CORPORATE INTEGRITY AGREEMENT

BETWEEN THE

OFFICE OF INSPECTOR GENERAL

OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

FORBA HOLDINGS, LLC

I. PREAMBLE

FORBA Holdings, LLC 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, FORBA Holdings, LLC is entering into a Settlement Agreement with the United States. FORBA Holdings, LLC also will enter into settlement agreements with various States (Related State Settlement Agreements) and FORBA Holdings, LLC's agreement to this CIA is a condition precedent to those agreements.

For the purposes of this CIA, "FORBA" shall mean the following: (1) FORBA Holdings, LLC and its wholly-owned subsidiaries and affiliates; and (2) any other corporation, limited liability corporation, partnership, joint venture, or any other legal entity or organization in which FORBA owns a direct or indirect equity interest of 5% or more, or in which FORBA has a control interest, at any time during the term of the CIA.

II. TERM AND SCOPE OF THE CIA

- A. The period of the compliance obligations assumed by FORBA under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). 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, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) FORBA's final annual report; or (2) any additional materials submitted by FORBA pursuant to OIG's request, whichever is later.

- C. The scope of this CIA shall be governed by the following definitions:
 - 1. "FORBA facility" includes any dental practice or other legal entity that FORBA operates or with whom FORBA has a contract or arrangement to provide management, administrative, or staffing services at any time during the term of the CIA.
 - 2. "Covered Persons" includes:
 - a. all owners, officers, directors, and employees of FORBA;
 - b. all owners, officers, directors, and employees of FORBA facilities; and
 - c. all contractors, subcontractors, agents, and other persons who on behalf of FORBA or FORBA facilities: (1) perform patient care duties; (2) make assessments of patients that affect treatment decisions or reimbursement; (3) perform billing, coding, audit, or review functions; (4) make decisions or perform managerial or administrative functions in connection with staffing, compensation, benefits, performance standards, patient care, reimbursement, policies and procedures, or this CIA; or (5) perform any function that relates to or is covered by this CIA, including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions.

Notwithstanding the above, the term "Covered Person" does not include:

- a. part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year; and
- b. vendors whose sole connection with FORBA or any affiliated company is selling supplies, materials or equipment.
- 3. "Billing and Reimbursement Covered Persons" includes all Covered Persons involved, directly or in a supervisory role, in the preparation,

- coding, billing, auditing or submission of claims for reimbursement by any Federal health care program.
- 4. "Clinical Quality Covered Persons" includes all Covered Persons involved in the delivery of patient care items or services at FORBA and/or FORBA facilities or involved in the monitoring of clinical quality at FORBA and/or FORBA facilities.
- 5. "Relevant Covered Persons" means all Billing and Reimbursement Covered Persons and Clinical Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

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

- A. <u>Compliance Responsibilities of Corporate Officers, Compliance Committee, Board of Directors, and Management.</u>
- 1. Compliance Officer. Prior to the Effective Date, FORBA appointed a Compliance Officer, and FORBA shall maintain a Compliance Officer during the term of the CIA. The Compliance Officer shall be responsible for 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. The Compliance Officer shall be a member of senior management of FORBA, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of FORBA, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by FORBA and FORBA facilities as well as for any reporting obligations created under this CIA. The Compliance Officer shall also ensure that FORBA is appropriately identifying and correcting quality of care problems. The Compliance Officer shall supervise the Compliance Department, including the responsibilities of the Patient Advocate. The Compliance Officer shall also serve as the Chair of the Compliance Liaisons Committee. Any noncompliance job responsibilities shall be limited and shall not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

FORBA 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 15 days after such a change.

2. Chief Dental Officer. Prior to the Effective Date, FORBA appointed a Chief Dental Officer, and FORBA shall maintain a Chief Dental Officer during the term of the CIA. The Chief Dental Officer shall be a pediatric dentist who is a graduate of an advanced education program approved by the United States Commission on Dental Accreditation. Further, the Chief Dental Officer shall be a member of the American Academy of Pediatric Dentistry and a diplomate of the American Board of Pediatric Dentistry. The Chief Dental Officer shall be responsible for developing and implementing policies and procedures that ensure that the services and items provided to patients by FORBA and FORBA facilities meet the professionally recognized standards of health care. The Chief Dental Officer shall review patient care matters at FORBA and FORBA facilities, including but not limited to quality protocols, quality assessments, patient safety issues, utilization review, performance improvement, and dental staff training. The Chief Dental Officer shall also conduct routine (at least monthly) audits of dental records. The Chief Dental Officer shall be a member of senior management and the Board of Directors of FORBA, shall make periodic (at least quarterly) written reports regarding quality of care matters directly to the Board of Directors of FORBA with a copy to the qualified monitoring team (the "Monitor") as set forth in section III.E, and shall be authorized to report on such matters directly to the Board of Directors or the Monitor at any time. The Chief Dental Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer.

FORBA shall report to OIG, in writing, any changes in the identity or position description of the Chief Dental Officer, or any actions or changes that would affect the Chief Dental Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. Compliance Liaisons. Within 90 days after the Effective Date, FORBA shall appoint a Compliance Liaison from each FORBA facility, and FORBA shall maintain a Compliance Liaison at each facility for the term of the CIA. The Compliance Liaison shall be either the Lead Dentist or the Office Manager of the FORBA facility. The Compliance Liaison shall be responsible for: (a) assisting the Compliance Officer to implement the policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, Federal health care program requirements, state dental board requirements, and professionally recognized standards of health care; (b) assisting the Compliance Officer to monitor the day-to-day compliance activities of the applicable FORBA facility; and (c) serving as the contact person for the Compliance Officer for compliance activities at the applicable FORBA facility. The Compliance Liaisons shall

make periodic (at least quarterly) written reports regarding compliance matters directly to the Compliance Officer, and shall be authorized to report on such matters directly to the Compliance Committee, the Board of Directors, and the Monitor at any time. The Compliance Liaisons shall meet as a group, at minimum, every month. Each Compliance Liaison is required to attend, at minimum, one Compliance Liaisons Group meeting per month. For each scheduled Compliance Liaisons Group meeting, individual Compliance Liaisons shall be chosen, on a rotating basis, to report to the Compliance Liaisons Group on the adequacy of care being provided at their facilities. Attendance at such committee meetings by Compliance Liaisons may be via conference phone or video conferencing equipment, although in person attendance is the desired and intended form of attendance.

FORBA shall report to OIG, in writing, any changes in the identity or position description of the Compliance Liaison, or any actions or changes that would affect the Compliance Liaisons' ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. Patient Advocate. Within 90 days after the Effective Date, FORBA shall appoint a Patient Advocate, and FORBA shall maintain a Patient Advocate for the term of the CIA. The Patient Advocate shall report to the Compliance Officer. The Patient Advocate shall be responsible for recording, remedying, and responding to comments, concerns, and complaints by patients of FORBA facilities. The Patient Advocate shall also be responsible for ensuring that materials disseminated to patients contain information related to FORBA's commitment to ensuring that all dental services and items provided meet professionally recognized standards of health care, including Federal health care program and state dental board requirements. The Patient Advocate shall ensure that materials disseminated to all patients are available in both English and Spanish and also include contact information for filing or registering a complaint with the Parent Compliance Hotline, the local state dental board, and the Office of Inspector General. Such publications shall be made in locations reasonably designed to reach members of the Medicaid population, existing and potential patients, such as FORBA's website, FORBA facilities, and any newsletters. The Patient Advocate shall make periodic (at least quarterly) written reports to the Compliance Committee and the Board Committee regarding patient care matters.

FORBA shall report to OIG, in writing, any changes in the identity or position description of the Patient Advocate, or any actions or changes that would affect the Patient Advocate's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

- 5. Compliance Committee. Within 90 days after the Effective Date, FORBA shall appoint a Compliance Committee. The purpose of this committee shall be to address issues concerning quality of care and to assist the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall, at a minimum, include the Compliance Officer, Chief Executive Officer, Chief Dental Officer, Patient Advocate, Director of Clinical Coordinators, other members of senior corporate management necessary to thoroughly implement the requirements of this CIA (e.g., senior managers of relevant departments such as billing, clinical, human resources, audit, compliance, marketing, licensing, and operations), and Regional Managers. At least seven Compliance Liaisons shall be selected on a rotating basis to participate in each Compliance Committee meeting. The Compliance Officer shall chair the Compliance Committee. The Compliance Committee shall meet, at a minimum, every month. Attendance at such committee meetings may be via conference phone or video conferencing equipment, although in person attendance is the desired and intended form of attendance. For each scheduled Compliance Committee meeting:
- a. senior management of FORBA shall report to the Compliance Committee on the adequacy of care being provided by FORBA facilities; and
- b. the Compliance Committee shall monitor the quality of care being provided by FORBA and FORBA facilities through the use of a "Quality of Care Dashboard" (Dashboard) which will function as a performance scorecard for the organization. Through the creation and monitoring of the Dashboard, the Compliance Committee shall oversee FORBA's progress towards its quality improvement and compliance goals.
 - 1. Within 120 days after the Effective Date, the Compliance Committee shall identify and establish the overall quality of care improvement goals for FORBA and FORBA facilities. The goals shall be patient-centric and shall be designed to promote the delivery of dental care items and services that meet or exceed professionally recognized standards of health care and are necessary, reasonable, and appropriate to the needs of patients. The Compliance Committee shall provide a copy of the quality improvement goals to the Board of Directors (Board) and the Monitor.

