

EXHIBIT D

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ABBOTT LABORATORIES**

I. PREAMBLE

Abbott Laboratories (Abbott) 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 by Abbott and its Covered Persons, as defined below, 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, Abbott 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, Abbott initiated certain voluntary compliance measures, which, as represented by Abbott, include regular training to Covered Persons concerning Abbott's Code of Business Conduct and include review and disciplinary procedures aimed, in part, at ensuring that Abbott's activities are in compliance with all Federal health care program requirements and meeting Abbott's goals of continuing to promote high ethical standards in the conduct of Abbott's business practices. Abbott agrees to continue the operation of its compliance measures in accordance with the terms set forth below for the term of this CIA. Abbott may modify its voluntary compliance measures as appropriate, but, at a minimum, Abbott will ensure that during the term of this CIA, it shall comply with the integrity obligations enumerated in this CIA. For purposes of clarification and subject to provisions relating to applicability set forth expressly below, this CIA shall be applicable only to those

operations of Abbott that are subject to United States Federal health care program laws, regulations, and requirements.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Abbott under this CIA shall be five (5) years from the effective date of this CIA (“Effective Date”) (unless otherwise specified). The Effective Date shall be the date on which the final signatory of this CIA executes this CIA, or the effective date of the Settlement Agreement into which this CIA is incorporated by reference, whichever is later. 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, VIII, IX, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Abbott’s final annual report; or (2) any additional materials submitted by Abbott 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 of Abbott;
 - b. all officers and employees of Abbott’s Ross Products Division (Ross);
 - c. all officers, directors, and employees of Abbott that engage in the marketing or sale of enteral nutrition items or services for which reimbursement may be made by the Federal health care programs; and
 - d. all individuals that sell or market on behalf of Ross or Abbott enteral nutrition items or services for which reimbursement may be made by the Federal health care programs, with the exception of unrelated third parties that purchase in arms-length transactions and then distribute such items or services i.e., wholesalers or distributors whose only relationship with Abbott is the purchase of such items or services.

Employees who work less than 160 hours per year on behalf of Abbott, with the exception of sales and marketing staff, are not Covered Persons.

2. “Relevant Covered Persons” includes all Covered Persons that engage in the marketing or sale on behalf of Ross or Abbott 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 and disposable bags and tubes), excluding oral, intravenous, or other routes.

III. CORPORATE INTEGRITY OBLIGATIONS

Abbott hereby agrees to maintain a Compliance Program that includes the following elements:

A. Compliance Officers and Committees.

1. *Chief Compliance Officer.* Abbott presently has a Chief Ethics and Compliance Officer (Chief Compliance Officer) with responsibility for administering Abbott’s Compliance Program. Abbott shall continue to employ an individual to serve as its Chief Compliance Officer during the term of this CIA. The Chief 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 Chief Compliance Officer shall be a member of senior management of Abbott, shall make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Abbott, or its designated subcommittee, in such form or manner as the Board of Directors of Abbott determines, and shall be authorized to report on such matters to the Board of Directors at any time.

The Chief Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Abbott as well as for any reporting obligations created under this CIA. Abbott shall report to OIG, in writing, any changes in the identity or position description of the Chief Compliance Officer, or any actions or changes that

would affect the Chief Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Ross Ethics and Compliance Officer.* Ross presently has an Ethics and Compliance Officer (Ross Compliance Officer) with responsibility for implementing Abbott's Compliance Program at Ross. Abbott shall continue to employ an individual to serve as Ross Compliance Officer during the term of this CIA. The Ross Compliance Officer shall be responsible for implementing the Abbott Compliance Program at Ross and ensuring Ross's compliance with this CIA and with Federal health care program requirements. The Ross Compliance Officer shall be a member of senior management of Ross and shall report on make periodic (at least semi-annual) reports regarding compliance matters at Ross to the Chief Compliance Officer and to the President of Ross.

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

3. *Business Conduct Committee.* Abbott presently has a Business Conduct Committee (Compliance Committee) with responsibility for supporting the Chief Compliance Officer in development, implementation and oversight of the Abbott Compliance Program. Abbott shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant divisions or departments, such as finance, human resources, operations, and audit). The Chief Compliance Officer shall chair the Compliance Committee and the Committee shall support the Chief 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).

Abbott 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.

