CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MCKESSON MEDICAL-SURGICAL MINNESOTA INC.

I. PREAMBLE

McKesson Medical-Surgical Minnesota Inc. and its subsidiaries (McKesson Minnesota) hereby enter 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, McKesson Minnesota 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, McKesson Medical-Surgical MediMart Inc., formerly XVIII B Medi Mart, Inc., a subsidiary of McKesson Minnesota, entered into a five-year CIA that became effective April 16, 2002 (MediMart CIA). McKesson Minnesota agrees that components of the existing Compliance Program will be modified or expanded, as necessary, in order to be in compliance with all of the corporate integrity obligations under this CIA for the term of this CIA.

Prior to the execution of the MediMart CIA, McKesson Minnesota established a Compliance Program which provided for a Chief 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 the McKesson Minnesota's participation in the Federal health care programs conforms to all applicable statutes, regulations, and other legal requirements.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by McKesson Minnesota under this CIA shall be five (5) years from the effective date of this CIA, unless otherwise specified. The Effective Date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) McKesson Minnesota's final annual report; or (2) any additional materials submitted by McKesson Minnesota 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 McKesson Minnesota;

   b. all employees of McKesson Minnesota that are involved in any way in the marketing, sale, or distribution of enteral nutrition items for which reimbursement may be made by the Federal health care programs; and

   c. all individuals that market, sell, or distribute on behalf of McKesson Minnesota enteral nutrition items or services for which reimbursement may be made by the Federal health care programs.

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

2. "Relevant Covered Persons" includes all Covered Persons identified in Section II.C.1.b and c, above, that are involved in any way in the marketing, sale, or distribution on a wholesale basis 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

McKesson Minnesota shall maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

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

McKesson Minnesota shall report to OIG, in writing, any changes in the identity of the Chief Compliance Officer within 30 days after such a change and report any changes in the 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 30 days after such a change.

2. *Compliance Committee.* McKesson Minnesota presently has a

Compliance Committee with responsibility for supporting the Chief Compliance Officer in the implementation and oversight of the Compliance Program. McKesson Minnesota shall maintain its 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 departments, such as finance, sales & marketing, human resources, etc.). The Chief Compliance Officer shall chair the Compliance Committee and the Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities.

McKesson Minnesota 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, McKesson Minnesota shall revise, if necessary, and redistribute the Code of Conduct to all Covered Persons within 120 days after the Effective Date of this CIA. McKesson Minnesota 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. McKesson Minnesota'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. McKesson Minnesota's requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements and with McKesson Minnesota'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 McKesson Minnesota's Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by McKesson Minnesota, suspected violations of any Federal health care program

requirements or of McKesson Minnesota's own Policies and Procedures;

d. the possible consequences to McKesson Minnesota and Covered Persons of failure to comply with applicable Federal health care program requirements and with McKesson Minnesota'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 McKesson Minnesota'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 McKesson Minnesota'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.

McKesson Minnesota 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.

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

2. *Policies and Procedures*. Within 120 days after the Effective Date, McKesson Minnesota shall implement revised written Policies and Procedures regarding the operation of McKesson Minnesota'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 McKesson Minnesota 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 regardless of whether Pumps and Sets are "rented" separately or "leased" as a Pump/Set combination, McKesson Minnesota shall take commercially reasonable efforts to collect all rental and/or lease payments in accordance with the terms of such rental or lease arrangements;

e. the requirement that, in the event that McKesson Minnesota has notice that Pumps have been refurbished or remanufactured, McKesson Minnesota shall disclose that fact, e.g., in the contract or other disclosure document, to customers who rent, lease, or purchase such Pumps;

f. the requirement that McKesson Minnesota shall maintain accurate records of all prices offered by McKesson Minnesota or on behalf of a manufacturer by McKesson Minnesota related to the sale 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; nothing in Section III.B.2.f, however, shall require McKesson Minnesota to maintain a record of any other prices offered to customers directly by manufacturers of pumps or other suppliers of enteral products;

g. the requirement that McKesson Minnesota 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

h. the requirement that McKesson Minnesota's individual enteral nutritional sales representatives shall not provide reimbursement recommendations related to medical necessity determinations in support of wholesale sales. However, McKesson Minnesota's sales representatives may provide Medicare reimbursement information to customers in support of the provision of services by its MediMart and MediNet subsidiaries.

