CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
XVIII B MEDI MART, INC.,
THROUGH
ITS PARENT CORPORATION
MCKESSON RED LINE HEALTHCARE CORPORATION

I. PREAMBLE

XVIII B Medi Mart, Inc., through its parent McKesson Red Line HealthCare Corporation, 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 ensure compliance by Medi Mart and its Covered Persons (as defined herein) with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))(hereinafter collectively referred to as the "Federal health care programs").

The terms of this CIA apply to the operations of XVIIIB Medi Mart, Inc. (referred to herein as "Medi Mart"). The terms of this CIA also apply to any other subsidiaries of McKesson Red Line HealthCare Corporation to the extent that and so long as they maintain Part B supply operations and bill the Medicare program on their own behalf and all references to Medi Mart also include such subsidiaries. The operations of Red Line Medical Supply, Inc., a wholesale medical supply business and its parent organization, McKesson Red Line HealthCare Corporation, were not the subject of the government settlement giving rise to this CIA. As such, McKesson Red Line HealthCare Corporation and Red Line Medical Supply, Inc. are governed by the terms of this CIA only insofar as such entities carry out Medi Mart or other Part B supply operations through employees engaged in Medi Mart operations or other Part B supply subsidiary operations.

Medi Mart's compliance with the terms and conditions in this CIA shall constitute an element of Medi Mart's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, the Companies are entering into a Settlement Agreement with the United States ("Related Settlement Agreement"), and this CIA is incorporated by reference into the Related Settlement Agreement.

Prior to the execution of this CIA, the Companies' corporate family voluntarily established a corporate compliance program (the "Corporate Compliance Program") in which the Companies all participate and which provides, *inter alia,* for a Corporate Compliance Officer, a compliance training and education program, a confidential reporting hotline, a screening methodology for prospective employees, and which includes various policies and procedures aimed at ensuring that the Companies' participation in the Federal health care programs conforms to all applicable statutes, regulations and other legal requirements contained in any program directives issued by appropriate governmental agencies, *e.g.,* the Health Care Financing Administration ("HCFA") and/or their agents applicable to nursing home suppliers' participation in Federal health care programs (collectively, the "Legal Requirements"). With respect to the Legal Requirements, nothing in this CIA is intended to limit Medi Mart's right to seek clarification and/or challenge any governmental interpretation or application of a statute, regulation, manual provision, or other government issuance to nursing home suppliers generally or to Medi Mart's operations in particular.

Pursuant to this CIA, Medi Mart agrees that it will operate a Corporate Compliance Program, or participate in its corporate family's Corporate Compliance Program, either of which will meet the requirements of this CIA and that any components of the existing Corporate 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.

For purposes of this CIA, the term "Covered Person" includes any of the Companies' employees or independent contractors, including but not limited to, dietitians and enterostomal therapists, who have any responsibility for or involvement with Medi Mart's operations relating to the provision, marketing, ordering, or billing of covered health care items and services ("Items and Services") furnished to Federal health care program beneficiaries.

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For purposes of this CIA, the term "Companies" shall mean XVIII B Medi Mart, Inc., Red Line HealthCare Corporation, Red Line Medical Supply, Inc. and any other subsidiary of Red Line HealthCare Corporation that is a Medicare Part B supplier and bills the Medicare program on its own behalf.

II. TERM OF THE CIA

The period of the compliance obligations under this CIA shall be ***five (5)*** years from the effective date of this CIA (unless otherwise specified), provided, however, that if during the term of this CIA the Federal health care program "Consolidated Billing" initiative becomes effective, the OIG and representatives of the Companies shall meet no less than sixty (60) days prior to the effective date of the Consolidated Billing initiative to reach an accord as to which, if any, of the terms of this CIA will remain in effect or be modified after the effective date of Consolidated Billing. The effective date of this CIA will be the latter of the date on which the final signatory of this CIA executes this CIA or the date on which the final signatory executes the Related Settlement Agreement (the "Effective Date").

III. CORPORATE INTEGRITY OBLIGATIONS

The Companies shall comply with the following corporate integrity obligations with respect to Medi Mart operations and shall ensure that the obligations specified below are incorporated into the existing Compliance Program or any other Compliance Program in which Medi Mart participates.