4. *Compliance Steering Committee.* Ross presently has a Compliance Steering Committee (Ross Compliance Committee) with responsibility for supporting the Ross Compliance Officer in the implementation and oversight of the Abbott Compliance

Program at Ross. Ross shall maintain its Compliance Committee during the term of this CIA. The Ross Compliance Committee shall, at a minimum, include the Ross Compliance Officer and other members of Ross senior management necessary to implement and oversee the Abbott Compliance Program at Ross (e.g., senior executives of relevant departments, such as finance, sales & marketing, human resources, etc). The Ross Compliance Officer shall chair the Ross Compliance Committee and the Committee shall support the Ross Compliance Officer in fulfilling his/her responsibilities.

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

B. Written Standards.

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

- a. Abbott's commitment to full compliance with all Federal health care program requirements, including the federal anti-kickback statute;
- b. Abbott's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Abbott's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of Abbott's Covered Persons shall be expected to report to the Chief Compliance Officer or other appropriate individual designated by Abbott suspected violations of any Federal health care program requirements or of Abbott's own Policies and Procedures;

- d. the possible consequences to both Abbott and Covered Persons of failure to comply with Federal health care program requirements and with Abbott'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 Abbott's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person, who has not already done so within 180 days prior to the Effective Date of this CIA, shall certify, in writing, that he or she has received, read, understood, and shall abide by Abbott's Code of Conduct. For purposes of this Section III.B.1, Abbott may use such electronic methods of distribution and/or certification as it deems appropriate, provided that a record is maintained, e.g., electronically, of such distributions and certifications. 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. At its own discretion, Abbott may fulfill its distribution obligations under this Section by revising and reissuing its current Code of Conduct or by issuing to all Covered Persons a newsletter, e-mail, or other update to the Code of Conduct addressing the requirements of this Section III.B.1.

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

2. *Policies and Procedures.* To the extent not already accomplished, Abbott shall revise and implement written Policies and Procedures regarding the operation of Abbott's compliance program and its compliance with Federal health care program requirements within 120 days after the Effective Date. 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. the requirement that Abbott shall not condition the purchase or sale of enteral nutrition items or services, including but not limited to enteral nutrition pumps (Pumps), on the purchase of any other item or service for which reimbursement may be made by the Federal health care programs, including but not limited to enteral nutrition disposable pump sets and containers (Sets) and/or enteral nutrition;
- c. the requirement that Pumps and Sets shall be billed to customers in such a manner that the line item price for each product may be separately and readily identified by each party to the transaction (e.g., on the invoice, rebate form, chargeback memorandum, or other document);
- d. the requirement that any “conversion bonuses,” or other payments to purchasers of enteral nutrition items or services purportedly to cover the purchaser’s costs of switching from one manufacturer to another shall be supported by documents or other evidence proving 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, Abbott shall take commercially reasonable efforts to collect all rental and/or lease payments in accordance with the terms of such rental or lease arrangements;
- f. in the event that a lower reimbursement amount applies for refurbished or remanufactured Pumps, the requirement that Abbott 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 Abbott shall maintain accurate records of all discounts related to the sale of enteral nutrition items or services and shall not interfere with a customer’s ability to report such discounts to any Federal health care program;

- h. the requirement that Abbott 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;
- i. the requirement that individual Abbott enteral nutritional sales representatives shall not provide reimbursement recommendations related to medical necessity determinations and that if reimbursement information relating to the enteral nutrition business is to be provided by Abbott, it shall be provided from and/or controlled by a centralized location or department, such as a toll-free call center for customers and/or an Abbott website; and
- j. the requirement that Ross shall develop and initiate a Transition Plan by which Ross shall diligently undertake to convert existing business relationships involving the marketing and sales of enteral nutrition products as may be needed in order to ensure that, upon completion of the Transition Plan, Ross's enteral nutrition sales and marketing business activities comply with applicable Federal health care program requirements and the Policies and Procedures set forth in this Section II.B.2.

Within 120 days after the Effective Date, the relevant portions of the 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 the Policies and Procedures. Distribution may include publishing such Policies and Procedures on Abbott's intranet or other internal web site available to all employees. If Abbott uses such an electronic method of distribution, it must notify the individuals receiving the Policies and Procedures that the Policies and Procedures will be distributed in such a manner and it must track the distribution to ensure that all appropriate individuals received the Policies and Procedures.

