

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
NOVARTIS NUTRITION CORPORATION

I. PREAMBLE

Novartis Nutrition Corporation (NNC) 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, NNC is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to the Effective Date of this CIA, NNC voluntarily established an Ethics and Compliance with Law Program (the "Compliance Program"), which includes regular training for employees about the Novartis Code of Conduct and provides for a Corporate Compliance Officer, a Compliance Committee, a compliance training and education program, a confidential reporting hotline, a screening methodology for prospective employees, and various policies and procedures aimed at ensuring that NNC's activities are in compliance with all Federal health care program requirements and meeting NNC's goal of promoting high ethical standards in the conduct of NNC's business practices. NNC shall continue the operation of its compliance measures in accordance with the terms of this CIA. NNC may modify its Compliance Program as appropriate, but, at a minimum, shall comply with the integrity obligations enumerated in this CIA. For purposes of clarification, and subject to provisions relating to applicability set forth below, this CIA shall be applicable only to those operations of NNC that relate to products that are reimbursable by Federal health care programs.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by NNC under this CIA shall be five (5) years from the Effective Date of this CIA, unless otherwise specified. The Effective Date shall be the same date as the Effective Date of the Settlement Agreement, into which this CIA is incorporated by reference (Effective Date). Each one-year period, beginning with the first day of the month closest to the Effective Date of this CIA, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) NNC's final Annual Report; or (2) any additional materials submitted by NNC pursuant to OIG's request, whichever is later.

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

1. "Covered Persons" includes:
 - a. all directors and officers of NNC;
 - b. all NNC employees who engage in the marketing or sale of items or services for which reimbursement may be made by the Federal health care programs; and
 - c. all individuals who market or sell, on behalf of NNC, enteral nutrition items or services, including those who perform these functions and are employed by Novartis Medical Health, Inc., with the exception of unrelated third parties that purchase in arms-length transactions and then distribute such items or services, e.g., wholesalers or distributors whose only relationship with NNC is the purchase, distribution, and/or shipping of such items or services.
2. "Relevant Covered Persons" includes all Covered Persons identified in Section II.C.1.b and c, above, who personally engage in the promotion, marketing, or sale, on behalf of NNC, of enteral nutrition items or services for which reimbursement may be made by the Federal health care programs.
3. "Enteral nutrition" means the provision of nutrients directly into the

intestinal organs of adult humans via one or more devices and/or device components (such as pumps, disposable bags, and tubes), excluding oral, intravenous, or other routes.

III. CORPORATE INTEGRITY OBLIGATIONS

NNC shall maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* NNC presently has a Corporate Compliance Officer with responsibility for administering NNC's Compliance Program. NNC shall continue to employ an individual to serve as its Corporate Compliance Officer for the term of the CIA. The Corporate 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 Corporate Compliance Officer shall be a member of senior management of NNC, shall make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of NNC, and shall be authorized to report on such matters to the President and/or Board of Directors at any time. The Corporate Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer of NNC. The Corporate Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by NNC as well as for any reporting obligations created under this CIA.

NNC shall report to OIG, in writing, any changes in the identity of the Corporate Compliance Officer within 30 days after such a change and report any changes in the position description of the Corporate Compliance Officer, or any actions or changes that would affect the Corporate Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 30 days after such a change.

2. *Compliance Committee.* NNC presently has a Compliance Committee with responsibility for supporting the Corporate Compliance Officer in the implementation and oversight of the Compliance Program. NNC shall maintain its Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Corporate Compliance Officer and other employees from a representative cross-section of NNC's operating divisions (*e.g.*, human resources, sales & marketing, contract operations, and finance) who are senior, experienced, and able to devote time and resources to the duties and responsibilities of the Compliance Committee and the requirements of this CIA. The Corporate Compliance Officer shall chair the

Compliance Committee and the Committee shall support the Corporate Compliance Officer in fulfilling his/her responsibilities.