A. Compliance Officer and Compliance Committee.

Compliance Officer. Medi Mart participates in a Voluntary Corporate Compliance Program under which a Compliance Officer is appointed and employed. For the term of this CIA, Medi Mart, or its corporate affiliates, shall continue to employ an individual to serve as Compliance Officer, who shall be responsible for developing and implementing policies, procedures, and practices designed to ensure Medi Mart's compliance with the requirements set forth in this CIA and with the Legal Requirements. The Compliance Officer shall be a member of senior management of Medi Mart or its corporate affiliate, shall make regular (at least biannually, i.e. twice per year) reports regarding compliance matters directly to the CEO and/or the Board of Directors of the Companies and shall be authorized to report to the Board of Directors of the Companies at any time. The Compliance Officer shall be responsible for monitoring the day-to-day

activities engaged in by Medi Mart to further its compliance objectives as well as any reporting obligations created under this CIA. In the event a new Compliance Officer is appointed during the term of this CIA, Medi Mart shall notify the OIG, in writing, within thirty (30) days of such a change.

Compliance Committee. Medi Mart shall also appoint a Compliance Committee within one hundred twenty (120) days after the Effective Date of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate personnel as necessary to meet the requirements of this CIA within the Companies' corporate structure (e.g., management and/or executives responsible for each major department of Medi Mart operations such as billing, human resources and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

B. Written Standards.

1. *Code of Conduct.* As part of the Voluntary Corporate Compliance Program in which Medi Mart participates, a Code of Conduct has been established which reflects an ongoing commitment to ethical conduct in all of Medi Mart's affairs, including compliance with all Legal Requirements. Within ninety (90) days of the Effective Date of this CIA, to the extent not already done, the Code of Conduct shall be distributed to all Covered Persons, and the promotion of, and adherence to the Code of Conduct shall be an element in evaluating the performance of Covered Persons. The Code of Conduct shall, at a minimum, include the following elements:

a. a commitment to full compliance with all Legal Requirements, including its commitment to prepare and submit accurate billings consistent with Legal Requirements;

b. the requirement that all Covered Persons shall be expected to comply with all Legal Requirements and with company policies and procedures that address or relate to Legal Requirements (including the requirements of this CIA);

c. the requirement that all Covered Persons shall be expected to report suspected violations of any of the Legal Requirements or of the Companies' policies and procedures that address or relate to the Legal Requirements;

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d. the possible consequences to both Medi Mart and to any Covered Person of failure to comply with any and all Legal Requirements and with the Companies' policies and procedures that address or relate to Legal Requirements or of failure to report such non-compliance; and

e. the right of all Covered Persons to use the confidential disclosure program (as described in Section III.F.), as well as a commitment to confidentiality with respect to all such disclosures made through the hot line and non-retaliation with respect to all disclosures made through this program.

Within one hundred and twenty (120) days of the Effective Date of the CIA, to the extent not already done, each Covered Person shall certify, in writing, that he or she has received, read, understands, and will abide by the Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after the commencement of their employment or relationship with Medi Mart or within one hundred twenty (120) days of the Effective Date of the CIA, whichever is later. Thereafter, Covered Persons shall certify on an annual basis that they have received, read, understand and will abide by the Code of Conduct. Certifications of Covered Persons obtained in the course of the 2000 and/or 2001 Training, described below, shall meet this initial certification requirement if performed within twelve (12) months prior to the effective date of this CIA.

The Code of Conduct will be reviewed and revised, as necessary, to ensure Medi Mart's compliance with Legal Requirements. These revisions shall be distributed to all Covered Person within ninety (90) days of the Effective Date of such a change.

2. *Policies and Procedures*. To the extent not already developed as part of its Voluntary Corporate Compliance Program, within one hundred and twenty (120) days of the Effective Date of this CIA, written Policies and Procedures shall be developed and distributed to all Pertinent Covered Persons (defined below) regarding the operation of the Compliance Program and compliance with all Legal Requirements, and compliance staff or supervisors shall be made available to explain any and all policies and procedures, if necessary. At a minimum, the Policies and Procedures shall specifically address: compliance with the Anti-Kickback Law (including issues regarding the provision of free goods); medical necessity guidelines and documentation issues, including certificate of medical necessity requirements; Advance Beneficiary Notice