At least annually (and more frequently, if appropriate), Abbott 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 Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, Abbott shall provide reasonable and appropriate general training to each Covered Person. This training, at a minimum, shall explain Abbott's:

- a. CIA requirements; and
- b. Abbott'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 training described above, each Covered Person shall receive such reasonable and appropriate general training annually. General compliance training (as described above) provided to Covered Persons by Abbott during the six months immediately prior to the execution of this CIA may be credited towards the training requirements set forth in this Section III.C.1. However, Abbott shall meet the requirements of this section by updating any such training, as appropriate, via e-mail, newsletter, flyer, or other appropriate medium.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive 4 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.

Persons providing the training shall be knowledgeable about the subject area. Specific Training that meets the requirements of this Section III.C.2 and that is provided via a computer-based or web-based training program may be applied toward the training time requirements of this Section.

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. To the extent that a new Relevant Covered Person's work relates to the marketing or sale of enteral nutrition items and services, such new Relevant Covered Person shall be subject to direct supervision (*i.e.*, shall be accompanied in-person during all contacts with existing and potential customers) by a Relevant Covered Person who has completed the specific training until such time as the new Relevant Covered Person completes his or her applicable training.

After receiving the initial training described in this Section, each Relevant Covered Person shall receive 4 hours of specific training annually. Abbott 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 Independent Review Organization (IRO) audits, and any other relevant information. Specific Training that meets the requirements of this Section III.C.2 and that was provided to Relevant Covered Persons during the six months immediately preceding the

execution of this CIA may be credited towards the training time requirements of this Section, provided that Abbott shall update such training with respect to the new Policies and Procedures required by Section III.B.2.

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

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 120 days after the Effective Date, Abbott shall retain an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Abbott in assessing and evaluating its sales and marketing systems, processes, policies, and procedures. Each IRO retained by Abbott shall have appropriate expertise in the engagements to be performed. Each IRO shall assess, along with Abbott, 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) will not preclude the OIG from making further comments or recommendations for future workplan(s) after reviewing the applicable IRO report(s).

b. IRO Engagements. The IRO shall perform engagements to assist Abbott in assessing and evaluating its systems, processes, policies and procedures related to the sales and marketing of enteral nutrition pumps and/or enteral nutritional disposable pump sets and containers (hereafter collectively “Enteral Products”) by the Ross Products

Division. Abbott may engage, at its discretion, a single entity to perform the following engagements, provided that the entity has the requisite experience and capabilities to perform each review: (i) Enteral Products Contracting Engagement; (ii) Enteral Products Transition Engagement; and (iii) Enteral Products Customer Related Expenditures Engagement, each of which are described in detail in Attachment A to the CIA. Each Enteral Products Contracting Engagement, Enteral Products Transition Engagement and Enteral Products Customer Related Expenditures Engagement shall be performed annually and shall cover each of the following periods: (i) for the first year, from the Implementation Report due date through the first anniversary of the Effective Date of the CIA and (ii) for the remaining years of the CIA, each successive Reporting Period, except that the Enteral Products Transition Engagement shall be conducted until all such pumps are transitioned in accordance with Ross's Transition Plan as described in Section III.B.2.j, above. The IRO(s) shall perform all components of each annual Enteral Products Contracting Engagement, Enteral Products Transition Engagement and Enteral Products Customer Related Expenditures Engagement.

c. Enteral Products Contracting Engagement. The Enteral Products Contracting Engagement shall consist of two separate components: (i) a Systems Consulting Review, focused on reviewing Ross'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 newly initiated or renewed Enteral Products contracts.

d. Enteral Products Transition Engagement. The Enteral Products Transition Engagement shall consist of a Documentation Review, focused on 1) testing of data provided by Ross management documenting the reconciliation of all Enteral Products pumps under agreements in place with customers at the beginning and end of the review period ("Pump Inventory") and 2) assessing a random sample of Enteral Products Transition Agreements executed during the review period.

e. Enteral Products Customer Related Expenditures Engagement.

The Enteral Products Customer Related Expenditures Engagement shall consist of two separate components: (i) a Systems Consulting Review, focused on reviewing Ross'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 testing of a random sample of Ross Enteral Products Customer Related Expenditures associated with those Enteral Products customers included in the Enteral Products Contracting Documentation Review described above to Ross policies and procedures related to Sales and Marketing Expenditures.

f. Retention of Records. The IRO and Abbott shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Abbott) related to the reviews, in accordance with the document retention requirements of Section VIII below.