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), McKesson Minnesota 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.

McKesson Minnesota 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, McKesson Minnesota shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain:

a. McKesson Minnesota's CIA requirements; and

b. McKesson Minnesota'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, McKesson Minnesota need only provide training during the first Reporting Period that meets the requirements of Section III.C.1.a.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least 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 on a wholesale basis 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, sale, or distribution on a wholesale basis 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 4 hours of Specific Training annually.

The requirements of this Section III.C.2 may be satisfied by completing the Specific Training required by the MediMart CIA, modified to include the Specific Training required in Section III.C.2. 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 Chief 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.* McKesson Minnesota 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, Unallowable Cost Review, and any other relevant information.

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

D. Review Procedures.

1. *General Description.*

a. *Annual Internal Review.* The annual review of McKesson Minnesota may be conducted internally by McKesson Minnesota. The reviews will assess and evaluate McKesson Minnesota's sales and distribution 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 beginning with the Effective Date of this CIA.

b. *Retention of Independent Review Organization.* Within 120 days after the Effective Date, McKesson Minnesota 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 sales and marketing systems, processes, policies, and procedures. If McKesson Minnesota 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, McKesson Minnesota 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 will notify McKesson Minnesota if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, McKesson Minnesota may continue to engage the IRO. Each IRO retained by McKesson Minnesota shall have appropriate expertise in the engagements to be performed. Each IRO shall assess, along with McKesson Minnesota, 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).

c. *Frequency of Review.* On an annual basis, McKesson Minnesota shall assess and evaluate McKesson Minnesota's systems, processes, policies, and procedures related to the sale and distribution of Enteral Products. McKesson Minnesota will perform the Enteral Product Contracting Review described in detail in Appendix A to the CIA subject to Section III.D.4. The Enteral Products Contracting Review shall be performed annually and shall cover each of the one-year Reporting Periods of the CIA beginning with the Effective Date of this 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 McKesson Minnesota'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 McKesson Minnesota'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 McKesson Minnesota'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 McKesson Minnesota Enteral Products Customer Related Expenditures associated with those Enteral Products customers included in the Enteral Products Contracting Documentation Review described above to McKesson Minnesota's policies and procedures related to Sales and Marketing Expenditures.

f. *Retention of Records.* The IRO and McKesson Minnesota shall retain and make available to OIG, upon request, all work papers,

supporting documentation, correspondence, and draft reports (those exchanged between the IRO and McKesson Minnesota) related to the reviews.

2. *Validation Review.* In the event OIG has reason to believe that: (a) McKesson Minnesota'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). McKesson Minnesota 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 McKesson Minnesota's final Annual Report shall be initiated no later than one year after McKesson Minnesota's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify McKesson Minnesota 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, McKesson Minnesota 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. McKesson Minnesota 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 McKesson Minnesota 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 McKesson Minnesota in the Enteral Products Contracting Review and Enteral Products Customer Related Expenditures Review.

As part of McKesson Minnesota'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 McKesson Minnesota's Annual Report, if, in its sole discretion, OIG determines that the McKesson Minnesota's 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 McKesson Minnesota 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.

McKesson Minnesota has represented to OIG that it presently has a Disclosure Program. During the term of the CIA, McKesson Minnesota 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 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 McKesson Minnesota'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. McKesson Minnesota 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 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, McKesson Minnesota shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Chief 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" means all prospective and current owners of McKesson Minnesota (other than shareholders who: (1) have an ownership interest of less than 5%, and (2) acquired the ownership interest through public trading); officers; directors; employees; contractors; and agents of McKesson Minnesota.