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requirements (only to the extent HCFA issues guidance regarding the relevance of ABNs to nursing home residents); waiver of co-payments and deductibles; correct coding for medical supplies, including proper use of modifiers; assurances that items or supplies were shipped before being billed; and adherence to applicable utilization guidelines. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for Covered Persons to make disclosures or otherwise report on compliance issues through the Confidential Disclosure Program required by Section III.F. The Policies and Procedures shall be assessed and updated at least annually and more frequently, as necessary. A listing of the Policies and Procedures will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

C. Contract Approval Policy The Companies will continue the policies reasonably designed to prevent contractual relationships with nursing homes and other referral sources that violate the Anti-Kickback statute and pursuant to which existing contracts (or template contracts) have been reviewed and approved by legal counsel. Any contracts or arrangements with nursing homes and other referral sources that materially deviate from the terms of the template contracts previously approved by the Companies' Legal Services Department or outside legal counsel, shall be reviewed and approved by the Companies' Legal Services Department or other attorneys at the request of the Legal Services Department ("Legal Review") in advance of the execution of such an arrangement and such approval shall be noted in the contract file. Any contracts entered into prior to the effective date of this CIA which deviate from approved templates or have not already undergone Legal Review shall be subject to Legal Review within one hundred and twenty (120) days of the effective date of this CIA, unless such contracts are terminated or modified in light of Consolidated Billing during such time period.

D. Training and Education.

1. *General Training.* Beginning with the effective date of this CIA, the Companies shall provide at least one (1) hour of annual training to all Covered Persons within one year of such Covered Person's prior annual voluntary corporate compliance training. This General Training shall explain the Companies:

a. Corporate Integrity Agreement requirements;
b. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues); and
c. Code of Conduct.

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At its discretion, the Companies may either conduct a training session for, or distribute a comprehensive memorandum to, all Covered Persons describing the CIA requirements. In addition, the Companies shall ensure that all Covered Persons review this memorandum and shall make available managers and supervisors to discuss with employees the impact and meaning of the explanatory memorandum concerning the CIA. The training material and explanatory memorandum, if utilized, shall be made available to the OIG upon request.

New Covered Persons shall receive the General Training described above within one (1) month of becoming a Covered Person or within one hundred and twenty (120) days after the Effective Date of this CIA, whichever is later. Thereafter, each Covered Person shall receive such general training on an annual basis.

2. *Specific Training*. Within one hundred and twenty (120) days of the Effective Date of this CIA, or within one year of such Covered Person's prior annual voluntary specific corporate compliance training, and annually thereafter, each Covered Person who is involved directly or indirectly in the preparation or submission of claims for reimbursement for such services (including, but not limited to, coding and billing) for any Federal health care programs ("Pertinent Covered Person") shall receive at least four (4) hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

a. the submission of accurate bills for services rendered to Medicare and/or Medicaid patients, including requirements regarding co-payments and deductibles;

b. policies, procedures and other requirements applicable to the documentation of medical records and delivery records;

c. the personal obligation of each individual involved in the billing and coding process to ensure that such billings are accurate;

d. applicable reimbursement Legal Requirements, including a discussion of the consolidated billing rules for Part A nursing homes;

e. the legal sanctions for improper billings;

f. examples of proper and improper billing practices;

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g. a summary of the Anti-Kickback Law and application of the law to nursing home suppliers' participation in Federal health care programs;

h. examples of violations of the Anti-Kickback Statute and potential sanctions to individuals and the Companies; and

i. requirements regarding approval of nursing home contracts or agreements.

These training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the subject area.

Affected new Pertinent Covered Persons shall receive this training within one (1) month of the beginning of their employment or relationship with the Companies or within one hundred and twenty (120) days of the Effective Date of this CIA, whichever is later. For new Pertinent Covered Persons who have not completed this specific training, an employee of the Companies engaged in Medi Mart operations, preferably a supervisor, who has completed the substantive training shall review, on a weekly basis until the untrained person receives such training, the untrained person's work regarding the preparation or submission of claims, the assignment of procedure codes, and/or the arrangements for the sale or delivery of Items and Services to nursing home residents.

Every Pertinent Covered Person shall receive such specific training on an annual basis.

3. *Certification.* Each Covered Person and Pertinent Covered Person who is required to attend any of the training requirements set forth above shall certify, in writing, that he or she has attended and has received the required training. The certification shall specify the type of training received and the date received. The Companies shall retain the certifications, along with specific course materials. These certifications shall be made available to OIG upon request.