3. *Validation Review.* In the event OIG has reason to believe that: (a) Abbott's Contracting Engagement, Transition Engagement, or Customer Related Expenditure Engagement fails to conform to the requirements of this CIA; or (b) the IRO's findings or engagement results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the particular engagement complied with the requirements of the CIA and/or the findings or engagement results are inaccurate ("Validation Review"). Abbott shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after Abbott's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Abbott 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, Abbott may request a meeting with OIG to discuss the results of any Contracting Engagement, Transition Engagement, or Customer Related Expenditure Engagement submissions or findings; present any additional or relevant information to clarify the results of the particular engagement or to correct the inaccuracy of the engagement findings; or propose alternatives to the proposed Validation Review. Abbott shall 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 engagement with Abbott prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence/Objectivity Certification.* The IRO shall include in its report(s) to Abbott 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 Contracting Engagement, Transition Engagement, and Customer Related Expenditure Engagements and that it has concluded that it is, in fact, independent and/or objective.

E. Disclosure Program.

Abbott presently has a disclosure program designed to facilitate communications relating to compliance with the law and Abbott's policies (Disclosure Program). During the term of the CIA, Abbott shall maintain its Disclosure Program, which includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Abbott'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. Abbott 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 non-retribution, non-retaliation policy, and shall continue to include a reporting mechanism for anonymous, confidential communications. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Chief 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, Abbott shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Chief 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 available to OIG, upon request.

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an “Ineligible Person” shall be an individual or entity who: (a) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (b) 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.

2. *Screening Requirements.* Abbott shall not hire or contract with as an Ineligibility Relevant Covered Person, as defined below, any Ineligible Person. To ensure that such persons are not Ineligible Persons, Abbott shall screen such persons prior to engaging their services by: (a) requiring such persons to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) (these lists shall hereinafter be referred to as the “Exclusion Lists”). Nothing in this Section affects the responsibility of (or liability for) Abbott to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* Within 120 days after the Effective Date, Abbott shall review its list of Covered Persons and a list of all individuals engaged in the marketing or sale of items or services for which reimbursement may be made by the Federal health care programs (hereafter collectively “Ineligibility Relevant Covered Persons”) against the Exclusion Lists. Thereafter, Abbott shall review its list of Ineligibility Relevant Covered Persons against the Exclusion Lists annually. In addition, Abbott shall require Ineligibility Relevant Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes such person an Ineligible Person.

If Abbott has actual notice that an Ineligibility Relevant Covered Persons has become an Ineligible Person, Abbott shall remove such person from responsibility for, or involvement with, Abbott'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 rendered, ordered, or prescribed by the person are paid in whole or in 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 Abbott has actual notice that an Ineligibility Relevant Covered Person is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment, involvement, or contract term, Abbott 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, Abbott shall notify OIG, in writing, of any ongoing investigation known to Abbott or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Abbott 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. Abbott 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 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 Abbott's 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 Abbott determines through any means that there is a Reportable Event, Abbott 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 Abbott's actions taken to correct the Reportable Event; and
- iii. any further steps Abbott 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, Abbott changes locations or sells, closes, purchases, or establishes a new business unit or location related to the sale or marketing of enteral nutrition items or services that are reimbursable by Federal health care programs, Abbott 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. Nothing in this Section IV of this CIA shall require Abbott to provide such notice to OIG if Abbott re-locates an existing facility related to the sale or marketing of enteral nutrition items or services from one business address to another, where the re-location of such an existing facility involves only a change of location of the facility but does not involve any other change in the ownership of or business operations conducted at such facility. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare provider number (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at each such business unit or location shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Abbott shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number, and position description of the Compliance Officers required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officers may have;
2. the names and positions of the members of the Compliance Committees required by Section III.A;
3. a copy of Abbott's Code of Conduct required by Section III.B.1;
4. a copy of all Policies and Procedures required by Section III.B.2, including a copy of all Policies and Procedures related to the Transition Plan described in Section III.B.2.j;
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 the training sessions were held;
6. a certification, conforming to the requirements of Section V.C. below, by the Chief 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 and 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 Abbott and the IRO, including, but not limited to, any outside financial audits or reimbursement consulting, and the proposed start and completion dates of the Enteral Products Contracting Engagement, Enteral Products Transition Engagement and Enteral Products Customer Related Expenditures Engagement;
9. a certification from the IRO regarding its professional independence and/or objectivity with respect to Abbott;
10. a summary of personnel actions (other than hiring) taken pursuant to Section III.F.;
11. a list of all of Abbott's locations related to the sales and marketing of enteral nutrition items and services (including locations and mailing addresses), the corresponding name under which each location is doing business, and the corresponding phone numbers and fax numbers; and
12. the certification required by Section V.C.