NNC shall report to OIG, in writing, on 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 30 days after such a change.

B. Written Standards.

1. *Code of Conduct.* To the extent not already accomplished, NNC shall revise, if necessary, and redistribute the Code of Conduct to all Covered Persons within 120 days after the Effective Date of this CIA. NNC shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all Covered Persons who are employees of NNC. The Code of Conduct shall, at a minimum, set forth:

- a. NNC's commitment to full compliance with all applicable Federal health care program requirements, including 42 U.S.C. § 1320a-7b(b) (the federal "Anti-Kickback Statute");
- b. NNC's requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements and with NNC's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
- c. the requirement that all of NNC's Covered Persons shall be expected to report to the Corporate Compliance Officer, or other appropriate individual designated by NNC, suspected violations of any Federal health care program requirements or of NNC's own Policies and Procedures;
- d. the possible consequences to NNC and Covered Persons of failure to comply with all applicable Federal health care program requirements and with NNC'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.E, and NNC's commitment to nonretaliation

and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date and annually thereafter, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by NNC'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 120 days after the Effective Date, whichever is later.

NNC shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Such revised Code of Conduct shall be distributed within 60 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 45 days after the distribution of the revised Code of Conduct.

NNC may use electronic methods of distribution and/or certification to comply with the terms described in Section III.B.1.

2. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, NNC shall revise and implement Policies and Procedures regarding the operation of NNC's Compliance Program and its compliance with applicable Federal health care program requirements. The revised Policies and Procedures at a minimum shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. the requirement that NNC shall not make the purchase or sale of enteral nutrition items or services, including but not limited to enteral nutrition pumps ("Pumps") and enteral nutrition disposable pump sets and containers ("Sets"), contingent on the purchase of any other item or service for which reimbursement may be made by the Federal health care programs;
- c. the requirement that Pumps and Sets shall be billed to customers in such a manner that the line item price for each product (including, if applicable, when the product is provided free of charge) may be separately and readily identified by each party to

the transaction (e.g., on the invoice, rebate form, or other document);

- d. the requirement that any payments to purchasers of enteral nutrition items or services to cover the purchaser's asserted costs of switching from one manufacturer to another shall be supported by documents or other evidence demonstrating that such costs, in fact, were incurred and the amount of such costs;
- e. the requirement that regardless of whether Pumps are "rented" separately or "leased" as a Pump/Set combination, NNC shall take commercially reasonable efforts to enforce the terms of such rental or lease arrangements, and in the case of "lease" arrangements, ensure that the line item price for the Pump reasonably corresponds with the line item price for "rented" Pumps;
- f. the requirement that, if Pumps have been refurbished or remanufactured, NNC shall disclose that fact, e.g., in the contract or other disclosure document, to customers who rent, lease, or purchase such Pumps;
- g. the requirement that NNC shall maintain accurate records of all rebates it provides on the sale, rental, or lease of enteral nutrition items or services and shall not interfere with a customer's ability to report such prices to any Federal health care program;
- h. the requirement that NNC shall refrain from violating the federal Anti-Kickback Statute in connection with its sales and marketing practices relating to the sale of enteral nutrition items and services; and
- i. the requirement that NNC's individual enteral nutritional sales representatives shall not provide reimbursement recommendations related to medical necessity determinations and that any reimbursement information from NNC be provided from and/or controlled by a centralized location or department, such as a toll-free call center for customers and/or an NNC website; and

Within 120 days after the Effective Date, the relevant portions of the revised Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain revisions to the Policies and Procedures.

At least annually (and more frequently, if appropriate), NNC shall assess and update as necessary the Policies and Procedures. Within 60 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures.

NNC may use electronic methods of distribution to comply with the terms of Section III.B.2.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, NNC shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain:

- a. NNC's CIA requirements; and
- b. NNC'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 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training annually.

