

**FIRST AMENDMENT TO THE
CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
BRADEN PARTNERS, LP, DOING BUSINESS AS
PACIFIC PULMONARY SERVICES**

I. PREAMBLE

Braden Partners, LP, doing business as Pacific Pulmonary Services (PPS), and the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) hereby enter into this First Amendment (Amendment) to the Corporate Integrity Agreement (CIA) that was executed by and between PPS and OIG and that became effective on March 31, 2017.

Pursuant to Section XI.B of the CIA, the CIA may not be amended except by written consent of the parties to the CIA. PPS and OIG hereby agree that the CIA between PPS and OIG shall be amended as described below in this Amendment.

II. AMENDMENT

Appendix B is replaced in its entirety by the attached Appendix B, incorporated by reference.

III. EFFECTIVE AND BINDING AGREEMENT

A. All terms and conditions of the CIA not modified in this Amendment shall remain in effect for the remainder of the five-year period of compliance obligations that began on the CIA's Effective Date of March 31, 2017. The Effective Date of this Amendment shall be the date the final signatory signs this Amendment (Amendment Effective Date).

B. The undersigned PPS signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatories represent that they are signing this Amendment in their official capacities and that they are authorized to execute this Amendment.

C. This Amendment may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Amendment.

Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Amendment.

ON BEHALF OF PPS

/Luke McGee/

4/15/19

LUKE MCGEE
Chief Executive Officer
Braden Partners LP d/b/a Pacific Pulmonary Services

DATE

/Brandy Miller/

4/11/2019

BRANDY R. MILLER
Chief Compliance Officer
Braden Partners LP d/b/a Pacific Pulmonary Services

DATE

/Barry Alexander/

4/11/2019

BARRY ALEXANDER
Polsinelli
Counsel for Braden Partners LP d/b/a Pacific Pulmonary Services

DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Lisa M. Re/

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

05/17/2019

DATE

/Kenneth Kraft/

KENNETH D. KRAFT ✓ ✓
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

5-1-2019

DATE

APPENDIX B
CLAIMS REVIEW

A. **Claims Review.** The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review.

1. ***Definitions.*** For the purposes of the Claims Review, the following definitions shall be used:

- a. **Overpayment:** The amount of money PPS has received in excess of the amount due and payable under Medicare program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix B.
- b. **Paid Claim:** A claim submitted by PPS and for which PPS has received reimbursement from the Medicare program.
- c. **Oxygen Population:** The Oxygen Population shall be defined as all Paid Claims for home oxygen equipment and accessories furnished during the period covered by the Claims Review with either an initial date of service or recertification date in such review period.
- d. **Continuous Positive Airway Pressure (CPAP) Population:** The CPAP Population shall be defined as all Paid Claims for CPAP devices and accessories furnished during the period covered by the Claims Review with either an initial date of service or a beneficiary compliance testing date in such review period.

2. ***Claims Review Sample.*** The IRO shall randomly select and review a sample of 100 Paid Claims (Claims Review Sample). The Claims Review Sample shall be comprised of the following two strata: 60 Paid Claims from the Oxygen Population (Oxygen Paid Claims) and 40 Paid Claims from the CPAP Population (CPAP Paid Claims). Each stratum shall be reviewed separately. The Paid Claims shall be reviewed based on the supporting documentation available at PPS's office or under PPS's control and applicable Medicare program requirements to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed. For each Paid Claim in the Claims Review Sample that results in an Overpayment, the IRO shall review the system(s) and process(es) that generated the Paid Claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the

system(s) and the process(es) that generated the Paid Claim. The Claims Review Sample shall be selected from a universe of Paid Claims as set forth below:

Review Period	Paid Claims Dates in Universe
Period 1	1/1/2016-3/30/2018
Period 2	1/1/2018-3/30/2019
Period 3	1/1/2019-3/30/2020
Period 4	1/1/2020-3/30/2021
Period 5	1/1/2021-3/30/2022

3. *Other Requirements.*

- a. **Supplemental Materials.** The IRO shall request all documentation and materials required for its review of the Paid Claims in the Claims Review Sample and PPS shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Claims Review Sample. If the IRO accepts any supplemental documentation or materials from PPS after the IRO has completed its initial review of the Claims Review Sample (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.
- b. **Paid Claims without Supporting Documentation.** Any Paid Claim for which PPS cannot produce documentation shall be considered an error and the total reimbursement received by PPS for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. **Use of First Samples Drawn.** For the purposes of the Claims Review Sample discussed in this Appendix, the first set of Paid Claims selected shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Claims Review Sample).

4. *Repayment of Identified Overpayments.* PPS shall repay within 60 days the Overpayment(s) identified by the IRO in the Claims Review Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers

for Medicare and Medicaid Services (CMS) guidance (the “CMS overpayment rule”). If PPS determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, PPS shall repay that amount at the mean point estimate as calculated by the IRO. PPS shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Claims Review Sample (and any related work papers) received from PPS to the appropriate Medicare program contractor for appropriate follow up by the payor.

B. **Claims Review Report.** The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report.

1. ***Claims Review Methodology.***
 - a. **Claims Review Population.** A description of the Oxygen Population and the CPAP Population subject to the Claims Review.
 - b. **Claims Review Objective.** A clear statement of the objective intended to be achieved by the Claims Review.
 - c. **Source of Data.** A description of (1) the process used to identify Oxygen Paid Claims in the Oxygen Population and CPAP Paid Claims in the CPAP Population and (2) the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
 - d. **Review Protocol.** A narrative description of how the Claims Review was conducted and what was evaluated.
 - e. **Supplemental Materials.** A description of any Supplemental Materials as required by A.3.a., above.
2. ***Statistical Sampling Documentation.***
 - a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.

- b. A description or identification of the statistical sampling software package used by the IRO.
3. *Claims Review Findings.*
- a. Narrative Results.
 - i. A description of PPS's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
 - ii. A description of controls in place at PPS to ensure that all items and services billed to Medicare are medically necessary and appropriately documented.
 - iii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Claims Review Sample.
 - b. Quantitative Results.
 - i. Total number and percentage of instances in which the IRO determined that the coding of the Oxygen Paid Claims and the CPAP Paid Claims submitted by PPS differed from what should have been the correct coding and in which such difference resulted in an Overpayment to PPS.
 - ii. Total number and percentage of instances in which the IRO determined that an Oxygen Paid Claim or a CPAP Paid Claim was not appropriately documented and in which such documentation errors resulted in an Overpayment to PPS.
 - iii. Total number and percentage of instances in which the IRO determined that an Oxygen Paid Claim or a CPAP Paid Claim was for items or services that were not medically necessary and resulted in an Overpayment to PPS.
 - iv. Total dollar amount of all Overpayments for each stratum in the Claims Review Sample.
 - v. Total dollar amount of Oxygen Paid Claims and CPAP Paid Claims included in the Claims Review Sample.

- vi. Error Rate for each stratum in the Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in each stratum of the Claims Review Sample by the total dollar amount associated with the Paid Claims in that stratum of the Claims Review Sample.
- vii. An estimate of the actual Overpayment in the Oxygen Population at the mean point estimate and an estimate of the actual Overpayment in the CPAP Population at the mean point estimate
- viii. A spreadsheet of the Claims Review results that includes the following information for each Oxygen Paid Claim and each CPAP Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

c. Recommendations. The IRO's report shall include any recommendations for improvements to PPS's billing and coding system or to PPS's controls for ensuring that all items and services billed to Medicare are medically necessary and appropriately documented, based on the findings of the Claims Review.

4. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.