B. Annual Reports. Abbott shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Abbott's compliance activities for each of the five Reporting Periods.

Each Annual Report shall include:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Chief 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 Chief Compliance Officer that:

- a. all Covered Persons have completed any Code of Conduct certifications 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 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) and copies of any Policies and Procedures related to compliance with Federal health care program requirements;
4. a copy of all training materials used for the training required by Section III.C (to the extent it has not already been provided as part of the Implementation Report), a description of such training conducted during the Reporting Period, 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 the training sessions were held;
5. a complete copy of all reports prepared pursuant to the IRO's Enteral Products Contracting Engagement, Enteral Products Transition Engagement and Enteral Products Customer Related Expenditures Engagement, including a copy of the methodology used, along with a copy of the IRO's engagement letter;
6. Abbott'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 Abbott 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 Abbott;

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 Abbott 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 (as updated) of Abbott's locations (including addresses) 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 Chief Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, Abbott is in compliance with all of the requirements of this CIA; and (2) the Chief Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information. Abbott 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. Abbott 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, D.C. 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Abbott:

Charles M. Brock
Chief Ethics and Compliance Officer
Abbott Laboratories, Dept. 036X, Bldg. AP6A/1
100 Abbott Park Road
Abbott Park, IL 60064-6008
Telephone: (847) 937-5210
Facsimile: (847) 937-5210

With a Courtesy Copy to:

Jose de Lasa, Esq.
Senior Vice President, Secretary,
and General Counsel

Abbott Laboratories, Dept. 364
100 Abbott Park Road
Abbott Park, IL 60064
Telephone: (847) 937-8905
Facsimile: (847) 938-6277

However, for purposes of this notice requirement, submission of notice to Abbott's Chief Compliance Officer shall be sufficient. 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.

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 Abbott's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Abbott's locations for the purpose of verifying and evaluating: (a) Abbott's compliance with the terms of this CIA; and (b) Abbott's compliance with the applicable requirements of the Federal health care programs. The documentation described above shall be made available by Abbott 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 Abbott'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. Abbott shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Abbott's employees may elect to be interviewed with or without a representative of Abbott present.

VIII. DOCUMENT AND RECORD RETENTION

Abbott shall maintain for inspection all documents and records related to the furnishing of enteral nutrition items or services reimbursable by Federal health care programs, or to compliance with this CIA, for six years from the Effective Date (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Abbott prior to any release by OIG of information submitted by Abbott pursuant to its obligations under this CIA and identified upon submission by Abbott as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Abbott shall have the rights set forth at 45 C.F.R. § 5.65(d). Nothing in this CIA, or any communication or report made pursuant to this CIA, shall constitute a waiver of, or be construed to require Abbott to waive, Abbott's attorney-client, work product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect Abbott's obligation to comply with the provisions of this CIA, e.g., by providing all documents necessary to determine whether Abbott is in compliance with the terms of the CIA.

X. BREACH AND DEFAULT PROVISIONS

Abbott is expected to fully and timely comply with all of its CIA obligations. A breach of this CIA does not constitute a breach of the Settlement Agreement between Abbott and the United States or the settlement agreements, if any, with individual States. Any breach of the terms of those agreements does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach of this CIA. Section X of this CIA specifies all of the remedies available to the OIG if Abbott fails to satisfy its obligations under this CIA. The remedies available to the OIG under this section X do not preempt or limit any actions that individual States may take against Abbott under appropriate authorities.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Abbott and OIG hereby agree that failure to comply with certain obligations 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 Abbott fails to have in place any of the obligations described in Section III:

a. a Chief Compliance Officer and a Ross Compliance Officer;

- b. a Compliance Committee and a Ross Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. a requirement that Covered Persons be trained; and
- f. a Disclosure Program.

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 Abbott fails to retain an IRO, as required in Section III.D.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Abbott fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Abbott employs or contracts with an Ineligible Person as an Ineligibility Relevant Covered Person and that person: (a) has responsibility for, or involvement with, Abbott's business operations related to the Federal health care programs; or (b) is in a position for which the person's salary or the items or services rendered, 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 (the Stipulated Penalty described in this Subsection shall not be demanded for any time period during which Abbott can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.F) as to the status of the person).