For those Covered Persons who have received training that satisfies the requirements of Section III.C.1.b within the six months prior to the Effective Date, NNC need only provide training during the first Reporting Period that meets the requirements of Section III.C.1.a. Training provided to Covered Persons within the two months prior to the Effective Date that satisfies the requirements of Section III.C.1.a. and b. shall be deemed to meet the training requirements of Section III.C.1.a. and b. for the first Reporting Period.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least four hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. proper methods of promoting, marketing, and selling enteral nutrition items and services for which Federal health care program reimbursement may be made, in accordance with all applicable statutes, regulations, and requirements, including, but not limited to, the federal Anti-Kickback Statute and the Policies and Procedures required by this CIA;
- b. the personal obligation of each individual involved in marketing and sales of enteral nutrition items and services for which Federal health care program reimbursement may be made to ensure that those products are marketed and sold in accordance with all applicable Federal health care program requirements;
- c. all applicable Federal health care program requirements (including the sanctions for violations) relating to promotion, marketing, and sales of enteral nutrition items and services for which Federal health care program reimbursement may be made (including, but not limited to, the federal Anti-Kickback Statute; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; and the Civil False Claims Act, 31 U.S.C. §§ 3729-3733); and
- d. examples of proper and improper promotion, marketing, and sales practices for enteral nutrition items.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. Each Relevant Covered Person who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the marketing or sale of enteral nutrition items or services for which reimbursement may be made by the Federal health care programs, 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 four hours of Specific Training annually.

Training provided to Relevant Covered Persons within the six months prior to the Effective Date that satisfies the requirements of Section III.C.2 shall be deemed to meet the training requirements of Section III.C.2 for the first Reporting Period.

3. *Certification.* Each individual 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 Corporate Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

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

5. *Update of Training.* NNC shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the IRO Verification Review and any other relevant information.

6. *Computer-based Training.* NNC may provide the training required under this CIA through appropriate computer-based training approaches. If NNC 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 individuals receiving such training.

D. Review Procedures.

1. *General Description.*

a. *Annual Internal Review.* The annual review of NNC may be conducted internally by NNC. The reviews shall assess and evaluate NNC's sales and marketing systems, processes, policies, and procedures related to sales of Pumps and/or Sets (hereafter collectively "Enteral Products"). Each annual review shall cover each of the one-year Reporting Periods of the CIA.

b. *Retention of Independent Review Organization.* Within 120 days after the Effective Date, NNC 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 it in assessing and evaluating its systems, processes,

policies, and procedures related to sales and marketing of Enteral Products. If NNC engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of Appendix A. If a new IRO is engaged, NNC shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG shall notify NNC if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, NNC may continue to engage the IRO. Each IRO retained by NNC shall have appropriate expertise in the engagements to be performed. Each IRO shall assess, along with NNC, whether it can perform the IRO reviews in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist. Prior to conducting the engagements set forth below, the IRO shall submit its workplan(s) to the OIG for approval. However, any comments or recommendations made by the OIG in connection with a review of the submitted workplan(s) shall not preclude the OIG from making further comments or recommendations for future workplan(s) after reviewing the applicable IRO report(s).

c. *Frequency of Review.* On an annual basis, NNC shall assess and evaluate NNC's systems, processes, policies, and procedures related to the sale and marketing of Enteral Products. Subject to Section III.D.4, NNC shall perform the Enteral Product Contracting Review described in detail in Appendix A to the CIA. The Enteral Products Contracting Review shall be performed annually and shall cover each of the one-year Reporting Periods of the CIA. The IRO shall perform a verification review, as described in Section III.D.3.

d. *Enteral Products Contracting Review.* The Enteral Products Contracting Review shall consist of two separate components: (i) a Systems Consulting Review, focused on reviewing NNC's Enteral Products contracting systems, processes, policies, and practices (including the controls on those systems, processes, policies and practices); and (ii) a Documentation Review, focused on assessing a random sample of NNC's newly initiated or renewed Enteral Products contracts.