- 2. Within 120 days after the Effective Date, the Compliance Committee shall identify and establish the quality indicators that FORBA will monitor through the Dashboard. These indicators shall measure the quality of dental care items and services furnished by FORBA and FORBA facilities. The indicators shall include, but are not limited to:
 - a. underutilization/overutilization of dental services:
 - b. patient adverse events and medical errors;
 - c. patient record documentation; and
 - d. patient and staff satisfaction.

The Compliance Committee shall also establish performance metrics for each quality indicator. The Compliance Committee shall provide a copy of the quality indicators and performance metrics to the Board and the Monitor.

The Compliance Committee shall review the quality indicators (at least semi-annually) to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Compliance Committee shall report to the Board and the Monitor, in writing, any changes in the quality indicators, within 15 days after such a change.

3. The Compliance Committee shall measure, analyze, and track performance metrics for the quality indicators on a monthly basis. Quality indicator data shall be collected and reported on a Dashboard. The Committee shall provide a copy of the Dashboard and a written report to the Board and the Monitor. As part of the report, the Committee shall: (a) identify high risk, high-volume, or problem-prone areas; (b) consider the incidence, prevalence, and severity of problems in those areas; (c) identify indicators that consistently fail to meet performance goals; and (d) recommend corrective actions for problem areas and indicators that fail to meet performance goals.

The Compliance Committee shall implement any corrective actions within 30 days of receiving Board approval.

- 4. A copy of the Dashboard shall be readily available to any Covered Person and shall be provided to Compliance Liaisons.
- 5. For each Reporting Period, FORBA shall provide to the Board a copy of the Dashboard that tracks FORBA's performance over the full 12-month period.

FORBA 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.

- 6. Board of Directors. The Board or a Committee of the Board, if applicable, shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, state dental board requirements, professionally recognized standards of health care, and the obligations of this CIA. The individuals who serve on the Board shall be readily available to the Compliance Officer and the Monitor required under this CIA to respond to any issues or questions that might arise. The Board, or a Committee of the Board, shall, at a minimum, be responsible for the following:
- a. meeting (at least quarterly) to review and oversee FORBA's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Department and review of the Quality of Care Dashboard;
- b. providing oversight on quality of care issues, including but not limited to: (1) reviewing the adequacy of FORBA and FORBA facilities' system of internal controls, quality assurance monitoring, and patient care; (2) ensuring that FORBA's response to state, federal, internal, and external reports of quality of care issues is complete, thorough, and resolves the issue(s) identified; (3) ensuring that FORBA adopts and implements policies and procedures that are designed to ensure that each individual cared for by FORBA and FORBA facilities receives the professionally recognized standards of health care; and (4) reviewing and responding to the Dashboard. As part of its review of the Dashboard, the Board shall ensure that FORBA implements effective responses when clinical quality problems are discovered or when quality indicators are not meeting established goals. For each Reporting Period, the Board shall present a written report that summarizes its oversight of the Dashboard, the status of quality of care at FORBA and FORBA facilities, and identifies any corrective action that took place in response to the Dashboard; and

c. for each Reporting Period of the CIA, adopting a resolution (consistent with the bylaws for adopting resolutions) summarizing its review and oversight of FORBA's compliance with Federal health care program requirements, state dental board requirements, and the obligations of this CIA. Each individual member of the Board or, if applicable, each member of the Committee of the Board having responsibility for compliance, shall sign a statement indicating that he or she agrees with the resolution.

At minimum, the resolution shall include the following language:

"The Board of Directors [or a Committee of the Board] has made a reasonable inquiry into the operations of FORBA's Compliance Program, including the performance of the Compliance Officer and the Compliance Department. The Board has also provided oversight on quality of care issues. Based on its inquiry and review, the Board [or Committee] has concluded that, to the best of its knowledge, FORBA has implemented an effective Compliance Program and FORBA is in compliance with the Federal health care program requirements, state dental board requirements, professionally recognized standards of health care, and the obligations of the CIA."

If the Board (or the Board Committee) is unable to provide such a conclusion in the resolution, the Board (or Committee) 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 ensure the implementation of an effective Compliance Program at FORBA.

FORBA 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.

7. Management Accountability and Certifications. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Covered Persons ("Certifying Employees") are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify in writing or electronically that the applicable area of authority is compliant with the obligations of this CIA, Federal health care program requirements, state dental board requirements, and professionally recognized standards of care. The Certifying Employees include, at a minimum, the following: Chairman and Chief Executive Officer, Executive Vice President and Chief Financial Officer, President and Chief Operating Officer, Chief Dental Officer, all Senior Vice Presidents, Regional Managers, Director of Clinical Coordinators, Marketing Coordinator, Assistant Vice President of Dentist Recruitment, Manager for Licensing and

Credentialing, Office Managers of FORBA facilities, and Lead Dentists of FORBA facilities.

For each Reporting Period, each Certifying Employee shall certify in writing or electronically that:

"I have been trained on and understand the compliance requirements and
responsibilities as they relate to [department or functional area], an area under my
supervision. My job responsibilities include ensuring compliance with regard to the
[insert name of the department, functional area, or FORBA facility.] To the best
of my knowledge, except as otherwise described herein, the [insert name of
department or functional area] of FORBA (or "(insert name of FORBA facility), a
FORBA facility,") is in compliance with all applicable Federal health care program
requirements, state dental board requirements, and the obligations of the CIA."

- 8. *Internal Audit Program*. Within 90 days after the Effective Date, FORBA shall create a program for performing internal quality audits and reviews (hereinafter "Internal Audit Program"). The Internal Audit Program shall:
 - a. make findings of whether the patients at FORBA facilities are receiving the quality of care consistent with professionally recognized standards of health care, including, but not limited to, any applicable federal and state statutes, state dental board requirements, regulations, and directives, and American Academy of Pediatric Dentistry Reference Manual and guidelines (AAPD guidelines);
 - b. make findings of whether the Policies and Procedures mandated by Section III.B (Written Standards) of this CIA are created, implemented, and enforced;
 - c. make findings of whether training is performed in accordance with Section III.C (Training and Education) of this CIA;
 - d. make findings of whether Disclosure Program (as described in Section III.F of this CIA) complaints are appropriately investigated;
 - e. make findings of whether the reporting obligations are complied with in accordance with Section III.I (Reporting) of this CIA; and

f. make findings of whether corrective action plans are timely created, implemented, and enforced.

The Compliance Officer shall report a summary of the internal audit reports to the Board as part of his or her written report.

B. Written Standards.

- 1. Code of Conduct. Within 90 days after the Effective Date, FORBA shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. FORBA shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:
 - a. FORBA's commitment to full compliance with all Federal health care program requirements, state dental board requirements, and professionally recognized standards of health care, including its commitment to prepare and submit accurate claims, and provide dental services and items consistent with such requirements;
 - b. FORBA's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements, state dental board requirements, professionally recognized standards of health care and with FORBA's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
 - c. the requirement that all Covered Persons shall be expected to report, within 30 days, to the Compliance Officer, or other appropriate individual designated by FORBA, suspected violations of any Federal health care program requirements, state dental board requirements, professional standards of health care, or of FORBA's own Policies and Procedures; if there are credible allegations of patient harm, such report shall be made immediately and shall be complete, full, and honest;
 - d. the possible consequences to both FORBA and Covered Persons of failure to comply with Federal health care program requirements, state dental board requirements, professionally recognized standards

of health care, and with FORBA's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.F, and FORBA's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by FORBA's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

FORBA shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

- 2. Policies and Procedures. Within 90 days after the Effective Date, FORBA shall implement written Policies and Procedures regarding the operation of FORBA's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:
 - a. the subjects relating to the Code of Conduct identified in Section III.B.1;
 - b. measures designed to ensure that FORBA fully complies with Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh and 1396-1396v, and all regulations, directives, and guidelines promulgated pursuant to these statutes, including, but not limited to, 42 C.F.R. Part 440 and any other state or local statutes, regulations, directives, or guidelines, and any that address quality of care in dental practices, such as state dental board requirements and the AAPD guidelines;
 - c. FORBA's commitment to ensuring that FORBA facilities provide services and items to their patients that meet professionally

recognized standards of health care, including but not limited to Federal health care program requirements, state dental board requirements, and the AAPD guidelines.