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

a. McKesson Minnesota 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. McKesson Minnesota 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. McKesson Minnesota 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) McKesson Minnesota to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If McKesson Minnesota has actual notice that a Screened Person has become an Ineligible Person, McKesson Minnesota shall remove such person from responsibility for, or involvement with, McKesson Minnesota'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 McKesson Minnesota 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, McKesson Minnesota 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, McKesson Minnesota shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to McKesson Minnesota conducted or brought by a governmental entity or its agents involving an allegation that McKesson Minnesota 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. McKesson Minnesota 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 McKesson Minnesota 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 McKesson Minnesota determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, McKesson Minnesota 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 McKesson Minnesota's actions taken to correct the Reportable Event; and

iii. any further steps McKesson Minnesota 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, McKesson Minnesota changes location or sells, closes, purchases, or establishes a new business unit or location related to the sale of enteral nutrition items or services that may be reimbursable by Federal health care programs, McKesson Minnesota 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 location, phone number, fax number, Medicare Provider number (if any), provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. All Covered Persons at each new business unit or 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, McKesson Minnesota 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 Chief Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Chief 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 McKesson Minnesota'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 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 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 McKesson Minnesota 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 McKesson Minnesota'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 McKesson Minnesota;

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

11. a list (including mailing addresses), of all of McKesson Minnesota's 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. McKesson Minnesota shall submit to OIG annually a report with respect to the status of, and findings regarding, McKesson Minnesota'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 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 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 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 McKesson Minnesota'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. McKesson Minnesota'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 McKesson Minnesota 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 McKesson Minnesota;

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

McKesson Minnesota 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 McKesson Minnesota's 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 Chief Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, McKesson Minnesota 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. McKesson Minnesota 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. McKesson Minnesota shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

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

McKesson Minnesota:

Bill D. Blanchfill
Chief Compliance Officer
McKesson Medical-Surgical Minnesota Inc.
8121 Tenth Avenue North
Golden Valley, MN 55427
Telephone: 763.595.6130
Facsimile: 763.545.9245

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 McKesson Minnesota's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of McKesson Minnesota's locations for the purpose of verifying and evaluating: (a) McKesson Minnesota's compliance with the terms of this

CIA; and (b) McKesson Minnesota's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above, to the extent it is not protected under appropriately asserted legal privilege as set forth in Section IX below, shall be made available by McKesson Minnesota 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 McKesson Minnesota'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. McKesson Minnesota shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. McKesson Minnesota's employees may elect to be interviewed with or without a representative of McKesson Minnesota present.

VIII. DOCUMENT AND RECORD RETENTION

McKesson Minnesota shall maintain for inspection all documents and records relating to 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 McKesson Minnesota prior to any release by OIG of information submitted by McKesson Minnesota pursuant to its obligations under this CIA and identified upon submission by McKesson Minnesota as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, McKesson Minnesota 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 or be construed as a waiver by McKesson Minnesota of McKesson Minnesota's attorney-client, work product, or other applicable and appropriately asserted privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by McKesson Minnesota to avoid its obligations to comply with the provisions of this CIA.

X. BREACH AND DEFAULT PROVISIONS

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

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

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

a. Compliance Officer;

b. Compliance Committee;

c. written Code of Conduct;

d. written Policies and Procedures;

e. the training of Covered Persons;

f. a Disclosure Program;

g. Ineligible Persons screening and removal requirements; and

h. notification of government investigations or legal proceedings.

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

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

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

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

6. A Stipulated Penalty of $1,000 for each day McKesson Minnesota fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to McKesson Minnesota, stating the specific grounds for its determination that the McKesson Minnesotas has failed to comply fully and adequately with the CIA obligation(s) at issue and steps McKesson Minnesota shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after McKesson Minnesota receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in Section X.A.6 shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-5 of this Section.

