

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
ORBIT MEDICAL, INC.**

**I. PREAMBLE**

Orbit Medical, Inc. (Orbit) hereby enters into this 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 this CIA, Orbit is entering into a Settlement Agreement with the United States.

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by Orbit under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Orbit’s final annual report; or (2) any additional materials submitted by Orbit pursuant to OIG’s request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “Covered Persons” includes:
  - a. all owners, officers, directors, and employees of Orbit;
  - b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Orbit, excluding vendors whose sole connection with Orbit is selling or otherwise

providing medical supplies or equipment to Orbit and who do not bill the Federal health care programs for such medical supplies or equipment; and

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during a Reporting Period.

2. “Relevant Covered Persons” includes Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Orbit shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Officer and Committee**

1. *Compliance Officer.* Within 90 days after the Effective Date, Orbit shall appoint a Covered Person to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be a member of senior management of Orbit, shall report directly to the Chief Executive Officer of Orbit, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Orbit. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Orbit, and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the

Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request;

- c. monitoring the day-to-day compliance activities engaged in by Orbit as well as for any reporting obligations created under this CIA;
- d. making on-site visits to each Orbit location at least annually.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Orbit shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Orbit shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as finance, sales, billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Orbit's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Orbit shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of Orbit (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non-executive) members.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Orbit's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to the OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of Orbit's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of Orbit's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Orbit has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Orbit.

Orbit shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Orbit employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas

of authority and shall annually certify that the applicable Orbit department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: President and Chief Executive Officer, Chief Operations Officer, Chief Financial Officer (or another member of senior management signing in the capacity of the Chief Financial Officer), National Sales Manager, Compliance Officer, and the Vice President of Operations.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Orbit policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of Orbit is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

B. Written Standards

1. *Code of Conduct.* Within 90 days after the Effective Date, Orbit shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Orbit shall make the performance of job responsibilities in a manner consistent with the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Orbit’s commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

- b. Orbit's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Orbit's own Policies and Procedures;
- c. the requirement that all of Orbit's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Orbit, suspected violations of any Federal health care program requirements or of Orbit's own Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.E, and Orbit's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, Orbit shall distribute the Code of Conduct to all Covered Persons. Orbit shall review the Code of Conduct at least annually to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be distributed at least annually to all Covered Persons.

2. *Policies and Procedures.* Within 90 days after the Effective Date, Orbit shall develop and implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Provider's compliance with Federal health care program requirements. Throughout the term of this CIA, Orbit shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

Within 90 days after the Effective Date, the Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Orbit shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions or addition of new Policies and Procedures, a description of the revisions shall be communicated to all affected Covered Persons and any revised or new Policies and Procedures shall be made available to all Covered Persons.

## C. Training and Education

1. *Training Plan.* Within 90 days after the Effective Date, Orbit shall develop a written plan (Training Plan) that outlines the steps Orbit will take to ensure that: (a) all Covered Persons receive adequate training regarding Orbit's CIA requirements and Compliance Program, including the Code of Conduct and (b) all Relevant Covered Persons receive adequate training regarding: (i) the Federal health care program requirements regarding the accurate coding and submission of claims; (ii) policies, procedures, and other requirements applicable to the documentation of medical records; (iii) the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; (iv) applicable reimbursement statutes, regulations, and program requirements and directives; (v) the legal sanctions for violations of the Federal health care program requirements; and (vi) examples of proper and improper claims submission practices including for power wheelchairs and accessories.

The Training Plan shall include information regarding the training topics, the categories of Covered Persons and Relevant Covered Persons required to attend each training session, the length of the training, the schedule for training, and the format of the training. Within 30 days of the OIG's receipt of Orbit's Training Plan, OIG will notify Orbit of any comments or objections to the Training Plan. Absent notification by the OIG that the Training Plan is unacceptable, Orbit may implement its Training Plan. Orbit shall furnish training to its Covered Persons and Relevant Covered Persons pursuant to the Training Plan during each Reporting Period.

3. *Board Member Training.* Within 90 days after the Effective Date, Orbit shall provide at least two hours of training to each member of the Board of Directors. This training shall address the Orbit's CIA requirements and Compliance Program (including the Code of Conduct), the corporate governance responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of the OIG's guidance on Board member responsibilities.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

3. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

5. *Update of Training Plan.* Orbit shall review the Training Plan annually, and, where appropriate, update the Training Plan to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Claims Review, and any other relevant information. Any updates to the Training Plan must be reviewed and approved by the OIG prior to the implementation of the revised Training Plan. Within 30 days of OIG's receipt of any updates or revisions to Orbit's Training Plan, OIG will notify Orbit of any comments or objections to the revised Training Plan. Absent notification from the OIG that the revised Training Plan is unacceptable, Orbit may implement the revised Training Plan.