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Abbott as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG) or otherwise required by this CIA.

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

B. Timely Written Requests for Extensions. Abbott 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 Abbott 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 submit the notification or report shall not begin to accrue until three business days after Abbott 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.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Abbott has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Abbott, in accordance with the notice provisions in Section VI above, of: (a) Abbott's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Abbott shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed

upon provisions set forth below in Section X.E. In the event Abbott elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Abbott cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

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

D. Exclusion for Material Breach of this CIA.

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

- a. a failure by Abbott to report a Reportable Event and take corrective and preventive action as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to retain and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Abbott constitutes an independent basis for Abbott's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Abbott has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Abbott of: (a) Abbott'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”).

3. *Opportunity to Cure.* Abbott 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. Abbott 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) Abbott has begun to take action to cure the material breach; (ii) Abbott is pursuing such action with due diligence; and (iii) Abbott has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Abbott fails to satisfy the requirements of Section X.D.3, OIG may exclude Abbott from participation in the Federal health care programs. OIG shall notify Abbott in writing of its determination to exclude Abbott (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of 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, Abbott may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG’s delivery to Abbott of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Abbott shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall

be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (“DAB”), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Abbott was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Abbott 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 Abbott to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Abbott requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 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 Abbott 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) Abbott had begun to take action to cure the material breach within that period; (ii) Abbott has pursued and is pursuing such action with due diligence; and (iii) Abbott provided to OIG within that period a reasonable timetable for curing the material breach and Abbott has followed the timetable.

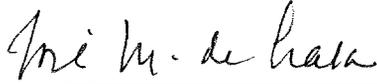
For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Abbott, only after a DAB decision in favor of OIG. Abbott's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Abbott 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 Abbott 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. Abbott 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 Abbott, Abbott shall be reinstated effective on the date of the original exclusion.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Abbott and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Abbott;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. The undersigned Abbott 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.

ON BEHALF OF ABBOTT LABORATORIES



JOSE DE LASA, ESQ.
Senior Vice President, Secretary,
and General Counsel

7/9/03

DATE



BRADLEY E. LERMAN, ESQ.
Counsel For Abbott Laboratories

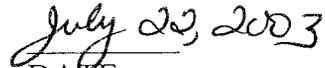
7/08/03

DATE

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



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



DATE

Attachment A

A. Enteral Products Contracting Engagement

1. General Description of Enteral Products Contracting Engagement

Ross Products Division's Policies and Procedures (referenced in Section III.B.2. of the CIA) set forth certain requirements relating to contracting with customers for the purchase or rental of Enteral Products. For each Enteral Products Contracting Review Period, the IRO shall conduct two engagements: (a) Enteral Products Contracting Systems Consulting Review; and (b) Enteral Products Contracting Documentation Review.

2. Enteral Products Contracting Systems Consulting Review

For each Reporting Period, the IRO shall review the systems, processes, policies and practices in place to control initiation or renewal of contracts with Enteral Products customers implemented subsequent to the Effective Date of the CIA. Specifically, this includes a review of:

- The processes and controls over the execution of contracts with customers for the purchase or rental of Enteral Products, including processes and controls over contract initiation, approval, establishing terms and conditions, entering contracts into systems, invoicing, pricing options, value-added services, warranty/repair provisions; and
- The controls and processes supported by computer systems used to manage the contracting process.

For each relevant Reporting Period, the IRO shall prepare a report based upon the Enteral Products Contracting Systems Consulting Review. Each report shall include the following items:

- A description of the systems, controls, processes, policies and practices in place to control and manage the Enteral Products Contracting Function;
- A general description of the documentation, information, and systems reviewed and the personnel interviewed;
- The findings and supporting rationale regarding any weaknesses in the contracting systems, controls, processes, policies and practices; and
- Any recommendations to improve any contracting related systems, processes, policies or practices.

3. Enteral Products Contracting Documentation Review

The IRO shall obtain from Ross Products Division a listing of all Enteral Products Customer Contracts (both newly initiated and renewals) executed during the review period and shall randomly select 50 of those contracts for testing. Specific to the 50 identified contracts, the IRO shall perform testing to assess whether:

- the contract was executed in accordance with all requirements set forth in Ross's policies and procedures;
- the contract and supporting documentation reflects approvals consistent with policy;
- for each contract, all supporting documentation exists in accordance with Ross policy; and
- for each contract, the first invoice or, if applicable, the chargeback claim related to the customer, subsequent to contract execution, reflects the approved contract terms.

