HBO LCD was implemented (04/11/16). First Coast currently has utilization editing in the system for HBO that denies greater than 60 in 12 months.

Therefore for Part A and Part B, editing was in place.

In the draft report, the OIG outlined four recommendations that First Coast has addressed as follows:

Recommendation #1

Recover the portion of the \$351,970 in identified Medicare overpayments,

Response #1

First Coast concurs and will proceed with overpayment recovery on the identified overpayments when the claims data is provided.

Recommendation #2

Notify the 70 providers responsible for the 46,737 non-sampled claims, with potential overpayments estimated at \$39.3 million, so that those providers can investigate and return any identified overpayments.

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Ms. Lori S. Pilcher
Office of Audit Services, Region IV
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Response #2

First Coast concurs, however in order for First Coast to take this action, additional information must be provided. At a minimum First Coast will need the NPI/PTAN's for the associated providers in the non-sampled claims. With the NPI/PTAN data, First Coast will pursue notifying providers to investigate and return identified overpayments in accordance with CMS requirements.

Recommendation #3

Identify and recover any improper payments for HBO therapy services made after the audit period.

Response #3

First Coast concurs and in order to ensure proper payment for HBO therapy services (and comply with TPE), First Coast intends to perform targeted medical record reviews on providers identified as statistical outliers. In addition First Coast will provide one-on-one education to those providers in order to prevent or reduce the possibility of further improper claim submission. Additionally, for those providers who do not become compliant after three rounds of education, a referral of those providers will be made to CMS for further actions.

Recommendation #4

Develop automated HBO therapy prepayment edits in the claims processing system, which would result in millions in future cost savings.

Response #4

First Coast partially concurs and we note that procedure to diagnosis (hard-coded) system logic is already in effect in the shared systems (Parts A and B) as a result of National Coverage Determination (NCD) for Hyperbaric Oxygen Therapy (20.29). Due to claims processing system limitations, implementing another automated prepayment edit for utilization across time in the Part A system cannot be accomplished. However, First Coast will perform targeted medical record reviews on providers identified as statistical outliers and provide one-on-one education to prevent or reduce the possibility of further improper claim submission. Additionally, for those providers who do not become compliant after three rounds of education, a referral of those providers will be made to CMS for further actions.

Again, First Coast appreciates the opportunity to review and provide comments prior to release of the final report. If you have any questions regarding the First Coast response, please contact Mr. Gregory W. England at 904-791-8364.

Sincerely,



Harvey B. Dikter

cc: Gregory W. England