- d. Measures designed to promote the delivery of patient items or services at FORBA and FORBA facilities that meet professionally recognized standards of health care, including but not limited to the following areas:
 - 1. patient safety;
 - 2. appropriate patient assessment and treatment planning;
- 3. appropriate documentation of dental records, including radiographs or digital photos consistent with professionally recognized standards of health care;
- 4. appropriate anesthesia guidelines for pediatric dental patients;
- 5. appropriate behavior guidance approaches for the pediatric dental patient, including dental team behavior, dentist behavior, communications, patient assessment, barriers, and deferred treatment:
- 6. advanced behavior guidance techniques for the pediatric dental patient, including protective stabilization, sedation, general anesthesia, and contraindications for each technique;
- 7. appropriate management of dental patients with special health care needs;
 - 8. time management;
 - 9. appropriate amount of treatment in an individual visit;
 - 10. parental accompaniment;
 - 11. informed consent;
 - 12. periodic audit of clinical quality;

- 13. the ethical responsibility to treat or refer patients;
- 14. infection control; and
- 15. appropriate use of medications, including antibiotic therapy for pediatric dental patients.
- e. Measures designed to promote adherence to the compliance and quality of care standards set forth in the applicable statutes, regulations, Federal health care program and state dental board requirements, AAPD guidelines, and the CIA, by including such adherence as a significant factor in determining the compensation to Covered Persons. These Policies and Procedures shall be designed to ensure that financial incentives do not motivate such individuals to engage in improper conduct, or provide excessive or substandard services or items. These Policies and Procedures shall include a requirement that compliance be a component of each employee's performance objectives and evaluation, and that compensation and incentive awards, such as bonuses, be directly linked to performance on clinical quality measures (if applicable) and compliance program effectiveness.
- f. Measures designed to ensure cooperation by FORBA and its Covered Persons with the Monitor in the performance of his or her duties as set forth in Section III.E of this CIA;
- g. Measures designed to ensure that compliance issues are identified internally (e.g., through reports to supervisors, complaints received through the Disclosure Program, internal audits, patient satisfaction surveys, quality indicators, facility-specific key indicators, clinical quality audits, or exit interviews) and that issues, whether identified internally or externally (e.g., through federal or state agency reports, consultants, or the Monitor's Reports) are promptly and appropriately investigated and, that if the investigation substantiates compliance issues, FORBA implements effective and timely corrective action plans and monitors compliance with such plans;
- h. Measures designed to effectively collect and analyze staffing data, including but not limited to staff turnover, reasons for staff

departures, and staff bonuses and compensation. The measures should ensure that exit interviews of employees of FORBA and FORBA facilities include the individual's impressions of patient care or harm;

- i. Measures designed to ensure that contractors, subcontractors, and agents that fall within the ambit of Covered Persons are appropriately supervised to ensure that they are acting within the parameters of the CIA, FORBA's Policies and Procedures, Federal health care program and state dental board requirements, and professionally recognized standards of health care;
- j. Measures designed to ensure that appropriate and qualified individuals perform the internal quality audits and reviews under the Internal Audit Program required by Section III.A.8;
- k. Nonretaliation policies and methods for Covered Persons to make disclosures or otherwise report on compliance issues through the Disclosure Program required by Section III.F of this CIA;
- 1. Disciplinary guidelines to reflect the Code of Conduct requirements as specified in Section III.B.1 of this CIA;
- m. Measures designed to ensure that FORBA has a system to require and centrally collect reports relating to patient care incidents, injuries, abuse, and neglect. The reports required under this system shall be of a nature to allow the Compliance Committee meaningful information to be able to determine: (1) whether a quality of care problem exists; and (2) the scope and severity of the problem. The measures should ensure that patients, parents, and guardians are provided with FORBA's Parent Compliance Hotline number, state dental board complaint numbers, and the OIG Hotline number. The measures should also develop a mechanism for informing all current patients, parents, and guardians who received care from a FORBA facility when a substantiated incident of patient harm occurs at that facility;
- n. Measures designed to ensure that FORBA and FORBA facilities comply with Federal health care program requirements on billing and reimbursement, including, but not limited to the following:

- 1. ensuring the proper and accurate preparation and submission of claims to Federal health care programs;
- 2. ensuring the proper and accurate documentation of dental records;
- 3. conducting periodic billing and coding reviews and audits of FORBA facilities; and
- 4. reporting and repaying all identified Overpayments to Federal health care programs and other payors.
- o. Measures that define the responsibilities and role of the Chief Dental Officer required by Section III.A;
- p. Measures that define the responsibilities and role of the Patient Advocate required by Section III.A;
- q. Measures that define the responsibilities and role of the Compliance Liaisons required by Section III.A;
- r. Measures that relate to the creation and use of the Quality Of Care Dashboard required by Section III.A, including, but not limited to:
- 1. the responsibilities of the Compliance Committee and the Board regarding the Dashboard;
- 2. the requirement to identify quality indicators and establish performance goals for each indicator;
- 3. the means by which quality indicator data is collected, analyzed, and monitored; and
- 4. the requirement to use the information from the Dashboard to monitor the quality of care at FORBA and FORBA facilities, including, but not limited to, identifying opportunities for improvement, and implementing and monitoring performance improvement activities;
- s. disciplinary policies and procedures for violations of FORBA's Policies and Procedures, including policies relating to professionally

recognized standards of health care, Federal health care program requirements, and state dental board requirements.

- t. measures to collect, verify, and assess current licensure, education, and training of all Relevant Covered Persons; and
- u. the requirement that FORBA terminate its relationship with any Covered Person that is found to have violated professionally recognized standards of health care.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures. The Policies and Procedures shall be available to OIG upon request.

At least annually (and more frequently, if appropriate), FORBA shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

All training required in this section shall be competency-based. Specifically, the training must be developed and provided in such as way as to focus on Covered Persons achieving learning outcomes to a specified competency and to place emphasis on what a Covered Person has learned as a result of the training.

- 1. General Training. Within 90 days after the Effective Date, FORBA shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain FORBA's:
 - a. CIA requirements; and
 - b. FORBA's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least two hours of General Training in each subsequent Reporting Period.

- 2. Specific Training. Within 90 days after the Effective Date, FORBA shall initiate the provision of Specific Training to each Relevant Covered Person under the following training modules in addition to the General Training required above in a manner relevant to the individual's job training responsibilities as follows:
- a. <u>Billing and Reimbursement Training</u>. Each Billing and Reimbursement Covered Persons shall receive at least three hours of Specific Training pertinent to their responsibilities in addition to the General Training required above. This Specific Training shall include a discussion of:
 - (1) Federal health care program and state requirements regarding the accurate preparation and submission of claims;
 - (2) Policies, procedures, and other requirements applicable to the documentation of dental records;
 - (3) the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
 - (4) applicable reimbursement statutes, regulations, and program requirements and directives;
 - (5) the legal sanctions for violations of Federal health care program requirements;
 - (6) examples of proper and improper claims submission practices; and
 - (7) policies and procedures for the reporting and repayment of Overpayments to Federal health care programs and other payors.
 - b. <u>Clinical Quality Training</u>. Each Clinical Quality Covered Person shall receive at least three hours of Clinical Quality Training that covers the following topics:

- (1) FORBA's policies, procedures, and other requirements relating to clinical quality, including, but not limited to the policies set forth in Section III.B.2.d;
- (2) the proper documentation of patient charts and dental records;
- (3) the personal obligation of each individual involved in the delivery of items or services at FORBA and FORBA facilities, or involved in the monitoring of clinical quality at FORBA facilities, to know the applicable legal requirements, FORBA's policies and procedures, and professionally recognized standards of health care;
- (4) legal sanctions for violating Federal health care program requirements; and
- (5) examples of proper and improper patient care at FORBA facilities.

New Relevant Covered Persons shall begin receiving this training within 10 days after the start of their employment or contract or within 90 days after the Effective Date, whichever is later. A FORBA employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least two hours of Specific Training in each subsequent Reporting Period.