E. Review Procedures. The Companies shall retain one or more entities, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to perform review procedures to assist in assessing the adequacy of Medi Mart's billing and compliance practices pursuant to this CIA. This shall be an annual requirement and shall cover a twelve (12) month period. The Independent Review

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Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which Medi Mart seeks reimbursement. The Independent Review Organization must be retained for the first year review within one hundred and twenty (120) days of the Effective Date of this CIA. The review shall be conducted and the report issued and delivered to the OIG during the one hundred and twenty (120) day period following the close of the first year of the CIA (the "anniversary date").

The Independent Review Organization(s) will determine whether the Companies are in compliance with this CIA ("compliance engagement"), and make certain findings regarding Medi Mart's billing operations ("billing operations engagement"). The Company's Internal Audit Department shall also conduct annual billing reviews separate from the billing operations engagement.

1. The billing operations engagement shall be performed by the Independent Review Organization annually and shall provide:

a. findings and the basis to support such findings regarding the adequacy of Medi Mart's billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, effectiveness of the system).

b. findings and the basis to support such findings regarding whether Medi Mart has adequate procedures for submitting accurate claims to the Federal health care programs. For purposes of these findings, Medi Mart shall not be held responsible in its policies and procedures for the adequacy of documentation in nursing home patient records.

c. findings and the basis to support such findings regarding whether Medi Mart has adequate procedures to correct inaccurate billings or codings to the Federal health care programs.

d. findings and the basis to support such findings regarding whether Medi Mart has adequate procedures for ensuring the proper collection of co-payments and deductibles.

e. findings and the basis to support such findings regarding Medi Mart's adherence to its co-payment and deductible collection policies.

f. findings and the basis to support such findings regarding whether Medi Mart's procedures for identifying and refunding overpayments (including amounts in Payor Credit Reserve) are adequate.

g. findings and the basis to support such findings regarding the steps Medi Mart is taking to bring its operations into compliance or to correct problems identified by the audit.

In those instances where Medi Mart has sought guidance from HCFA and/or OIG as appropriate, and can document that such clarification has been sought, the Independent Review Organization shall include such information in its report. Further, for purposes of compliance with this CIA, once HCFA and/or OIG has issued guidance or clarification to Medi Mart specifically or to the supplier community generally, if such guidance requires modification of Medi Mart's procedures, Medi Mart shall be permitted a reasonable period of time up to ninety (90) days to bring its procedures into compliance with any such HCFA or OIG guidance or clarification. This ninety day period for Medi Mart to alter its procedures for compliance with HCFA or OIG guidance or clarification, if necessary, shall not affect Medi Mart's obligation to submit claims in accordance with such guidance or clarification upon its effective date nor shall it affect the effective date of such guidance for Federal health care program purposes.

Further, nothing herein is intended to limit the Independent Review Organization from making independent findings with regard to Medi Mart's current policies and procedures which were the subject of the government's investigation of Medi Mart and which Medi Mart believes to be in compliance with any and all Legal Requirements, whether or not Medi Mart seeks guidance or clarification from HCFA or OIG, as appropriate.

2. *Compliance Engagement.* An Independent Review Organization shall also conduct a compliance engagement, that shall provide findings regarding whether Medi Mart's program, policies, procedures, and operations comply with the terms of this CIA. This engagement shall include section-by-section findings regarding the requirements of this CIA.

A complete copy of the Independent Review Organization's compliance engagement shall be included in each of the Companies' Annual Reports to OIG.

3. *Internal Billing Review.* Medi Mart shall conduct an annual internal billing review, which shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims for the relevant period. Medi Mart shall prepare an audit work plan in connection with the internal billing review and shall, for the first year of the term of the CIA, present the audit work plan to OIG for review and prior approval no less than four months before such time as the audit is scheduled to be started. OIG shall approve or suggest modifications to the audit work plan within two months of OIG's receipt of the proposed audit work plan and shall notify the Company in writing of OIG's approval or proposed modifications for the audit work plan.