6. *Computer-based Training.* Orbit may provide the training required under this CIA through appropriate computer-based training approaches. If Orbit chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

#### D. Review Procedures

##### 1. *General Description*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Orbit shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.D. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Retention of Records.* The IRO and Orbit shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports

(those exchanged between the IRO and Orbit) related to the reviews.

2. *Claims Review.* The IRO shall review Orbit's coding, billing, and claims submission to the Medicare and state Medicaid programs and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) Orbit's Claims Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate (Validation Review). Orbit shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Orbit's final Annual Report shall be initiated no later than one year after Orbit's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Orbit of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Orbit may request a meeting with OIG to: (a) discuss the results of any Claims Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review; and/or (c) propose alternatives to the proposed Validation Review. Orbit agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Claims Review issues with Orbit prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Orbit a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

#### E. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, Orbit shall develop and implement a centralized annual risk assessment and internal review process to identify and address

risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The risk assessment and internal review process should include: (1) a process for identifying and prioritizing risks, (2) developing remediation plans in response to those risks, including internal auditing and monitoring of the identified risk areas, and (3) tracking results to assess the effectiveness of the remediation plans. The risk assessment and internal review process should require compliance, legal and department leaders, at least annually, to evaluate and identify risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries and develop and implement specific plans to address and mitigate the identified risks. The risk assessment and internal review work plans shall be developed annually. Orbit shall implement the risk assessment and internal review work plans and track the implementation of the work plans. Orbit shall maintain the risk assessment and internal review process for the term of the CIA. Copies of any internal audit reports developed pursuant to the risk assessment and internal review process shall be made available to OIG upon request.

F. Disclosure Program

Within 90 days after the Effective Date, Orbit shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Orbit's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Orbit shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Orbit shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within 48 hours of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons

1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration’s System for Award Management (SAM) (available through the Internet at <http://www.sam.gov>).

2. *Screening Requirements.* Orbit shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Orbit shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of

the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

- b. Orbit shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.
- c. Orbit shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in Section III.G. affects Orbit's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. Orbit understands that items or services furnished, ordered or prescribed by excluded persons are not payable by Federal health care programs and that Orbit may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Orbit meets the requirements of Section III.G.

3. *Removal Requirement.* If Orbit has actual notice that a Covered Person has become an Ineligible Person, Orbit shall remove such Covered Person from responsibility for, or involvement with, Orbit's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Orbit has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term Orbit shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

## H. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, Orbit shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Orbit conducted or brought by a governmental entity or its agents involving an allegation that Orbit has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Orbit shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

## I. Repayment of Overpayments

1. *Definition of Overpayments.* For purposes of this CIA, an “Overpayment” shall mean the amount of money Orbit has received in excess of the amount due and payable under any Federal health care program requirements.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, Orbit shall develop and implement written policies and procedures regarding the identification, quantification and repayment of Overpayments received from any Federal health care program.

3. *Repayment of Overpayments.*

- a. If, at any time, Orbit identifies any Overpayment, Orbit shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) within 60 days after identification of the Overpayment and take remedial steps within 90 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 60 days after identification, Orbit shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies.
- b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted

pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

J. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- a. a substantial Overpayment;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by Orbit.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Orbit determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Orbit shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.J.1.a.* For Reportable Events under Section III.J.1.a, the report to OIG shall be made within 30 days of the identification of the Overpayment, and shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

- b. the Federal health care programs affected by the Reportable Event;
- c. a description of the steps taken by Orbit to identify and quantify the Overpayment; and
- d. a description of Orbit's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, Orbit shall provide OIG with a copy of the notification and repayment (if quantified) to the payor required in Section III.I.3.

4. *Reportable Events under Section III.J.1.b.* For Reportable Events under Section III.J.1.b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of Orbit's actions taken to correct the Reportable Event and prevent it from recurring; and
- e. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Orbit to identify and quantify the Overpayment.

5. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Persons employment or contractual relationship;
- c. a description of the Exclusion Lists screening that Orbit completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Reportable Event was discovered; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

6. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

7. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Orbit to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.I.3 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP. If Orbit identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Orbit is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

#### **IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS**

##### **A. Sale of Business, Business Unit or Location.**

In the event that, after the Effective Date, Orbit proposes to sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, Orbit shall notify OIG of the proposed sale at least 30 days prior to the sale of its business, business unit or location. This notification shall include a description of the business, business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of the business, business unit or location, unless otherwise determined and agreed to in writing by the OIG.

##### **B. Change or Closure of Business, Business Unit or Location**

In the event that, after the Effective Date, Orbit changes locations or closes a business, business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Orbit shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the business, business unit or location.

##### **C. Purchase or Establishment of New Business, Business Unit or Location**

In the event that, after the Effective Date, Orbit purchases or establishes a new business, business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Orbit shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit or location. This notification shall include the address of the new business, business unit or location, phone number, fax number, the location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Orbit currently submits claims. Each new business, business unit or location and all Covered Persons at each new business, business unit or location shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by the OIG.

## **V. IMPLEMENTATION AND ANNUAL REPORTS**

### **A. Implementation Report**

Within 120 days after the Effective Date, Orbit shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Orbit's Code of Conduct required by Section III.B.1;
6. a summary of all Policies and Procedures required by Section III.B (copies of the Policies and Procedures shall be made available to OIG upon request);
7. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training; and when the training was provided);
8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between Orbit and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Orbit;
9. a description of the risk assessment and mitigation process required by Section III.E;

10. a description of the Disclosure Program required by Section III.F;
11. a certification that Orbit has conducted the screening required by Section III.G regarding Ineligible Persons, or a description of why Orbit cannot provide such a certification;
12. a copy of Orbit's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I;
13. a list of all of Orbit's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Orbit currently submits claims;
14. a description of Orbit's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
15. the certifications required by Section V.C.

B. Annual Reports

Orbit shall submit to OIG annually a report with respect to the status of, and findings regarding, Orbit's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; any change in the membership of the Compliance Committee in Section III.A, any change in the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3, and any change in the group of Certifying Employees described in Section III.A.4;
2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

3. the Board resolution required by Section III.A.3, and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;
4. a summary of any significant changes or amendments to the Code of Conduct or the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);
5. a copy of Orbit's Training Plan developed under Section III.C and the following information regarding each type of training required by the Training Plan: a description of the training, including a summary of the topics covered; the length of sessions, a schedule of training sessions, a general description of the categories of individuals required to complete the training, and the process by which Orbit ensures that all designated employees receive appropriate training. A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.
6. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter;
7. Orbit's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;
8. a summary and description of any and all current and prior engagements and agreements between Orbit and the IRO (if different from what was submitted as part of the Implementation Report);
9. a certification from the IRO regarding its professional independence and objectivity with respect to Orbit;
10. a. a description of the risk assessment and internal review process required by Section III.E, a summary of any changes to the process, and a description of the reasons for such changes;
11. a copy of Orbit's internal review work plans, and a list of all reviews completed during the Reporting Period pursuant to Section III.E;
12. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

13. a certification that Orbit has completed the screening required by Section III.G regarding Ineligible Persons;
14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
15. a description of any changes to the Overpayment policies and procedures required by Section III.I, including the reasons for such changes;
16. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;
17. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;
18. a summary describing any audits conducted during the applicable Reporting Period by a Medicare or state Medicaid program contractor or any government entity or contractor, involving a review of Federal health care program claims, and Orbit's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;
19. a description of all changes to the most recently provided list of Orbit's locations (including addresses) as required by Section V.A.14; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Orbit currently submits claims; and
20. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

1. *Certifying Employees.* In each Annual Report, Orbit shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Orbit is in compliance with all of the requirements of this CIA; and
- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer (or another member of senior management signing in the capacity of the Chief Financial Officer) that, to the best of his or her knowledge, Orbit has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

Orbit shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Orbit shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

Orbit:

Fabian Martinez  
Orbit Medical, Inc.  
4516 S. 700 E. #360  
Salt Lake City, UT 84107

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Orbit may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

## **VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine and/or request copies of Orbit's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Orbit's locations for the purpose of verifying and evaluating: (a) Orbit's compliance with the terms of this CIA; and (b) Orbit's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Orbit to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of

this provision, OIG or its duly authorized representative(s) may interview any of Orbit's Covered Persons who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Orbit shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Orbit's Covered Persons may elect to be interviewed with or without a representative of Orbit present.