3. Periodic Training. In addition to the Specific Training described above, FORBA shall provide Periodic Training to all Covered Persons at FORBA facilities who are responsible for patient care on the quality of care issues identified by the Compliance Committee. This periodic training shall be provided on an "as needed" basis, but shall be provided at least semi-annually. In determining what training should be performed, the Compliance Committee shall review the complaints received, satisfaction surveys, staff turnover data, the Dashboard, any state or federal audits or reports, any internal audits, and the findings, reports, and recommendations of the Monitor. Such training shall be for a minimum of two hours annually.

- 4. Certification. Each Covered Person who is required to attend training shall certify, in writing, or in electronic form, if applicable, 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 and documentation evidencing that the individual attained competency in the required training areas. These shall be made available to OIG, upon request.
- 5. *Qualifications of Trainer*. Persons providing the training shall be knowledgeable about the subject area.
- 6. *Update of Training*. FORBA shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or by the Independent Monitor, and any other relevant information.
- 7. Computer-based Training. FORBA may provide the training required under this CIA through appropriate computer-based training approaches. If FORBA 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, FORBA shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist FORBA in assessing and evaluating its billing, coding, and quality of care practices and certain other obligations pursuant to this CIA and the Settlement Agreement. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by FORBA shall have expertise in applicable Federal health care program and other requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with FORBA, whether it can perform the

engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

The IRO(s) shall conduct reviews that assess FORBA's coding, billing, and claims submission to the Federal health care programs, the reimbursement received, and the quality of items and services provided to patients.

- b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the Reviews shall consist of at least two components a Claims Review and an Additional Items Review. An Unallowable Cost Review may also be included, if applicable.
- (1) <u>Claims Review</u>. The Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Claims Review. The Claims Review shall include three Discovery Samples, each of 50 Paid Claims (as described further in Appendix B) and, if the Error Rate for any Discovery Sample is 5% or greater, a Full Sample and Systems Review. The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this CIA, which is incorporated by reference.

The IRO shall prepare a report based upon the Claims Review performed (Claims Review Report). Information to be included in the Claims Review Report is described in Appendix B. In accordance with Section III.I, FORBA shall repay within 30 days any Overpayment(s) identified in the Discovery Samples or the Full Sample(s) (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. FORBA shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

(2) <u>Additional Items Review</u>. In addition, beginning with the second Reporting Period, each Review shall also include a review of up to three additional areas or practices of FORBA identified by the OIG in its discretion (hereafter "Additional Items").

For purposes of identifying the Additional Items to be included in the Reviews for a particular Reporting Period, the OIG may consult with FORBA and may consider internal audit work conducted or planned by FORBA, the nature and scope of FORBA's practices, and other information known to it. As set forth more fully in Appendix B, FORBA may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO. The OIG retains sole discretion over whether, and in what manner, to allow FORBA's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify FORBA of the nature and scope of the IRO review for each of the Additional Items no later than 90 days prior to the end of the second through fifth Reporting Periods. Prior to undertaking the review of the Additional Items, the IRO and/or FORBA shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

(3) Unallowable Cost Review. If applicable, the IRO shall perform the Unallowable Cost Review for the first Reporting Period. The IRO shall conduct a review of FORBA's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether FORBA has complied with its obligations not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from the United States, or any state Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by FORBA or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years. If applicable, the IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether FORBA has complied with its obligation not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from such payor.

c. *Retention of Records*. The IRO and FORBA shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and FORBA) related to the reviews.

2. Validation Review. In the event OIG has reason to believe that: (a) FORBA's Claims Review, Additional Items Review, or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO's findings, Claims Review results, Additional Items Review results, or Unallowable Cost Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review, Additional Items Review, or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Claims Review results, Additional Items Review results, or Unallowable Cost Review results are inaccurate (Validation Review). FORBA 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 FORBA's final Annual Report shall be initiated no later than one year after FORBA's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify FORBA of its intent to do so and provide a written explanation regarding the necessity of such review. To resolve any concerns raised by OIG, FORBA may request a meeting with OIG to: (a) discuss the results of any Claims Review, Additional Items Review, or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review, Additional Items Review, or Unallowable Cost Review or to correct the inaccuracy of the Claims Review, Additional Items Review, or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. FORBA agrees to provide any additional information as may be requested by OIG under this Section III.D.2 in an expedited manner. OIG will attempt in good faith to

resolve any Claims Review, Additional Items Review, or Unallowable Cost Review issues with FORBA 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.

3. Independence and Objectivity Certification. The IRO shall include in its report(s) to FORBA a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Claims Review, Additional Items Review, or Unallowable Cost Review and that it has concluded that it is, in fact, independent and objective.

E. Independent Monitor

Within 60 days after the Effective Date, FORBA shall retain an appropriately qualified monitoring team (the "Monitor"), appointed by OIG after consultation with FORBA. The Monitor may retain additional personnel, including, but not limited to. independent consultants, if needed to help meet the Monitor's obligations under this CIA. FORBA shall be responsible for all reasonable costs incurred by the Monitor, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, or additional personnel. The Monitor shall charge a reasonable amount for his or her fees and expenses. Failure to pay the Monitor within 30 calendar days of submission of its invoices for services previously rendered shall constitute a breach of the CIA and shall subject FORBA to one or more of the remedies set forth in Section X: provided, however, nothing in this section shall prevent or prohibit FORBA from bringing disputed bills to OIG's attention. The Monitor may be removed solely at the discretion of OIG. If the Monitor resigns or is removed for any reason prior to the termination of the CIA, FORBA shall retain another Monitor appointed by OIG after consultation with FORBA, with the same functions and authorities. The Monitor may confer and correspond with FORBA and OIG on an ex parte basis. The Monitor and FORBA shall not negotiate or enter into a financial relationship, other than the monitoring engagement required by this section, until after the date of OIG's CIA closure letter to FORBA.

- 1. The Monitor shall be responsible for assessing the effectiveness, reliability, and thoroughness of the following:
 - a. FORBA's internal quality control systems, including, but not limited to:

- i. whether the systems in place to promote quality of care and to respond to quality of care issues are operating in a timely and effective manner;
- ii. whether the communication system is effective, allowing for accurate information, decisions, and results of decisions to be transmitted to the proper individuals in a timely fashion; and
- iii. whether the training programs are effective and thorough.
- b. FORBA's response to quality of care issues, which shall include an assessment of:
 - i. FORBA's ability to identify the problem;
 - ii. FORBA's ability to determine the scope of the problem, including, but not limited to, whether the problem is isolated or systemic;
 - iii. FORBA's ability to create a corrective action plan to respond to the problem;
 - iv. FORBA's ability to execute the corrective action plan; and
 - v. FORBA's ability to evaluate whether the assessment, corrective action plan, and execution of that plan was effective, reliable, and thorough.
- c. FORBA's development and implementation of corrective action plans and the timeliness of such actions;
- d. FORBA's proactive steps to ensure that each patient receives care in accordance with:
- i. professionally recognized standards of health care, including but not limited to the AAPD guidelines;
- ii. State and local statutes, regulations, and other directives or guidelines; and

iii. the Policies and Procedures adopted by FORBA and set forth in Section III.B of this CIA.

2. The Monitor shall have:

- a. immediate access to FORBA, at any time and without prior notice, to assess compliance with this CIA, to assess the effectiveness of the internal quality assurance mechanisms, and to ensure that the data being generated is accurate;
- b. immediate access to (1) internal or external audits, surveys, or reports; (2) Disclosure Program complaints; (3) patient satisfaction surveys; (4) reports of abuse, neglect, or any incident that required emergency or other responsive treatment; (5) reports of any incident involving a patient that prompts a full internal investigation; (6) patient records; (7) documents in the possession or control of any quality assurance committee, peer review committee, dental review committee, or other such committee; (8) exit interviews; (9) Eaglesoft Program and data; (10) Board minutes; (11) Navigant tracking tools and data; (12) Dashboard; (13) training materials; and (14) any other data in the format the Monitor determines relevant to fulfilling the duties required under this CIA;
- c. immediate access to patients, parents and/or guardians, and Covered Persons for interviews outside the presence of FORBA supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals. The Monitor shall give full consideration to a patient's clinical condition before interviewing a patient; and
- d. immediate access to all FORBA facilities and the Board.

3. FORBA's Obligations. FORBA shall:

- a. provide the Monitor a report monthly, or sooner if requested by the Monitor, regarding each of the following occurrences:
 - i. Deaths or injuries related to use of restraints;

- ii. Deaths or injuries related to use of sedation, local anesthesia, nitrous oxide/oxygen analgesia/anxiolysis, pain medication, or any other medication prescribed at a FORBA facility;
- iii. Deaths or injuries related to abuse or neglect;
- iv. Any other incident that involves or causes actual harm to a patient when such incident is required to be reported to any local, state, or federal government agency.