The statistically valid sample size shall be determined through the use of a probe sample. At a minimum, the full sample must be within a ninety (90) percent confidence level and a precision of twenty-five (25) percent. The probe sample must contain at least thirty (30) units and cannot be used as part of the full sample, unless those units are selected at random during the full sample. Both the probe sample and the sample must be selected through simple random sampling. Medi Mart shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/progorg/oas/ratstat.html". Medi Mart shall conduct a variable stratified sample pursuant to Section 4 of the RAT-STATS User Manual. The following strata should be used: urological supply claims; ostomy supply claims; enteral nutrition therapy supply claims; tracheostomy care supply claims; surgical dressings claims; blood glucose monitors and testing supplies. The universe for each strata shall be Medicare paid claims only. For the first year of the term of the CIA the universe shall only include Medicare paid claims with dates of service beginning on or after the effective date of the CIA and ending one year following that date. For each year of the term of the CIA thereafter, the universe shall include Medicare paid claims only with dates of service occurring during that year.

Each annual billing review which shall be a variable appraisal, must include the following components in its methodology:

a. Objective: A clear statement of the objective intended to be achieved by the billing review and the procedure or combination of procedures that will be applied to achieve the objective.

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b. Billing Review Population: Identify the population, which is the group about which information is needed. Explain the methodology used to develop the population and provide the basis for this determination.

c. Sources of Data: Provide a full description of the source of the information upon which the billing review conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.

d. Sampling Unit: Define the sampling unit, which is any of the designated elements that comprise the population of interest.

e. Sampling Frame: Identify the sampling frame, which is the totality of the sampling units from which the sample will be selected.

4. *Verification/Validation.* In the first and third year of the term of the CIA, an independent review organization shall be engaged by the Company to conduct a validation review of either 10% or a 40 unit sample (whichever is greater) of the Company's statistically valid sample from the current year's internal review to validate the Company's internal billing review sample and findings. Included with the Company's Annual Report to the OIG, the Independent Review Organization shall furnish a report and its work papers to OIG of its findings regarding the validity of the Company's internal billing review sample and related findings. Should the Independent Review Organization determine as part of its validation that the Company's internal billing review was materially deficient, the Company agrees to engage an Independent Review Organization to conduct a validation review, as set forth above in this paragraph, in the subsequent year.

In the event that the OIG reasonably determines during any of the years of this CIA that it is necessary to conduct an independent review to determine whether or the extent to which the Companies are complying with its obligations under this CIA (e.g., the Independent Review Organization engagement and/or report was not completed or was materially deficient), the Companies agree to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

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F. Confidential Disclosure Program.

1. *Reporting System.* As part of its Voluntary Corporate Compliance Program, the Companies already have implemented a reporting system enabling individuals to disclose any practices or procedures, alleged by an individual to be inappropriate, to an individual who is not in the disclosing individual's direct chain of command (the "Confidential Disclosure Program"). The Companies shall continue to operate their Confidential Disclosure Program in a manner that allows individuals to make such disclosures on an anonymous basis and shall maintain a policy of non-retribution and non-retaliation for disclosures.

2. *Hot Line.* The Companies shall continue to provide for, and make known throughout the Companies, a toll-free compliance hot line available to all Covered Persons 24-hours a day, seven days a week, for the purpose of making disclosures regarding the Companies' Corporate Compliance Program, the obligations of this CIA and compliance with Legal Requirements.

3. *Review of Disclosure.* Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary good faith inquiry for every disclosure to ensure that all of the information has been obtained that is necessary to determine whether an internal review should be conducted or whether the disclosure warrants other appropriate action. For any disclosure that is sufficiently specific so that it can be determined that it reasonably: (1) relates to compliance with the Legal Requirements, this CIA, or policies and procedures relating to the Legal Requirements; (2) permits a determination of the appropriateness of the alleged improper practice; and (3) provides an opportunity for taking corrective action, the Companies shall conduct an internal review of the allegations set forth in such disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

G. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise

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ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. *Screening Requirements*. The Companies shall not hire or engage as contractors any Ineligible Person for Medi Mart or other Part B supply operations. To prevent hiring or contracting with any Ineligible Person, the Companies shall continue the procedures already adopted for screening all prospective employees and prospective independent contractors prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.dhhs.gov/oig) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement*. Within one hundred and twenty (120) days of the Effective Date of this CIA, the Companies will review their list of current employees and contractors assigned to Medi Mart and other Part B supply operations against the Exclusion Lists, or certify, through its Compliance Officer, that such a review has already been conducted pursuant to its Voluntary Corporate Compliance Program. Thereafter, the Companies will review the list once annually. If any of the Companies have notice that an employee or agent assigned to Medi Mart or other Part B supplier operations has become an Ineligible Person, the Companies will remove such person from responsibility for, or involvement with, its business operations related to the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If any of the Companies has notice that an employee or contractor assigned to Medi Mart or other Part B supplier operations is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with the Companies, within ten (10) days of receiving such notice, the Companies will remove such individual from responsibility for, or involvement with, Medi Mart or other Part B supplier business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

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H. Reporting.