## **VIII. DOCUMENT AND RECORD RETENTION**

Orbit shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

## **IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Orbit prior to any release by OIG of information submitted by Orbit pursuant to its obligations under this CIA and identified upon submission by Orbit as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Orbit shall have the rights set forth at 45 C.F.R. § 5.65(d).

## **X. BREACH AND DEFAULT PROVISIONS**

Orbit is expected to fully and timely comply with all of its CIA obligations.

### **A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, Orbit and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Orbit fails to establish and implement any of the following obligations as described in Sections III and IV:

a. a Compliance Officer;

- b. a Compliance Committee;
- c. the Board of Directors compliance obligations;
- d. the management certification obligations;
- e. a written Code of Conduct;
- f. written Policies and Procedures;
- g. the development and/or implementation of a Training Plan for the training of Covered Persons, Relevant Covered Persons, and Board Members;
- h. a risk assessment and mitigation process as required in Section III.E;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. notification of Government investigations or legal proceedings;
- l. policies and procedures regarding the repayment of Overpayments;
- m. the repayment of Overpayments as required by Section III.I;
- n. reporting of Reportable Events; and
- o. disclosure of changes to business units or locations.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Orbit fails to engage and use an IRO, as required in Section III.D, Appendix A, and Appendix B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Orbit fails to submit the

Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Orbit fails to submit any Claims Review Report in accordance with the requirements of Section III.D and Appendix B.

5. A Stipulated Penalty of \$1,500 for each day Orbit fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Orbit fails to grant access.)

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Orbit as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Orbit fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Orbit stating the specific grounds for its determination that Orbit has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Orbit shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Orbit receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions

Orbit may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Orbit fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after Orbit receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Orbit has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Orbit of: (a) Orbit's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Orbit shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Orbit elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Orbit cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Orbit has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Orbit to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.I;

- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D, Appendix A, and Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Orbit constitutes an independent basis for Orbit's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Orbit has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Orbit of: (a) Orbit's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* Orbit shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) Orbit has begun to take action to cure the material breach; (ii) Orbit is pursuing such action with due diligence; and (iii) Orbit has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Orbit fails to satisfy the requirements of Section X.D.3, OIG may exclude Orbit from participation in the Federal health care programs. OIG shall notify Orbit in writing of its determination to exclude Orbit. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Orbit's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Orbit may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

## E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Orbit of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Orbit shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Orbit was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Orbit shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Orbit to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Orbit requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Orbit was in material breach of this CIA and, if so, whether:

- a. Orbit cured such breach within 30 days of its receipt of the Notice of Material Breach; or

- b. the alleged material breach could not have been cured within the 30-day period, but that, during the 30-day period following Orbit's receipt of the Notice of Material Breach: (i) Orbit had begun to take action to cure the material breach; (ii) Orbit has pursued such action with due diligence; and (iii) Orbit provided to OIG a reasonable timetable for curing the material breach and Orbit has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Orbit, only after a DAB decision in favor of OIG. Orbit's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Orbit upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Orbit may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Orbit shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Orbit, Orbit shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

Orbit and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. OIG may agree to a suspension of Orbit's obligations under this CIA based on a certification by Orbit that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal

health care program. If Orbit is relieved of its CIA obligations, Orbit will be required to notify OIG in writing at least 30 days in advance if Orbit plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. The undersigned Orbit signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF ORBIT MEDICAL, INC.**

/Brandon Bliss/  
\_\_\_\_\_

BRANDON BLISS  
Orbit Medical, Inc.

5/11/15  
\_\_\_\_\_

DATE

/William Michael, Jr./  
\_\_\_\_\_

WILLIAM MICHAEL, JR.  
Mayer Brown LLP

5/12/15  
\_\_\_\_\_

DATE

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

/Robert K. DeConti/

5/15/15

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ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

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DATE

/Tamara T. Forys/

5-12-2015

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TAMARA T. FORYS  
Senior Counsel  
Office of Counsel to the Inspector General  
U. S. Department of Health and Human Services

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DATE

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

#### A. IRO Engagement

1. Orbit shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by Orbit in response to a request by OIG, whichever is later, OIG will notify Orbit if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Orbit may continue to engage the IRO.