Each such report shall contain the full name, social security number, and date of birth of the patient(s) involved, the date of death or incident, and a brief description of the events surrounding the death or incident.

- b. address any written recommendation made by the Monitor within 15 business days, either by substantially implementing the Monitor's recommendations or by explaining in writing why FORBA has elected not to do so and thereafter timely addressing the Monitor's concern(s) to the OIG's satisfaction;
- c. provide to its Compliance Committee and its Board Compliance Committee copies of all documents and reports provided to the Monitor;
- d. pay the Monitor's bills within 30 days of receipt. While FORBA must pay all the Monitor's bills within 30 days, FORBA may bring any disputed Monitor's Costs or bills to OIG's attention;
- e. ensure the Monitor's immediate access to FORBA facilities, FORBA corporate offices, patients, Covered Persons, and documents, and assist in obtaining full cooperation by its current employees, contractors, and agents;
- f. provide access to current patients and provide contact information for their families and guardians consistent with the rights of such individuals under state or federal law, and not impede their cooperation with the Monitor;
- g. assist in locating past employees, contractors, agents, patients and their families, and, if requested, attempt to obtain their cooperation with the Monitor;

- h. provide the last known contact information for former patients, their families, or guardians consistent with the rights of such individuals under state or federal law, and not impede their cooperation; and
- i. not sue or otherwise bring any action against the Monitor related to any findings made by the Monitor or related to any exclusion or other sanction of FORBA under this CIA; provided, however, that this clause shall not apply to any suit or other action based solely on the dishonest or illegal acts of the Monitor, whether acting alone or in collusion with others.

4. The Monitor's Obligations. The Monitor shall:

- a. abide by all state and federal laws and regulations concerning the privacy, dignity, and employee rights of all Covered Persons and patients;
- b. abide by the legal requirements of FORBA to maintain the confidentiality of each patient's personal and clinical records. Nothing in this subsection, however, shall limit or affect the Monitor's obligation to provide information, including information from patient clinical records, to OIG, and, when legally or professionally required, reporting to other agencies;
- c. at all times act reasonably in connection with its duties under this CIA, including when requesting information from FORBA;
- d. simultaneously provide quarterly reports to FORBA and OIG concerning the findings made to date;
- e. if the Monitor has concerns about corrective action plans that are not being enforced or systemic problems that could affect FORBA and the FORBA facilities' ability to render quality care to its patients, then the Monitor shall: (a) report such concerns in writing to OIG and (b) simultaneously provide notice and a copy of the report to FORBA's Compliance Committee and Board Compliance Committee referred to in Sections III.A.5 and III.A.6 of this CIA;
- f. where independently required to do so by applicable law or professional licensing standards, report any finding to an appropriate regulatory or law enforcement authority, and simultaneously submit copies of such reports to OIG and to FORBA;

g. submit bills to FORBA on a consolidated basis, but no more than once per month;

h. submit a report for each Reporting Period representing an accounting of its costs throughout the year to FORBA and to OIG by the submission deadline of FORBA's Annual Report;

i. not be bound by any other private or governmental agency's findings or conclusions, including, but not limited to, JCAHO, CMS, or the state Medicaid agencies. Likewise, such private and governmental agencies shall not be bound by the Monitor's findings or conclusions. The Monitor's reports shall not be the sole basis for determining deficiencies by the state Medicaid agencies. The parties agree that CMS and its contractors shall not introduce any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence into any proceeding involving a Medicaid survey, certification, or other enforcement action against FORBA, and FORBA shall similarly be restricted from using material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence in any of these proceedings. Nothing in the previous sentence, however, shall preclude OIG or FORBA from using any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor in any action under this CIA or pursuant to any other OIG authorities or in any other situations not explicitly excluded in this subsection;

j. abide by the provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 to the extent required by law including, without limitation, entering into a business associate agreement with FORBA;

k. except to the extent required by law, maintain the confidentiality of any proprietary financial and operational information, processes, procedures, and forms obtained in connection with its duties under this CIA and not comment publicly concerning its findings except to the extent authorized by OIG;

l. visit FORBA as often as the Monitor reasonably believes it necessary to perform its functions; and

m. shall not negotiate or enter into a financial relationship with FORBA until after the date of OIG's CIA closure letter to FORBA.

F. Disclosure Program.

Within 90 days after the Effective Date, FORBA 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 FORBA's policies, conduct, practices, or procedures with respect to quality of care or a Federal health care program, believed by the individual to be a potential violation of criminal, civil, or administrative law, including but not limited to violations of professionally recognized standards of health care and/or patient harm. FORBA 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). This publication shall include contact information for the applicable state licensing board.

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) and, if the allegations involve patient care or documentation of patient care, the Chief Dental Officer, 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, FORBA shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted. If the inappropriate or improper practice(s) places patients at risk of harm, then FORBA will ensure that that practice ceases immediately and that appropriate action is taken.

FORBA shall disclose any finding of violation(s) of professionally recognized standards of health care resulting in patient death to all current patients of the involved FORBA facility by way of written notice that conforms with all State and federal privacy laws and regulations. The notice shall include the contact information for the applicable state licensing board and note that the patient may want to explore his/her legal rights.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and 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. The disclosure log shall be sent to the Monitor not less than monthly. The Compliance Officer shall review the disclosure log with the Board Compliance Committee not less than quarterly.

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 (available through the Internet at http://www.oig.hhs.gov); and
 - ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).
- 2. Screening Requirements. FORBA shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.
 - a. FORBA shall screen all prospective and current 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. FORBA shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. FORBA 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 this Section affects the responsibility of (or liability for) FORBA to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. FORBA understands that items or services furnished by excluded persons are not payable by Federal health care programs and that FORBA may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether FORBA meets the requirements of Section III.G.

- 3. Removal Requirement. If FORBA has actual notice that a Covered Person has become an Ineligible Person, FORBA shall remove or cause the removal of such Covered Person from responsibility for, or involvement with, the operations of FORBA and FORBA facilities 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 FORBA 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, FORBA 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 any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, FORBA shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to FORBA conducted or brought by a governmental entity or its agents involving an allegation that FORBA and/or any Covered Person has committed a crime, engaged in fraudulent activities, or violated professionally recognized standards of health care. 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. Within 30 days after the resolution of the government investigation or legal proceeding, FORBA shall provide written notice and a description of the findings and/or results of the investigation or proceedings, if any to OIG and any applicable state licensing board.

In addition, within 15 days after notification, FORBA shall notify OIG, in writing, of any adverse final determination made by a federal, state, or local government agency or licensing, accrediting or certifying agency (e.g. State licensing board) relating to quality of care issues.

I. Reporting.

1. Overpayments.

- a. *Definition of Overpayments*. For purposes of this CIA, an "Overpayment" shall mean the amount of money FORBA has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Reporting of Overpayments. If, at any time, FORBA identifies or learns of any Overpayment, FORBA shall notify the payor (e.g., Medicaid fiscal agent or contractor) within 30 days after identification of the Overpayment and take remedial steps within 60 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. Also, within 30 days after identification of the Overpayment, FORBA shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, FORBA 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, and, for Medicaid fiscal agents or contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix C to this CIA. 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.

2. Reportable Events.

- a. *Definition of Reportable Event*. For purposes of this CIA, a "Reportable Event" means anything that involves:
 - i. a substantial Overpayment;
 - ii. 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; or
 - iii. a matter that a reasonable person would consider likely to render FORBA insolvent.