1. *Reporting of Overpayments.* If, at any time, Medi Mart identifies or learns of any billing, coding or other policies, procedures and/or practices that result in an overpayment from a Federal health care program payor, Medi Mart shall notify the Federal health care program payor of any overpayment within 30 days of discovering the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem to the extent possible, including, preventing the underlying problem and the overpayments from recurring, and/or developing a mechanism for routine repayments or adjustments of such overpayments. Notification to the payor should be done in accordance with the Federal health care program payor's policies, and can be done pursuant to a form similar to the Overpayment Refund Form, provided as Attachment 1 to this CIA. Alternatively, the Company may disclose overpayments through the OIG's Voluntary Disclosure Protocol and place such amounts in an interest bearing escrow account pending resolution.

2. *Reporting of Material Deficiencies.* If Medi Mart determines that there is a material deficiency, Medi Mart shall notify the OIG within 30 days of making the determination that the material deficiency exists. The report to the OIG shall include the following information:

a. If the material deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the Federal health care program payor required in section H.1., and shall include all of the information on the Overpayment Refund Form or other notification, as well as:

(i) the name, address, and contact person of the Federal health care program if the overpayment was repaid; and
(ii) the date of the check and identification number (or electronic transaction number), if the overpayment was repaid.

b. Regardless of whether the material deficiency resulted in an overpayment; the report to the OIG shall include:

(i) a complete description of the material deficiency,

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including the relevant facts, personnel positions involved as appropriate, and legal and program authorities;

(ii) Medi Mart's actions to correct the material deficiency; and

(iii) any further steps Medi Mart plans to take to address such material deficiency and prevent it from recurring.

3. *Definition of "Overpayment."* For purposes of this CIA, an "overpayment" shall mean the amount of money Medi Mart has received from a Federal health care program in excess of the amount due and payable under the Legal Requirements. Notwithstanding the preceding sentence, notification to the OIG shall not be required for any overpayments for which routine adjustments are obtained from Federal healthcare programs. Where it is unclear whether an overpayment constitutes a routine adjustment, no stipulated penalties shall be imposed for the failure to report such an overpayment prior to the submission of the Company's annual report to OIG under the terms of the CIA.

4. *Definition of "Material Deficiency."* For purposes of this CIA, a "material deficiency" means anything that involves:

a. a substantial overpayment relating to any Federal health care program;

b. a matter that a reasonable person would consider a material violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion are authorized; or

c. a material violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances that presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations. For purposes of this provision, Medi Mart's adherence to Federal health care program guidelines regarding utilization or coverage for items and services shall constitute quality that meets professionally recognized standards of health care.

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A material deficiency may be the result of an isolated event or a series of occurrences. Where it is unclear that a deficiency constitutes a material deficiency no stipulated penalties shall be imposed for the failure to report such a material deficiency prior to the submission of Medi Mart's annual report to the OIG under the terms of the CIA.

5. *Notification of Proceedings.* Within thirty (30) days of discovery, the Companies shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that any of the Companies has committed a crime or has engaged in fraudulent activities or any other knowing misconduct with respect to Medi Mart or other subsidiary Part B supplier operation. 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. The Companies shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

IV. NEW LOCATIONS

In the event that any of the Companies purchase or establish new business units that maintain Federal health care program billing numbers and/or submit claims to Federal health care programs after the Effective Date of this CIA, the Companies shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program identification number(s) (if any), and the corresponding Federal health care program payor(s) (contractor specific) that issued each identification number. All employees at such locations shall be subject to the requirements in this CIA that apply to new employees (e.g., completing certifications and undergoing training). For purposes of this provision, the establishment of a new business unit shall not include the movement of existing offices to new office space, or the establishment of additional warehouse space for inventory storage.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within one hundred and fifty (150) days after the Effective Date of this CIA, the Companies shall submit a written report to OIG summarizing the status of implementation of the requirements of this CIA. This Implementation Report shall include:

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1. the name, address, phone number and position description of the Compliance Officer required by section III.A;

2. the names and positions of the members of the Compliance Committee required by Section III.A.;

3. a copy of the Code of Conduct required by section III.B.1;

4. a listing of the Policies and Procedures required by section III.B.2;

5. a description of the specific training programs required by section III.D.2. including a description of the targeted audiences and a schedule of when the training sessions were held;

6. a certification by the Compliance Officer that:
   a. the Policies and Procedures required by section III.B have been developed, pursuant to this CIA or as part of the voluntary Corporate Compliance Program in which Medi Mart participates, and have been distributed to all Pertinent Covered Persons;
   b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1; and
   c. all Covered Persons have completed the training and executed the certification required by section III.D.3.

