AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND TAMPA PAIN RELIEF CENTERS, INC.

I. PREAMBLE

On April 6, 2020, Tampa Pain Relief Centers, Inc. (TPRC) entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with that CIA, TPRC entered into a Settlement Agreement with the United States. Currently, Collier Anesthesia Pain, LLC (Collier), is entering into a Settlement Agreement with the United States. TPRC serves as the manager of Collier.

Pursuant to Section X.B, the CIA may not be amended except with the written consent of the parties to the CIA. TPRC and OIG hereby agree that the CIA shall be amended as provided below.

II. AMENDMENTS

A. As of the Effective Date of this Amendment and throughout the remaining term of the CIA, Collier shall be an additional party to the CIA and Collier and its (1) owners who are natural persons, officers, directors, employees; and (2) contractors, subcontractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of Collier, excluding vendors whose sole connection with Collier is selling or otherwise providing medical supplies or equipment to Collier (Covered Persons) shall be subject to the requirements of the CIA; provided, however, that the requirements of Section III (Corporate Integrity Obligations) other than Section III.D.2, as amended below, and the requirements of the new Appendix C, discussed below, may be satisfied by TPRC on behalf of Collier.

B. Section III.D.2 of the CIA shall be amended to read as follows:

2. *Claims Review.* The IRO shall review claims submitted by TPRC and reimbursed by the Medicare and Medicaid programs, to determine whether (a) the items and services furnished were medically necessary and appropriately documented and

whether the claims were correctly coded, submitted and reimbursed; and (b) whether any diagnostic testing ordered was medically reasonable and necessary (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference. The IRO shall conduct a separate review of claims submitted by Collier and reimbursed by the Medicare and Medicaid programs to determine whether (a) the items and services furnished were medically necessary and appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed; and (2) whether all cost-sharing amounts (e.g., copayments) were collected or waived in accordance with applicable payor requirements (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix C to this CIA, which is incorporated by reference.

C. The CIA shall be amended to include the new attached Appendix C.

III. EFFECTIVE AND BINDING AGREEMENT

A. The undersigned TPRC and Collier signatories represent and warrant that they are authorized to execute this Amendment to the CIA. The undersigned OIG signatories represent that they are signing this Amendment to the CIA in their official capacities and that they are authorized to execute this Amendment to the CIA.

B. This Amendment to the CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Amendment to the CIA. Electronically transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this Amendment to the CIA.

ON BEHALF OF TPRC AND COLLIER

___/John Calta/_____ ____December 18, 2020_____
JOHN CALTA DATE
Chief Executive Officer
Tampa Pain Relief Centers, Inc.
o/b/o Tampa Pain Relief Centers, Inc. and
Collier Anesthesia

__/Matthew L. Knowles/_____ _____12/18/2020_____
MATTHEW KNOWLES DATE
Counsel for Tampa Pain Relief Centers, Inc.
McDermott Will & Emery LLP
200 Clarendon Street, 58th Floor
Boston MA 02116

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

/Lisa M. Re/ 12/23/2020

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

DATE

/Tonya Keusseyan/ 1/12/2021

TONYA KEUSSEYAN
Senior Counsel
Administrative and Civil Remedies Branch
Office of Inspector General
U. S. Department of Health and Human Services

DATE

APPENDIX C

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 Collier has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix C.

b. Paid Claim: A claim submitted by Collier and for which Collier has received reimbursement from the Medicare program or a state Medicaid program.

c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.

2. *Claims Review Sample.* The IRO shall randomly select and review a sample of 100 Paid Claims (Claims Review Sample). The Paid Claims shall be reviewed based on the supporting documentation available at Collier's office or under Collier's control and applicable Medicare and state Medicaid program requirements to determine whether (1) the items and services furnished were medically necessary and appropriately documented, (2) the claim was correctly coded, submitted, and reimbursed; and (3) all copayments and other cost-sharing amounts were collected or waived in accordance with applicable payor requirements. For each Paid Claim in the Claims Review Sample that results in an Overpayment or for which the IRO identifies a copayment or cost-sharing amount that was not collected or waived in accordance with applicable payor requirements, the IRO shall review the system(s) and process(es) that generated the Paid Claim or resulted in an inappropriate waiver of the copayment or cost-sharing amount and identify any problems or weaknesses that may have resulted in the identified Overpayments or inappropriate waiver of the copayment or cost-sharing amount. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the Paid Claim or resulted in an inappropriate waiver of a copayment or other cost-sharing amount.

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 Collier 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 Collier 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 Collier cannot produce documentation shall be considered an error and the total reimbursement received by Collier 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.* Collier 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 Collier determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Collier shall repay that amount at the mean point estimate as calculated by the IRO. Collier 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 Collier to the appropriate Medicare or state Medicaid 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 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 Paid Claims in the 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 Collier'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 Collier to ensure that all items and services billed to Medicare or a state Medicaid program are medically necessary and appropriately documented, including controls relating to the collection and waiver of copayment or cost-sharing amounts.

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 Paid Claims submitted by Collier differed from what should have been the correct coding and in which such difference resulted in an Overpayment to Collier.

ii. Total number and percentage of instances in which the IRO determined that a Paid Claim was not appropriately documented and in which such documentation errors resulted in an Overpayment to Collier.

iii. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items or services that were not medically necessary and resulted in an Overpayment to Collier.

iv. Total dollar amount of all Overpayments in the Claims Review Sample.

v. Total dollar amount of Paid Claims included in the Claims Review Sample.

vi. Error Rate in the Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in the Claims Review Sample by the total dollar amount associated with the Paid Claims in the Claims Review Sample.

vii. An estimate of the actual Overpayment in the Population at the mean point estimate.

viii. Total number and percentage of instances in which the IRO determined that copayments and other cost-sharing amounts were not collected or waived in accordance with applicable payor requirements and the total amount of such copayments or cost-sharing amounts.

ix. A spreadsheet of the Claims Review results that includes the following information for each 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, copayment or other cost sharing amount collected, 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 Collier's billing and coding system, including requirements relating to the collection or waiver of copayment and other cost-sharing amounts, or to Collier's controls for ensuring that all items and services billed to Medicare or a state Medicaid program are medically necessary, appropriately documented, and the copayments and other cost-sharing amounts are collected or waived in accordance with applicable payor requirements 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.