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

- b. Reporting of Reportable Events. If FORBA determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, FORBA shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:
 - i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.I.1, and shall include all of the information on the Overpayment Refund Form, as well as:

- (A) the payor's name, address, and contact person to whom the Overpayment was sent; and
- (B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;
- ii. a complete description of the Reportable Event, including the relevant facts, persons involved, legal and Federal health care program authorities implicated, and potential impact, if any, on Federal health care program beneficiaries;
- iii. a description of FORBA's actions taken to correct the Reportable Event;
- iv. any further steps FORBA plans to take to address the Reportable Event and prevent it from recurring; and
- v. if the Reportable Event involves the filing of a bankruptcy petition, the report to OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.
- c. Definition of Quality of Care Reportable Event. For purposes of this CIA, a "Quality Reportable Event" means anything that involves a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care.
- d. Reporting of Quality of Care Reportable Events. If FORBA receives a report that involves a potential violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care, FORBA shall initiate an investigation of the report within 5 days after receiving the report. Within 30 days after receiving the report, and, on finding a violation, FORBA shall provide written notice of FORBA's investigation and the actions taken to correct the violation to OIG, the Monitor, and the applicable state licensing board.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

- A. Change or Closure of FORBA facility, Practice, Unit or Location. In the event that, after the Effective Date, FORBA changes locations or closes a business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, or terminates a contractual relationship with a practice owner or dental practice, FORBA shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change, closure of the location, or termination.
- B. Purchase or Establishment of New FORBA facility, Practice, Unit or Location. In the event that, after the Effective Date, FORBA purchases or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, or enters into a contractual relationship with a practice owner or dental practice, FORBA shall notify OIG at least 30 days prior to such transaction. For each new business unit, location or contractual relationship with a practice owner or dental practice, this notification shall include the address of the new practice owner or dental practice, business unit or location, phone number, fax number, Medicaid provider number(s), and the name and address of the contractor that issued each number. Each new business unit or location, practice owner or dental practice and all Covered Persons at each new business unit, location, or dental practice shall be subject to the applicable requirements of this CIA.
- C. <u>Sale or Transfer of FORBA facility, Asset, Unit or Location</u>. In the event that, after the Effective Date, FORBA proposes to transfer or sell any or all of its assets, business units or locations related to the furnishing of items or services that may be reimbursed by Federal health care programs, FORBA shall notify OIG of the proposed transfer or sale at least 30 days prior to the transfer or sale of such asset, business unit or location. This notification shall include a description of the asset, business unit or location to be transferred or sold, a brief description of the terms of the transfer or sale, and the name and contact information of the prospective investor/purchaser. This CIA shall be binding on the investor/purchaser of such asset, business unit or location, unless otherwise determined and agreed to in writing by OIG.
- D. Expansion of Services. In the event that, after the Effective Date, FORBA and/or a FORBA facility expands the scope of services provided at any FORBA facility related to the furnishing of items or services that may be reimbursed by Federal health care programs, FORBA shall notify OIG at least 30 days prior to such expansion of services. For each expansion of services, this notification shall include a description of the expanded scope of services, the

address of the involved FORBA facilit(ies), the governing regulations, any required applications, and the name and address of every entity that issued a license, certificate, or provider number. Each new service related to the furnishing of items or services that may be reimbursed by Federal health care programs shall be subject to the scope of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

- A. <u>Implementation Report</u>. Within 120 days after the Effective Date, FORBA 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 name, address, phone number, and position description of the Chief Dental Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Chief Dental Officer may have;
- 3. the names and positions of the Compliance Liasions required by Section III.A;
- 4. the name, address, phone number, and position description of the Patient Advocate required by Section III.A, and a summary of other noncompliance job responsibilities the Patient Advocate may have;
- 5. the names and positions of the members of the Compliance Committee required by Section III.A;
- 6. the names and positions of the members of the Board Compliance Committee and a copy of the committee's charter required by Section III.A;
- 7. a description of the Internal Audit Program required by Section III.A;
 - 8. a copy of FORBA's Code of Conduct required by Section III.B.1;
 - 9. a copy of all Policies and Procedures required by Section III.B.2;

- 10. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
- 11. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including the targeted audience, a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

- 12. a description of the Disclosure Program required by Section III.F;
- 13. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between FORBA and the IRO(s);
- 14. a certification from the IRO regarding its professional independence and objectivity with respect to FORBA;
- 15. a description of the process by which FORBA fulfills the requirements of Section III.G regarding Ineligible Persons;
- 16. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

- 17. a list of all of FORBA's locations, including but not limited to all FORBA facililites (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 Medicaid provider number and/or supplier number(s); and the name and address of each Medicaid contractor to which FORBA and/or each FORBA facility currently submits claims;
- 18. a description of FORBA's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;
 - 19. a certification by the Compliance Officer that:
 - a. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been distributed to all pertinent Covered Persons;
 - b. all Covered Persons have completed the Code of Conduct certification required by Section III.B.1; and
 - c. all Covered Persons have completed the General Training and executed the certification required by Section III.C.
 - 20. the certifications required by Section V.C.
- B. <u>Annual Reports</u>. FORBA shall submit to OIG annually a report with respect to the status of, and findings regarding, FORBA'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 and Chief Dental Officer, any change in the membership of the Compliance Committee or Board Compliance Committee; and any change to the Board Compliance Committee's charter described in Section III.A;
- 2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

- 3. a summary of findings under FORBA's Internal Audit Program and a summary of any corrective action taken under that program;
- 4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
- 5. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including the targeted audience, a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

- 6. FORBA's response and corrective action plan(s) related to any issues raised by the Monitor pursuant to Section III.E;
- 7. a copy of the disclosure log required under Section III.F (excluding any communications that relate solely to human resources issues unless those communications relate to production);
- 8. a copy of any patient death disclosure required under Section III.F;
- 9. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
- 10. a copy of all exit interviews that reference production, quality of care issues, or patient harm concerns;
- 11. any changes to the process by which FORBA fulfills the requirements of Section III.G regarding Ineligible Persons;

- 12. the name, title, and responsibilities of individuals any person who is determined to be an Ineligible Person under Section III.G; the actions taken by FORBA in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
- 13. 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;
- 14. a description of all changes to the most recently provided list of FORBA facilities (including addresses) as required by Section V.A.17; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicaid provider number(s) and/or supplier number(s); and the name and address of each Medicaid fiscal agent or contractor to which FORBA and/or each FORBA facility currently submits claims;
- 15. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
- 16. FORBA's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;
- 17. a summary and description of any and all current and prior engagements and agreements between FORBA and the IRO, if different from what was submitted as part of the Implementation Report;
- 18. a certification from the IRO regarding its professional independence and objectivity with respect to FORBA;
 - 19. a certification by the Compliance Officer that:
 - a. all Covered Persons have completed the annual Code of Conduct certification required by Section III.B.1;

- b. all Covered Persons have completed the training and executed the certification required by Section III.C;
- c. FORBA has effectively implemented all plans of correction related to problems identified under this CIA, FORBA's Compliance Program, internal and external audits, and/or the Monitor; and
- d. For all problems identified under the CIA, FORBA's Compliance Program, internal and external audits, and/or the Monitor, for which FORBA has not yet implemented a plan of correction, FORBA will provide the date the issue was identified, the status of the efforts to implement the Plan of Correction, and reasons for any delay.
- 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.

Within 180 days of the submission of each Annual Report, FORBA shall schedule and hold an in-person meeting with a representative of OIG to review FORBA's performance under the CIA. OIG, in its discretion, may waive this meeting requirement.

C. Certifications.

The following certifications shall be included in the Implementation Report and Annual Reports:

- 1. <u>Certifying Employees</u>: In the Annual Reports, FORBA shall include the certifications of Certifying Employees as required by Section III.A.
- 2. <u>Compliance Officer</u>: In the Implementation Report and Annual Reports, FORBA shall include the following individual certification by the Compliance Officer, that:
 - a. to the best of his or her knowledge, except as otherwise described in the applicable report, FORBA 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. <u>Board of Directors</u>: In the Annual Reports, FORBA shall include the Board resolution as required by Section III.6.c, certifying that they have reviewed the Report and agree with the statements made therein.
- D. <u>Designation of Information</u>. FORBA 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. FORBA 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

FORBA:

Chief Compliance Officer FORBA Holdings, LLC 618 Church Street, Suite 520 Nashville, TN 37219-2457 Telephone: 615.750.0338 Facsimile: 615-750-0304 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, FORBA 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), either instead of, or 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 or request copies of FORBA's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of FORBA facility for the purpose of verifying and evaluating: (a) FORBA's compliance with the terms of this CIA; and (b) FORBA's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by FORBA to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of FORBA's employees, contractors, or agents 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. FORBA shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. FORBA's employees may elect to be interviewed with or without a representative of FORBA present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. <u>DISCLOSURES</u>

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify FORBA prior to any release by OIG of information submitted by FORBA pursuant to its obligations under this CIA and identified upon submission by FORBA as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules.