7. a description of the confidential disclosure program required by section III.F;

8. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first review;

9. a summary of personnel actions taken pursuant to section III.G; and

10. a list of all of Medi Mart's locations (including mailing addresses), the corresponding name under which each location is doing business, the corresponding phone and fax numbers, each location's Federal health care program provider identification number(s), and the corresponding Federal health care program payor(s) (contractor specific) that issued each identification number.

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B. Annual Reports. For each year after the Effective Date of this CIA until the Termination Date, the Companies shall submit to OIG an Annual Report with respect to the status and findings of compliance activities. The Annual Reports shall include:

1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:
   a. all Covered Persons have completed the annual Code of Conduct certification required by section III.B.1; and
   b. all Covered Persons have completed the training and executed the certification required by section III.D.; provided that, in the First Annual Report, the Compliance Officer need not recertify the specific training that was certified to in the Implementation Report.

3. notification 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);

4. a complete copy of the report prepared pursuant to each Independent Review Organization engagement. Each Independent Review Organization's workpapers relied upon by the Independent Review Organization in preparing the Independent Review Organization report shall be made available to the OIG upon request;

5. the Companies' response/corrective action plan to any issues raised by the Independent Review Organization(s);

6. a summary of material deficiencies reported throughout the course of the previous twelve (12) months pursuant to III.H;

7. a report of the aggregate Overpayments (as defined in III.H.3) that have been returned or disclosed to the Federal health care programs pursuant to section III.H.1. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;

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8. a copy of the confidential disclosure log required by section III.F;

9. a summary of any personnel action (other than hiring) taken by the Companies as a result of the obligations in section III.G;

10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that any of the Companies has committed a crime or has engaged in fraudulent activities with respect to Medi Mart or other subsidiary Part B supplier operations, which have been reported pursuant to section III.H.5. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;

11. a corrective action plan to address any probable violations of law identified in section III.H.4;

12. a description of all changes to the most recently provided list (as updated) of all of Medi Mart's locations (including mailing addresses), the corresponding name under which each changed location is doing business, the corresponding phone and fax numbers, each location's Federal health care program identification number(s) and the corresponding Federal health care program payor (contractor specific) that issued each identification number; and

13. a description of the general training for each year of the CIA and a description of specific training for years two (2) through five (5).

The first Annual Report shall be received by the OIG no later than one year and one hundred and twenty days after the Effective Date of this CIA. Subsequent Annual Reports shall be submitted 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 Compliance Officer under penalty of perjury, that: (1) the Companies are in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made

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reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful, to the best of his or her knowledge.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the Effective Date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit
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, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

Medi Mart:

Bill D. Blanchfill
Chief Compliance Officer
XVIII B Medi Mart, Inc.
8121 10th Avenue, North
Golden Valley, Minnesota 55427
Phone 763.595.6130
Fax 763.545.9245

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, subject to properly asserted legal privileges, the Companies' books, records, and other documents and supporting materials and/or conduct an onsite review of the Companies' operations for the purpose of verifying and evaluating: (a) the Companies' compliance with the terms of this CIA; and (b) Medi Mart's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made

available by the Companies 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 the Companies' employees who consent to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and OIG. The Companies agree to assist OIG in contacting and arranging interviews with such employees upon OIG's request, and OIG agrees to contact the Companies' Compliance Officer or qualified designee whenever OIG desires to contact any of the Companies' employees for the purpose of conducting the verification or evaluation described in this Section VII. The Companies' employees may elect to be interviewed with or without the presence of a representative of the Companies and/or legal counsel.

VIII. DOCUMENT AND RECORD RETENTION

The Companies shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, one year longer than the term of this CIA (or longer if otherwise required by law).