2. If Orbit engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Orbit shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Orbit at the request of OIG, whichever is later, OIG will notify Orbit if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Orbit may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the billing, coding, reporting, and other requirements of submitting claims for power wheelchairs and accessories and in the general requirements of the Federal health care program(s) from which Orbit seeks reimbursement;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have

maintained this certification (e.g., completed applicable continuing education requirements); and

4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Claims Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare and Medicaid rules and reimbursement guidelines in making assessments in the Claims Review;

3. if in doubt of the application of a particular Medicare and Medicaid policy or regulation, request clarification from the appropriate authority (e.g., Medicare contractor);

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *Provider and IRO.* If Orbit terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Orbit must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Orbit must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Orbit to engage a new IRO in accordance with Paragraph A of this Appendix. Orbit must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Orbit to engage a new IRO, OIG shall notify Orbit of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Orbit may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Orbit prior to requiring Orbit to terminate the IRO. However, the final determination as to whether or not to require Orbit to engage a new IRO shall be made at the sole discretion of OIG.

## 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 Orbit has received in excess of the amount due and payable under any Federal health care program requirements, as determined by the IRO in connection with the claims reviews performed under this Appendix B, and which shall include any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.
- b. Paid Claim: A claim submitted by Orbit and for which Orbit has received reimbursement from the Medicare or Medicaid program.
- c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.
- d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Paid Claims in the sample.

2. *Discovery Sample.* The IRO shall randomly select and review a sample of 100 Paid Claims (Discovery Sample). The Paid Claims shall be reviewed based on: (i) the supporting documentation available at Orbit's office or under Orbit's control; (ii) appropriate contacts by the IRO with ordering physicians and Orbit customers and/or caregivers of Orbit customers; and (iii) applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. Among the issues to be reviewed are: (i) whether the power wheelchairs and accessories were correctly coded, submitted, billed to Federal health care programs appropriately; (ii) whether Orbit maintained in its records documentation of all supporting documentation described in 42 C.F.R. § 410.38(c); and (iii) whether Orbit's documentation mirrors the documentation the ordering physician's documentation. At least 25 claims in the Discovery Sample shall include a review of whether Orbit's documentation mirrors the documentation of the ordering physician.

If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Orbit should, as appropriate, further analyze any errors identified in the Discovery Sample. Orbit recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample.* If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at Orbit or under Orbit's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Orbit to the

appropriate Federal health care program payor (e.g., Medicare contractor), for appropriate follow-up by that payor.

4. *Systems Review.* If Orbit's Discovery Sample identifies an Error Rate of 5% or greater, Orbit's IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

- a. a review of Orbit's billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system, the process by which claims are coded, safeguards to ensure proper coding, claims submission and billing; and procedures to identify and correct inaccurate coding and billing);
- b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the 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 claim.

5. *Other Requirements*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and Orbit shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from Orbit after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (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 Orbit cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Orbit 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 all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims selected in each first sample 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 Discovery Sample or Full Sample).

6. *Repayment of Identified Overpayments.* Orbit shall repay within 30 days any Overpayment(s) identified in the Discovery Sample, regardless of the Error Rate, and (if applicable) the Full Sample, including the IRO's estimate of the actual Overpayment in the Population as determined in accordance with Section A.3 above, in accordance with payor refund policies. Orbit shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to 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 for each Discovery Sample and Full Sample (if applicable).

- 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 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.5.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 copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.
- c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings*

- a. Narrative Results
  - i. A description of Orbit’s billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
  - ii. 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 Discovery Sample, and the results of the Full Sample (if any).

b. Quantitative Results

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Orbit (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Orbit.

iii. Total dollar amount of all Overpayments in the Discovery Sample and the Full Sample (if applicable).

iv. Total dollar amount of Paid Claims included in the Discovery Sample and the Full Sample and the net Overpayment associated with the Discovery Sample and the Full Sample.

v. Error Rate in the Discovery Sample and the Full Sample.

vi. 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, 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.

vii. If a Full Sample is performed, the methodology used by the IRO to estimate the actual Overpayment in the Population and the amount of such Overpayment.

- c. Recommendations. The IRO's report shall include any recommendations for improvements to Orbit's billing and coding system based on the findings of the Claims Review.

4. *Systems Review Findings*. The IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the IRO's observations, findings, and recommendations regarding:

- a. the strengths and weaknesses in Orbit's billing systems and processes;
- b. the strengths and weaknesses in Orbit's coding systems and processes; and
- c. possible improvements to Orbit's billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

5. *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.