With respect to such releases, FORBA shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. Breach and Default Provisions

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

- A. Specific Performance of CIA Provisions. If OIG determines that FORBA is failing to comply with a provision or provisions of this CIA and decides to seek specific performance of any of these provisions, OIG shall provide FORBA with prompt written notification of such determination (hereinafter referred to as "Noncompliance Notice"). FORBA shall have 30 days from receipt of the Noncompliance Notice within which to either: (1) cure the alleged failure to comply and provide OIG a written description of FORBA's corrective action; or (2) reply in writing that FORBA disagrees with the determination of noncompliance and request a hearing before an HHS Administrative Law Judge (ALJ), pursuant to the provisions set for in Section X.F of this CIA. The purpose of the hearing is to determine whether FORBA has failed to comply with the CIA and whether FORBA shall be required to implement the particular provisions at issue.
- B. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, FORBA 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 FORBA fails to establish and implement any of the following obligations as described in Section III:
 - a. a Compliance Officer;
 - b. a Chief Dental Officer;
 - c. Compliance Liaisons;
 - d. a Compliance Committee;
 - e. a Board Compliance Committee;

- f. an Internal Audit Program;
- g. a Patient Advocate;
- h. a written Code of Conduct;
- i. written Policies and Procedures;
- j. the training of Covered Persons in the manner required by Section III.C:
- k. retention of a Monitor;
- 1. a Disclosure Program;
- m. Ineligible Persons screening and removal requirements; and
- n. notification of Government investigations or legal proceedings.
- 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 FORBA 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.
- 3. A Stipulated Penalty of \$1,500 for each day FORBA fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date FORBA fails to grant access.)
- 4. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of FORBA as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.
- 5. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day FORBA fails to pay the Monitor, pursuant to Section III.E.
- 6. A Stipulated Penalty of \$1,000 for each day FORBA fails to comply fully and adequately with any of its obligations with respect to the

Monitor, as set forth in Section III.E. OIG shall provide notice to FORBA stating the specific grounds for its determination that FORBA has failed to comply fully and adequately with the CIA obligation(s) at issue and steps FORBA shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after FORBA receives this notice from OIG of the failure to comply.)

- 7. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day FORBA fails to engage an IRO, as required in Section III.D and Appendix B.
- 8. A Stipulated Penalty of \$1,000 for each day FORBA fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to FORBA stating the specific grounds for its determination that FORBA has failed to comply fully and adequately with the CIA obligation(s) at issue and steps FORBA shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after FORBA 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 1-7 of this Section.
- C. <u>Timely Written Requests for Extensions</u>. FORBA 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 FORBA 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 business days after FORBA 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 business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

D. Payment of Stipulated Penalties.

1. Demand Letter. Upon a finding that FORBA has failed to comply with any of the obligations described in Section X.B and after determining that Stipulated Penalties are appropriate, OIG shall notify FORBA of: (a) FORBA's failure to comply; and (b) OIG's exercise of its contractual right to

demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

- 2. Response to Demand Letter. Within 10 days after the receipt of the Demand Letter, FORBA 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.F. In the event FORBA elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until FORBA 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.E.
- 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.E.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that FORBA has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.E, below.

E. Exclusion for Material Breach of this CIA.

- 1. Definition of Material Breach. A material breach of this CIA means:
 - a. a failure by FORBA to report a Reportable Event, take corrective action to OIG's satisfaction, and make the appropriate refunds, as required in Section III.I;
 - b. a failure by FORBA to report a Quality of Care Reportable Event, take corrective action to OIG's satisfaction, and make the appropriate notifications, as required in Section III.I.2.c-d;
 - c. a repeated or flagrant violation of any obligation under this CIA, including, but not limited to, the obligations addressed in Section X.B;

- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.D;
- e. a failure to respond to a Noncompliance Notice concerning specific performance in accordance with Section X.A;
- f. a failure to retain, pay, utilize, or respond to OIG's satisfaction to the recommendations of the Monitor in accordance with Section III.E;
- g. a false certification submitted by or on behalf of FORBA as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA;

or

- h. a failure to meet an obligation under the CIA that has a material impact on the quality of care rendered to any patients of FORBA facilities
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by FORBA constitutes an independent basis for FORBA's exclusion from participation in the Federal health care programs. Upon a determination by OIG that FORBA has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify FORBA of: (a) FORBA's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude"). The exclusion may be directed at FORBA, its_subsidiary, agent, or affiliate, or any FORBA facility or Covered Person, depending upon the facts of the breach.
- 3. Opportunity to Cure. FORBA shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:
 - a. FORBA is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
 - b. the alleged material breach has been cured; or

- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) FORBA has begun to take action to cure the material breach; (ii) FORBA is pursuing such action with due diligence; and (iii) FORBA has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If, at the conclusion of the 30-day period, FORBA fails to satisfy the requirements of Section X.E.3, OIG may exclude FORBA from participation in the Federal health care programs. OIG shall notify FORBA in writing of its determination to exclude FORBA (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.F, below, the exclusion shall go into effect 30 days after the date of FORBA's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, FORBA may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

F. Dispute Resolution

- 1. Review Rights. Upon OIG's delivery to FORBA of its Noncompliance Notice, Demand Letter, or Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, FORBA 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 specific performance or 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.
- 2. Specific Performance 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 specific performance of CIA provisions shall be:
 - (a) whether, at the time specified in the Noncompliance Notice,

FORBA was in full and timely compliance with the obligations of this CIA for which OIG seeks specific performance; and

(b) whether FORBA failed to cure to OIG's satisfaction.

FORBA 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 specific performance. If the ALJ agrees with OIG, FORBA shall take the actions OIG deems necessary to cure within 20 days after the ALJ issues such a decision unless FORBA 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, FORBA shall take the actions OIG deems necessary to cure within 20 days after the DAB issues its decision

- 3. 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 FORBA was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. FORBA 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 FORBA to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless FORBA 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.
- 4. *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:
 - a. whether FORBA was in material breach of this CIA;
 - b. whether such breach was continuing on the date of the Exclusion Letter; and
 - c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) FORBA had

begun to take action to cure the material breach within that period; (ii) FORBA has pursued and is pursuing such action with due diligence; and (iii) FORBA provided to OIG within that period a reasonable timetable for curing the material breach to OIG's satisfaction and FORBA 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 FORBA, only after a DAB decision in favor of OIG. FORBA's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude FORBA 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 FORBA 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. FORBA 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 FORBA, FORBA shall be reinstated effective on the date of the original exclusion.

5. 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. <u>Effective and Binding Agreement</u>

FORBA and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of FORBA.
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA.
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.
- D. OIG may agree to a suspension of FORBA's obligations under the CIA in the event of FORBA's cessation of participation in Federal health care

programs. If FORBA ceases participating in Federal health care programs and is relieved of its CIA obligations by OIG, FORBA shall notify OIG at least 30 days in advance of FORBA's intent to resume participating as a provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

- E. The undersigned FORBA signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.
- F. 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 FORBA HOLDINGS, LLC

/Michael G. Lindley/	
MICHAEL G. LINDLEY Chairman and CEO FORBA Holdings, LLC	DATE
/Grace M. Rodriguez/	1/14/10
GRACE M. RODRIGUEZ Counsel to FORBA Holdings, LLC King & Spalding LLP	DATE

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

/Gregory E. Demske/

GREGORY E. DEMSKE

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

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.

FORBA 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 written notice of the identity of the selected IRO, OIG will notify FORBA if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, FORBA may continue to engage the IRO.

If FORBA 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, FORBA shall submit the information identified in Section V.A.13 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify FORBA if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, FORBA may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

- 1. assign individuals to conduct the Claims Review, Additional Items Review, and Unallowable Cost Review engagement who have expertise in the billing, coding, reporting, and other requirements of dental claims, professionally recognized standards of dental care, and in the general requirements of the State and Federal health care program(s) from which FORBA seeks reimbursement;
- 2. assign individuals to design and select the Claims Review sample, and if applicable, the Additional Items Review sample, who are knowledgeable about the appropriate statistical sampling techniques;
- 3. assign individuals to conduct the coding review portions of the Claims Review and, if applicable, the Additional Items Review, who have a nationally recognized coding certification (e.g., CCA, CCS, CCS-P, CPC, RRA, etc.) 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 Claim Review and Additional Items Review in accordance with the specific requirements of the CIA;
- 2. follow all applicable Federal health care program rules and reimbursement guidelines, state dental board requirements, and professionally recognized standards of health care in making assessments in the Claims Review and Additional Items Review;
- 3. if in doubt of the application of a particular Federal health care program or state dental board policy or regulation, request clarification from the appropriate authority;
 - 4. respond to all OIG inquires 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 and the Additional Items Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and FORBA.