The IRO shall annually prepare a report based upon each Enteral Products Contracting Documentation Review performed. Each report shall include the following:

Elements to be included:

- Enteral Products Contracting Documentation Review Objectives: A clear statement of the objectives intended to be achieved by the review;
- Review Protocol: A detailed narrative description of the procedures performed and a description of each sampling unit and universe utilized in performing the procedures; and
- Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the review.

Results to be included:

- A list of the contracts selected for testing;
- Findings as to whether, based on the procedures performed, the contract was completed in accordance with the requirements set forth in Ross's policies and procedures; and
- For each contract, the IRO shall identify any Material and Non-Material errors discovered.

- For the Non-Material errors, the IRO shall describe what the errors were. The IRO shall describe those situations when corrective action was taken prior to the initiation of the IRO's review, including a description of the circumstances requiring corrective action and the nature of corrective action.
- For Material Errors, the IRO shall describe the error and the additional procedures performed to assess the root cause of the Material Error.

B. Enteral Products Transition Engagement

1. Transition Review

The IRO shall obtain from Ross Products Division, a reconciliation of all Enteral Products pumps under Pump Set Agreements in place with customers at the beginning and end of each review period ("Pump Inventory") and agree the total activity by major category (i.e., reductions of pumps under Pump Set Agreements) for the Review Period to source systems.

2. Transition Agreement Review

The IRO shall obtain from Ross Products Division, a listing of all Transition Agreements executed during the review period (such detail to reconcile to activity included on the Pump Inventory described above) and shall randomly select 30 of those Agreements as the basis for this Review. Specific to the 30 identified Transition Agreements, the IRO shall perform testing to assess whether the Transition Agreements were executed, approved and billed in accordance with Ross policies and procedures related to the transition process.

The IRO shall annually prepare a report based upon each Enteral Products Transition Engagement performed. Each report shall include the following:

Elements to be included:

- Enteral Products Transition Engagement Objectives: A clear statement of the objectives intended to be achieved by the review;
- Review Protocol: A detailed narrative description of the procedures performed and a description of each sampling unit and universe utilized in performing the procedures; and
- Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Enteral Products Transition Engagement.

Results to be included:

- Any instances where amounts on the Pump Inventory do not agree to underlying systems
- For each Enteral Products Transition Agreement reviewed, the IRO shall state its findings and supporting rationale as to whether: (a) the agreement was executed and managed in accordance with all requirements set forth in Ross policies and procedures related to the transition process; (b) the agreement and supporting documentation reflects that all written approvals were obtained in accordance with Ross policies and procedures related to the transition process; and (c) for each agreement, all supporting documentation and invoicing exists in accordance with Ross policies and procedures related to the transition process;
- The IRO shall identify all Material and Non-Material errors discovered.
 - For the Non-Material errors, the IRO shall describe what the errors were. The IRO shall describe those situations when corrective action was taken prior to the initiation of the IRO's review, including a description of the circumstances requiring corrective action and the nature of corrective action.
 - For Material Errors, the IRO shall describe the error and the additional procedures performed to assess the root cause of the Material Error.

C. Enteral Products Customer Related Expenditures Engagement

1. General Description of Enteral Products Customer Related Expenditures Engagement

Ross Products Division's business policies and procedures and the Policies and Procedures referenced in III.B.2. of the CIA (hereafter collectively "Ross Sales and Marketing Policies"), set forth certain requirements relating to potential sales and marketing activities engaged in and expenditures made with Enteral Products customers. For each Review Period, the IRO shall conduct two reviews: (a) Enteral Products Customer Related Activities Systems Consulting Review; and (b) Enteral Products Customer Related Expenditures Documentation Review.

2. Enteral Products Customer Related Activities Systems Consulting Review

For each reporting period, the IRO shall review Ross's sales and marketing systems, controls, policies and practices pertaining to the following types of potential activities engaged in with Enteral Products customers:

- Conversion Bonuses
- Consulting, Speaking and Other Advisory Fee-for Service Agreements
- Debt Forgiveness, Debt Reduction, and Customer Credits
- General Program Support (e.g., Exhibit and Display Fees)
- Free Goods
- Medical Education Grants
- Product Trials
- Rebates and Administrative Fees
- Reimbursement or Claims Submission Advice
- Value-Added Services

This list of activities shall hereafter be referred to as the "Enteral Products Customer Related Activities" or the "Activities." The documents that identify and support these Activities are referred to as "Control Documents."