B. Timely Written Requests for Extensions. McKesson Minnesota 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 McKesson Minnesota fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after McKesson Minnesota 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 McKesson Minnesota 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 McKesson Minnesota of: (a) McKesson Minnesota's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, McKesson Minnesota 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 McKesson Minnesota elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until McKesson Minnesota 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 McKesson Minnesota 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 McKesson Minnesota to report a Reportable Event, take corrective action, and make the appropriate refunds, 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 engage 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 McKesson Minnesota constitutes an independent basis for exclusion from participation in the Federal health care programs. Upon a determination by OIG that McKesson Minnesota has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify McKesson Minnesota of: (a) McKesson Minnesota'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.* McKesson Minnesota 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. McKesson Minnesota 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) McKesson Minnesota has begun to take action to cure the material breach; (ii) McKesson Minnesota is pursuing such action with due diligence; and (iii) McKesson Minnesota has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, McKesson Minnesota fails to satisfy the requirements of Section X.D.3, OIG may exclude McKesson Minnesota from participation in the Federal health care programs. OIG shall notify McKesson Minnesota in writing of its determination to exclude McKesson Minnesota (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 McKesson Minnesota's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, McKesson Minnesota 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 McKesson Minnesota 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, McKesson Minnesota 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 Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether McKesson Minnesota was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. McKesson Minnesota 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 McKesson Minnesota to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless McKesson Minnesota requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the

United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

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

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

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, McKesson Minnesota and OIG

agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of McKesson Minnesota.

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 McKesson Minnesota 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 MCKESSON MINNESOTA

BILL BLANCHFILL
MCKESSON MEDICAL-SURGICAL MINNESOTA INC.
Chief Compliance Officer

November 11, 2004
DATE

ELIZABETH CARDER-THOMPSON
COUNSEL FOR MCKESSON MINNESOTA

DATE

JEFFREY CHANIN
COUNSEL FOR MCKESSON MINNESOTA

DATE

ON BEHALF OF MCKESSON MINNESOTA

_____ _____

BILL BLANCHFILL — DATE
MCKESSON MEDICAL-SURGICAL MINNESOTA INC.
Chief Compliance Officer

Elizabeth Carder-Thompson 11/11/04

ELIZABETH CARDER-THOMPSON — DATE
COUNSEL FOR MCKESSON MINNESOTA

_____ _____

JEFFREY CHANIN — DATE
COUNSEL FOR MCKESSON MINNESOTA

ON BEHALF OF MCKESSON MINNESOTA

BILL BLANCHFILL
MCKESSON MEDICAL-SURGICAL MINNESOTA INC.
Chief Compliance Officer

DATE

Elizabeth Carder-Thompson

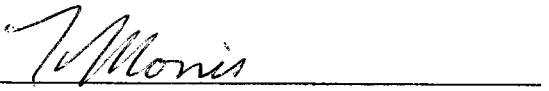
ELIZABETH CARDER-THOMPSON
COUNSEL FOR MCKESSON MINNESOTA

11/11/04
DATE

JEFFREY CHANIN
COUNSEL FOR MCKESSON MINNESOTA

11/12/04
DATE

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



LEWIS MORRIS
Chief Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

11/4/04
DATE

Appendix A

A. Enteral Products Contracting Review

1. General Description of Enteral Products Contracting Review

McKesson Minnesota'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, McKesson Minnesota shall conduct and the IRO shall verify, the following two reviews: (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, McKesson Minnesota, 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 or customer transaction process.

For each relevant Reporting Period, McKesson Minnesota 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

McKesson Minnesota shall prepare a listing of all Enteral Products Customer Contracts or customer transactions (both newly initiated and renewals) executed during the review period and shall randomly select 50 transactions for testing. Specific to the 50 identified transactions, McKesson Minnesota shall perform testing to assess whether:

- A contract was executed and/or documentation of the transaction maintained, and if so, whether such activities were conducted in accordance with all requirements set forth in McKesson Minnesota's policies and procedures;
- The contract and/or supporting documentation reflect approvals consistent with policy;
- For each contract or transaction, all supporting documentation exists in accordance with McKesson Minnesota policy; and
- For each contract or transaction, the first invoice or, if applicable, the rebate report claim related to the customer, subsequent to contract execution, reflects the approved contract or other sale terms.