e. *Enteral Products Customer Related Expenditures Review.* The Enteral Products Customer Related Expenditures Review shall consist of two separate components: (i) a Systems Consulting Review, focused on reviewing NNC's Enteral Products systems, processes, policies and practices pertaining to Customer Related Activities (including the controls on those systems, processes, policies and practices); and (ii) a Documentation Review, consisting of a comparison of a random sample of NNC Enteral Products Customer Related Expenditures associated with those Enteral Products customers included in the Enteral Products Contracting Documentation Review described above to NNC's Policies and Procedures related to Sales and Marketing Expenditures.

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

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

Prior to initiating a Validation Review, OIG shall notify NNC of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, NNC may request a meeting with OIG to: (a) discuss the results of any Enteral Products Contracting Review or Enteral Products Customer Related Expenditures Review submissions or findings; (b) present any additional information to clarify the results of the Enteral Products Contracting Review or Enteral Products Customer Related Expenditures Review or to correct the inaccuracy of the Enteral Products Contracting Review or Enteral Products Customer Related Expenditures Review findings; and/or (c) propose alternatives to the proposed Validation

Review. NNC agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any questions regarding an Enteral Products Contracting Review or Enteral Products Customer Related Expenditures Review with NNC 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. *IRO Verification Review.* The IRO shall conduct a review (“Verification Review”) of at least 20% of the sampling units reviewed by NNC in the Enteral Products Contracting Review and Enteral Products Customer Related Expenditures Review.

As part of NNC’s Annual Report, the IRO shall submit a report that verifies that the requirements outlined in Section III.D and in Appendix A to this CIA have been satisfied and shall report the results, sampling unit by sampling unit, of the Verification Review performed.

4. *IRO Enteral Products Contracting Review and Enteral Products Customer Related Expenditures Review.* Following its review of NNC’s Annual Report, if, in its sole discretion, OIG determines that the NNC internal reviews were not satisfactory, OIG can require that all aspects of future Enteral Products Contracting Reviews and Enteral Products Customer Related Expenditures Reviews be done by the IRO.

5. *Independence/Objectivity Certification.* The IRO shall include in its report(s) to NNC a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Enteral Products Contracting Review and Enteral Products Customer Related Expenditures Review and that it has concluded that it is, in fact, independent and/or objective.

E. Disclosure Program.

NNC has represented to OIG that it presently has a Disclosure Program. During the term of the CIA, NNC shall continue to maintain the Disclosure Program, which includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Corporate Compliance Officer, or some other person who is not in the disclosing individual’s chain of command, any identified issues or questions associated with NNC’s policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or

administrative law. NNC shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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

The Corporate Compliance Officer, or designee, maintains 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 made available to OIG, upon request.

F. 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 ambit 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://oig.hhs.gov>); and
 - ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>).

- c. "Screened Persons" include:
 - i. prospective and current owners, officers, directors, and employees; and
 - ii. all Covered Persons (including contractors and agents of NNC) as described in Section II.C.1.c.

2. *Screening Requirements.* NNC shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements:

- a. NNC shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.

- b. NNC shall screen all Screened Persons against the Exclusion Lists within 120 days after the Effective Date, to the extent not already accomplished, and on an annual basis thereafter.

- c. NNC shall implement a policy requiring all Screened 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) NNC to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If NNC has actual notice that a Screened Person has become an Ineligible Person, NNC shall remove such person from responsibility for, or involvement with, NNC's business operations related to the Federal health care

programs and shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the 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 person is reinstated into participation in the Federal health care programs.