For each relevant Reporting Period, the IRO shall prepare a report based upon the Enteral Products Customer Related Activities Systems Consulting Review. Each report shall include the following items:

- A description of the systems, processes, policies and practices in place to control and manage Enteral Products Customer Related Activities;
- A general description of the documentation, information, and systems reviewed and the personnel interviewed;
- The findings and supporting rationale regarding the weaknesses in the sales and marketing related systems, processes, policies and practices; and
- Any recommendations to improve any sales and marketing related systems, processes, policies or practices.

3. Enteral Products Customer Related Expenditures Documentation Review

Selection of Documentation

The IRO shall utilize the first 30 customers selected in the Enteral Products Contracting Documentation Review (described in Section A.3 above) as the basis for this review. Specific to those 30 identified customers, Ross shall aggregate all Enteral Products

Customer Related Expenditures from Ross's payments systems and select a sample of 50 Control Documents or, if there are fewer than 50 Control Documents related to the first 30 customers, the IRO shall randomly select additional sample units from the remaining 20 customers for testing. If there are not sufficient Control Documents associated with the remaining 20 customers so that a sample of 50 units may be reviewed, Ross and/or the IRO shall contact OIG regarding how to proceed.

Attributes to be Tested

During each reporting period, the IRO shall review each expenditure to assess:

- whether documentation consistent with policies and procedures relating to the Enteral Products Customer Related Expenditures exists;
- whether the documentation was completed in accordance with Ross's Policies and Procedures. This includes a review of whether all required written approvals were obtained in accordance with Ross's Policies and Procedures;
- to the extent the expenditures are made pursuant to the customer contract, perform testing to agree the expenditure to the payment terms included in the contract.

The IRO shall annually prepare a report based upon each Enteral Products Customer Related Expenditures Documentation Review performed. Each report shall include the following:

Elements to be included:

- Enteral Products Customer Related Expenditures Documentation Review Objectives: A clear statement of the objectives intended to be achieved by the review;
- Review Protocol: A detailed narrative description of the procedures performed and a description of each sampling unit and universe utilized in performing the procedures; and
- Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the review.

Results to be included:

- For each Control Document reviewed, the IRO shall state its findings and supporting rationale as to whether: (a) the expenditure represented by the Control Document was made in accordance with all requirements set forth

in Ross Sales and Marketing Policies; (b) the expenditure and supporting Control Documentation reflect that all written approvals were obtained in accordance with Ross Sales and Marketing Policies; (c) if applicable, whether the expenditure agreed to the terms included in the customer contract; and (d) for each expenditure, all supporting documentation exists in accordance with Ross Sales and Marketing Policies.

- For each Control Document, the IRO shall identify all Material and Non-Material errors discovered.
 - For the Non-Material errors, the IRO shall describe what the errors were. The IRO shall describe those situations when corrective action was taken prior to the initiation of the IRO's review, including a description of the circumstances requiring corrective action and the nature of corrective action.
 - For material errors, the IRO shall describe the error and the additional procedures performed to assess the root cause of the Material Error.

D. Definition of Material Error

The IRO shall perform each review using the criteria set forth above and shall identify any Material and Non-Material errors discovered. For purposes of the reviews described in this Attachment A only, the contract, Transition Agreement, or expenditure (as applicable) will be found to have a Material Error if: (1) the appropriate and required documentation does not exist and no corrective action has been taken prior to the initiation of the IRO's review of the relevant Review Period; or (2) information or data is omitted from key fields in the documentation that restricts the IRO's ability to understand the nature of the contract, Transition Agreement, expenditure or activity and/or assess compliance with Ross's policies and procedures and no corrective action has been taken prior to the initiation of the IRO's review of the relevant Review Period. All other errors shall be considered Non-Material.

E. Additional Engagement if Material Errors Rates Are Discovered

In instances in which the IRO finds Material Errors, the IRO shall conduct an additional review of the contract, Transition Agreement, expenditure or activity to determine the root cause of the Material Errors. For instance, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Errors. The IRO shall report the results of this additional review to Ross Management and the OIG.