McKesson Minnesota and the IRO shall annually prepare reports 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 McKesson Minnesota when performing the review.

Results to be included:

- A list of the contracts and/or customer transactions selected for testing;

- Findings as to whether, the contract or customer transaction was completed in accordance with the requirements set forth in McKesson Minnesota's policies and procedures; and

- For each contract or transaction, McKesson Minnesota and the IRO shall identify any Material and Non-Material errors discovered.

  - For the Non-Material errors, McKesson Minnesota and the IRO shall describe what the errors were. They shall also describe those situations when corrective action was taken prior to the initiation of the review, including a description of the circumstances requiring corrective action and the nature of corrective action.

  - For Material Errors, McKesson Minnesota and the IRO shall describe the error and the additional procedures performed to assess the root cause of the Material Error.

B. Enteral Products Customer Related Expenditures Review

1. General Description of Enteral Products Customer Related Expenditures Review

McKesson Minnesota's business policies and procedures and the Policies and Procedures referenced in Section III.B.2 of the CIA (hereafter collectively "McKesson Minnesota 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, McKesson Minnesota shall conduct and the IRO shall verify 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, McKesson Minnesota shall review McKesson Minnesota's sales and marketing systems, controls, policies, and practices pertaining to the following types of potential activities engaged in with Enteral Products customers:

- Debt Forgiveness, Debt Reduction, and Customer Credits
- Rebates and Administrative Fees

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."

McKesson Minnesota and the IRO shall prepare reports based upon the Enteral Products Customer Related Activities Systems Consulting Review for each relevant Reporting Period. 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

McKesson Minnesota shall utilize the first 30 customers selected in the Enteral Products Contracting Documentation Review (described in Section A.3 of this Appendix above) as the basis for this review. Specific to those 30 identified customers, McKesson Minnesota shall aggregate all Enteral Products Customer Related Expenditures from McKesson Minnesota's payments systems during the Review Period and select a sample of 50 Control Documents or, if there are fewer than 50 Control Documents related to the first 30 customers, McKesson Minnesota 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, McKesson Minnesota and/or the IRO shall contact OIG regarding how to proceed.

Attributes to be Tested

During each reporting period, McKesson Minnesota 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 McKesson Minnesota's Policies and Procedures. This includes a review of whether all required written approvals were obtained in accordance with McKesson Minnesota'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.

McKesson Minnesota and the IRO shall annually prepare reports based upon each Enteral Products Customer Related Expenditures Documentation Review performed. McKesson Minnesota and the IRO shall prepare reports that includes 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 McKesson Minnesota and the IRO when performing the review.

Results to be included:

- For each Control Document reviewed, McKesson Minnesota and the IRO shall state their 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 McKesson Minnesota Sales and Marketing Policies; (b) the expenditure and supporting Control Documentation reflect that all written approvals were obtained in accordance with McKesson Minnesota 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 McKesson Minnesota Sales and Marketing Policies.

- For each Control Document, McKesson Minnesota and the IRO shall identify all Material and Non-Material errors discovered.

    - For the Non-Material errors, McKesson Minnesota and the IRO shall describe what the errors were. McKesson Minnesota shall describe those situations when corrective action was taken prior to the initiation of its review, including a description of the circumstances requiring corrective action and the nature of corrective action.

- For material errors, McKesson Minnesota and the IRO shall describe the error and the additional procedures performed to assess the root cause of the Material Error.

C. Definition of Material Error

McKesson Minnesota and 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 Appendix A only, the contract, transaction, 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 McKesson Minnesota's review of the relevant Review Period; or (2) information or data is omitted from key fields in the documentation that restricts the McKesson Minnesota's ability to understand the nature of the contract, transaction, expenditure, or activity and/or to assess compliance with McKesson Minnesota's policies and procedures and no corrective action has been taken prior to the initiation of the McKesson Minnesota's review of the relevant Review Period. All other errors shall be considered Non-Material.

D. Additional Engagement if Material Errors Rates Are Discovered

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