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

G. Notification of Government Investigation or Legal Proceedings.

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

H. Reporting of Reportable Events.

1. *Reportable Events.*

a. Definition of Reportable Event. For purposes of this CIA, a "Reportable Event" means anything that involves a matter, brought to the attention of senior management at NNC corporate headquarters, 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. A Reportable Event may be the result of an isolated event or a series of occurrences.

b. Reporting of Reportable Events. If NNC determines (after a reasonable opportunity to conduct an appropriate review or

investigation of the allegations) through any means that there is a Reportable Event, NNC 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. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- ii. a description of NNC's actions taken to correct the Reportable Event; and
- iii. any further steps NNC plans to take to address the Reportable Event and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, NNC changes location or sells, closes, purchases, or establishes a new business unit or facility location related to the sale of enteral nutrition items or services that may be reimbursable by Federal health care programs, NNC shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or facility location, phone number, fax number, Medicare Provider number (if any), provider identification number and/or supplier number (if any), and the corresponding contractor's name and address that has issued each Medicare number. All Covered Persons at each new business unit or facility location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, NNC 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 Corporate Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Corporate Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee, as required by Section III.A;
3. a copy of NNC's Code of Conduct required by Section III.B.1;
4. a copy of all Policies and Procedures required by Section III.B.2;
5. a copy of all training materials used for the training required by Section III.C, a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when training sessions were held;
6. a certification, conforming to the requirements of Section V.C below, by the Corporate Compliance Officer that:
 - a. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been made available to all appropriate 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 applicable training executed the certification(s) required by Section III.C.

The documentation supporting this certification shall be available to OIG, upon request.

7. a description of the Disclosure Program required by Section III.E;
8. the identity of the IRO(s), a summary/description of all engagements between NNC and the IRO, including, but not limited to, any outside financial audits or reimbursement consulting, and the proposed start and completion dates of the verification of NNC's Enteral Products Contracting Review and Enteral Products Customer Related Expenditures Review;
9. a certification from the IRO regarding its professional independence and/or objectivity with respect to NNC;

10. a summary of personnel actions (other than hiring) taken pursuant to Section III.F;

11. a list (including mailing addresses), of all of NNC's facility locations related to the sale of enteral nutrition items or services that may be reimbursable by Federal health care programs, the corresponding name under which each location is doing business, and the corresponding phone numbers and fax numbers; and

12. the certifications required by Section V.C.

B. Annual Reports. NNC shall submit to OIG annually a report with respect to the status of, and findings regarding, NNC'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 Corporate Compliance Officer, and any change in the membership of the Compliance Committee described in Section III.A;
2. a certification, conforming to the requirements of Section V.C below, by the Corporate Compliance Officer that:
 - a. all Covered Persons have completed any Code of Conduct certifications as required by Section III.B.1; and
 - b. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C.

The documentation supporting this certification shall be available to OIG, upon request.

3. a summary of any changes or amendments to the Policies and Procedures required by Section III.B.2 and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;
4. a copy of all training materials used for the training required by Section III.C (to the extent it has not been already provided as part of the

Implementation Report), a description of such training conducted during the Reporting Period, including a description of the targeted audiences, the length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when training sessions were held;

5. a complete copy of all reports prepared pursuant to the IRO's verification of NNC's Enteral Products Contracting Review and Enteral Products Customer Related Expenditures Review, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

6. NNC's response and corrective action plan(s) related to any issues raised by the IRO(s);

7. a revised summary/description of all engagements between NNC and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO regarding its professional independence and/or objectivity with respect to NNC;

9. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

10. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs;

11. a description of any personnel actions (other than hiring) taken by NNC as a result of the obligations in Section III.F, and the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F, and the actions taken in response to the obligations set forth in that Section;

12. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. 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;

13. a description of all changes to the most recently provided list of NNC's facility locations (including addresses) related to the sale of enteral nutrition items or services that may be reimbursable by Federal health care programs, as required by Section V.A.11, the corresponding name under which each location is doing business, and the corresponding phone numbers and fax numbers; and

14. the certification required by Section V.C.

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

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Corporate Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, NNC is in compliance with all of the requirements of this CIA; and (2) 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.

D. Designation of Information. NNC 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. NNC shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