E. IRO Removal/Termination.

- 1. Provider. If FORBA terminates its IRO during the course of the engagement, FORBA must submit a notice explaining its reasons to OIG no later than 30 days after termination. FORBA must engage a new IRO in accordance with Paragraph A of this Appendix.
- 2. OIG Removal of IRO. In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or 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 FORBA to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring FORBA to engage a new IRO, OIG shall notify FORBA of its intent to do so and provide a written explanation regarding the necessity of such a step. To resolve any concerns raised by OIG, FORBA may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. FORBA shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with FORBA prior to requiring FORBA to terminate the IRO. However, the final determination as to whether or not to require FORBA to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B CLAIMS REVIEW AND ADDITIONAL ITEMS REVIEW

A. Claims Review.

- 1. *Definitions*. For the purposes of the Claims Review, the following definitions shall be used:
 - a. <u>Overpayment</u>: The amount of money FORBA has received in excess of the amount due and payable under any State or Federal health care program requirements.
 - b. <u>Item</u>: Any discrete unit that can be sampled (<u>e.g.</u>, code, line item, beneficiary, patient encounter, etc.).
 - c. <u>Paid Claim</u>: A code or line item submitted by FORBA and for which FORBA has received reimbursement from any State or Federal health care program, including but not limited to Medicaid.
 - d. <u>Population</u>: For the first Reporting Period, the Population shall be defined as all Items for which a code or line item has been submitted by or on behalf of FORBA and for which FORBA has received reimbursement from any State or Federal health care program, including but not limited to Medicaid (<u>i.e.</u>, Paid Claim) during the 12-month period covered by the first Claims Review.

For the remaining Reporting Periods, the Population shall be defined as all Items for which FORBA has received reimbursement from any State or Federal health care program, including but not limited to Medicaid (<u>i.e.</u>, Paid Claim) during the 12-month period covered by the Claims Review.

To be included in the Population, an Item must have resulted in at least one Paid Claim.

e. <u>Error Rate</u>: 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 Items in the sample.

2. Discovery Sample. Within 15 days after the end of the Reporting Period, FORBA will provide OIG with a list of the FORBA facilities, including the volume and type of services provided at each facility as well as any Federal health care reimbursement for each facility. OIG shall select three facilities from the list. The IRO will review a sample of 50 Paid Claims submitted by or on behalf of FORBA at each of the three facilities selected by OIG (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation and other information available at FORBA's offices, the offices at FORBA facilities, or under FORBA's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for all three Discovery Samples 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, FORBA should, as appropriate, further analyze any errors identified in the Discovery Samples. FORBA 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 Samples or any other segment of the universe.)

3. Full Sample. If any of the three Discovery Samples indicate that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims only from the facility or facilities with an Error Rate which is 5% or greater (Full Sample) using commonly accepted sampling methods. The Full Sample(s) shall be designed to: (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims selected for the Full Sample(s) shall be reviewed based on supporting documentation and other information available at FORBA, FORBA facilities, or under FORBA'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(s), the Discovery Sample(s) may serve as the probe sample, if statistically appropriate. Additionally, FORBA may use the Items sampled as part of each of the three Discovery Samples, and the corresponding findings for those Items, as part of its Full Sample(s), if: (1) statistically appropriate and (2) FORBA selects the Full Sample Items using the seed number generated by the Discovery Sample(s). OIG, in its sole discretion, may refer the findings of the Full Sample(s) (and any related workpapers) received from FORBA to the appropriate State

or Federal health care program payor, including the contractor (e.g., fiscal agents), for appropriate follow-up by that payor.

4. Systems Review. If any of FORBA's Discovery Samples identifies an Error Rate of 5% or greater, FORBA's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample(s) and Full Sample(s) that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es), that generated the claim to 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. <u>Paid Claims without Supporting Documentation</u>. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which FORBA cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by FORBA for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- b. <u>Replacement Sampling</u>. Considering the Population shall consist only of Paid Claims and that Items with missing documentation cannot be replaced, there is no need to utilize alternate or replacement sampling units.
- c. <u>Use of First Samples Drawn</u>. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used (<u>i.e.</u>, 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).
- B. <u>Claims Review Report</u>. 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. <u>Sampling Unit</u>. A description of the Item as that term is utilized for the Claims Review.

- b. <u>Claims Review Population</u>. A description of the Population subject to the Claims Review.
- c. <u>Claims Review Objective</u>. A clear statement of the objective intended to be achieved by the Claims Review.
- d. <u>Sampling Frame</u>. A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.
- e. <u>Source of Data</u>. A description of the specific documentation relied upon by the IRO when performing the Claims Review (<u>e.g.</u>, dental records, dentist orders, requisition forms, local dental review policies (including title and policy number), CMS program memoranda (including title and issuance number), Federal health care program carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
- f. <u>Review Protocol</u>. A narrative description of how the Claims Review was conducted and what was evaluated.
- 2. Statistical Sampling Documentation.
 - a. The number of Items appraised in each Discovery Sample and, if applicable, in the Full Sample(s).
 - b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.
 - c. A copy of the statistical software printout(s) estimating how many Items are to be included in each Full Sample, if applicable.
 - d. 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 FORBA'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 each Discovery Sample, and the results of each 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 FORBA (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 FORBA.
- iii. Total dollar amount of all Overpayments in each sample.
- iv. Total dollar amount of paid Items included in each sample and the net Overpayment associated with each sample.
- v. Error Rate in each sample.
- vi. Spreadsheets of the Claims Review results for each sample that includes the following information for each Paid Claim appraised: State or Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure 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. (See Attachment 1 to this Appendix.)

- 4. *Systems Review*. Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).
- 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.

B. Additional Items Review

As set forth in Section III.D of the CIA and beginning with the second Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items".) No later than 90 days prior to the end of the second through fifth Reporting Periods, the OIG shall notify FORBA of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or FORBA shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Additional Items Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in FORBA's systems, processes, policies, and procedures based on its review of each Additional Item.)

FORBA may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow FORBA's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of FORBA's planned internal audit work, the results of the Review(s) during prior Reporting Period(s), and FORBA's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies FORBA's request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, FORBA shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of FORBA's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review,

the IRO shall review at least 20% of the sampling units reviewed by FORBA in its internal audits.

- 1. Additional Items Review Report. For each Reporting Period beginning with the Second Reporting Period, the IRO shall prepare a report based on its Additional Items Review. The report shall include the following:
 - a) <u>Review Objectives</u>: A clear statement of the objectives intended to be achieved by each Additional Items review;
 - b) <u>Review Protocol</u>: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
 - c) <u>Sources of Data</u>: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Additional Items Review.
 - d) <u>Results of the Review</u>: The following results shall be included in each Additional Items Review Report:
 - i. for each Additional Item reviewed, a description of the review conducted:
 - ii. for each Additional Item reviewed, the IRO's findings based on its review;
 - iii. for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in FORBA's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
 - iv. for each Additional Item reviewed, recommendations, if any, for changes in FORBA's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

Attachment 1

Claim Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt
\$500 Marian Control of the Control o								

Attachment 1 to Appendix B FORBA Holdings, LLC

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICAID CONTRACTOR								
Date:								
Contractor Deposit Control #	Date of Deposit:Phone #							
Contractor Contact Name:	Phone #		_					
Contractor Address:								
Contractor Fax:								
TO BE C	OMPLETED BY PROVIDER/P	<u>'HYSICIAN/SUPPLI</u>	<u>ER</u>					
Please complete and forward	to Medicaid Contractor. This	form, or a similar d	ocument containing the					
following information, should a	accompany every voluntary refund	l so that receipt of ch	eck is properly recorded					
and applied.	RNAME							
PROVIDER/PHYSICIAN/SUPPLIEI	RNAME		_					
ADDRESS			_					
PROVIDER/PHYSICIAN/SUPPLIE	R #CHECK NUMB	ER#						
CONTACT PERSON:	PHONE #		AMOUNT OF CHECK					
\$ CHECK DATE_	R #CHECK NUMB PHONE #							
	REFUND INFORMAT							
For each Claim, provide the f	Collowing:							
		nafiajam ID 4						
Madianid Claim Number	Bo	eneficiary ID #						
Passon Code for Claim Adjustment:	(Salact rasson code from list below	cu p	.)					
Reason Code for Claim Adjustment	(Select leason code from list below	. Ose one reason per ciam	1)					
(Please list <u>all</u> claim numbers involved. Attach separate sheet, if necessary)								
Note: If Specific Patient/Beneficiary ID/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment:								
For Institutional Facilities Or	nlv·							
Cost Report Year(s)	<u>,</u> .							
Cost Report Year(s) (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)								
For OIG Reporting Requirements: Do you have a Corporate Integrity Agreement with OIG? Yes No								
Do you have a Componete Integr	ity A manmant with OIC?	Vac No						
Do you have a Corporate integr	nty Agreement with OlG?	YesNo						
Reason Codes: Billing/Clerical Error 01 - Corrected Date of Service 02 - Duplicate 03 - Corrected CDT Code 04 - Not Our Patient(s) 05 - Modifier Added/Removed 06 - Billed in Error 07 - Corrected CDT Code	MSP/Other Payer Involvement 08 - MSP Group Health Plan Insurance 09 - MSP No Fault Insurance 10 - MSP Liability Insurance 11 - MSP, Workers Comp.(Including Black Lung 12 - Veterans Administration							