IX. DISCLOSURES AND PRIVILEGES

As appropriate, nothing in this CIA, or any communications or report made pursuant to this CIA, shall constitute a waiver by the Companies of the Companies' attorney-client, work product or other applicable legal privileges.

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify the Companies prior to any release by OIG of information submitted by the Companies pursuant to the obligations under this CIA and identified upon submission by the Companies as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. The Companies shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

The Companies are expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, the Companies 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 $1,500 for each day, beginning one hundred and twenty-one (121) days after the Effective Date of this CIA and concluding at the end of the term of this CIA, the Companies fail to have in place for Medi Mart or other subsidiary Part B supplier operations, any of the following:

   a. a Compliance Officer;
   b. a Compliance Committee;
   c. a written Code of Conduct;
   d. written Policies and Procedures;
   e. a training program encompassing the requirements of this CIA; and
   f. a Confidential Disclosure Program;

   provided that a stipulated penalty for failure to have a Compliance Officer shall not be imposed in the event of the death, disability, termination or resignation of the Companies' Compliance Officer, so long as the Companies are making reasonable efforts to fill the position.

2. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day the Companies fail to meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG without a timely written request for extension as provided in section X.B.2.

3. A Stipulated Penalty of $1,000 (which shall begin to accrue on the date the failure to comply began) for each day the Companies:

   a. hire or enter into a contract with an Ineligible Person , for Medi Mart or other Part B supply operations, after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in

Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which the Companies can demonstrate that they did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.G) as to the status of the person);

b. employ or contract with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Medi Mart's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period during which the Companies can demonstrate that they did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.G) as to the status of the person); or

c. employ or contract with a person who: (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, Medi Mart's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before ten (10) days after the Companies received notice of the relevant matter or after the resolution of the matter).

4. A Stipulated Penalty of $1,000 (which shall begin to accrue on the date the Companies fail to grant access) for each day the Companies fail to grant access to the information or documentation as required in section V of this CIA.

5. A Stipulated Penalty of $1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to the Companies of the failure to comply) for each day the Companies fail to comply fully and adequately with any obligation of this CIA where the failure to comply does not form the basis for stipulated penalties under provisions 1-4 above. With respect to the Stipulated Penalty provision described in this Section X.A.5 only, the OIG shall not seek a Stipulated Penalty if the Companies demonstrate to the OIG's reasonable satisfaction that the alleged failure to comply could

not be cured within the 10-day period, but that (i) the Companies had taken steps to cure the failure to comply, (ii) the Companies are pursuing such action with due diligence, and (iii) the Companies have provided to OIG a reasonable timetable for curing the failure to comply. In its notice to the Companies, the OIG shall state the specific grounds for its determination that the Companies have failed to comply fully and adequately with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that the Companies have failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify the Companies by personal service or certified mail of (a) the Companies' failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within fifteen (15) days of the date of the Companies' receipt of a duly delivered Demand Letter, the Companies shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event the Companies elect to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until the Companies cure, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to a duly delivered 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.C. The Companies' election of its contractual right to seek ALJ review of OIG's non-compliance determination shall not preclude the Companies from paying the applicable stipulated penalties at any time after receiving the Demand Letter. The Companies decision to cure any alleged breach shall not be construed as or constitute evidence of an admission of non-compliance under this CIA in any subsequent legal proceeding.

2. *Timely Written Requests for Extensions.* The Companies may submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA, approval of which shall not be unreasonably withheld by OIG. 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 the Companies fail to meet the revised deadline as agreed to by the OIG-approved extension. 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 two (2) business days after the Companies receive OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) 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.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by 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 otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that the Companies have materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.C, below.

C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by the Companies constitutes an independent basis for Medi Mart's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that the Companies have materially breached this CIA and that exclusion should be imposed, the OIG shall notify the Companies by certified mail of (a) the Companies' 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").

2. *Opportunity to cure.* The Companies shall have thirty (30) days from the date of its receipt of a duly delivered Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

a. The Companies are in full compliance with this CIA;

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b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the thirty (30) day period, but that: (i) the Companies have begun to take action to cure the material breach, (ii) the Companies are pursuing such action with due diligence, and (iii) the Companies have provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the thirty (30) day period, the Companies fail to satisfy the requirements of section X.C.2, OIG may exclude Medi Mart from participation in the Federal health care programs. OIG will notify Medi Mart in writing of its determination to exclude Medi Mart (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (30) days after the date of Medi Mart's receipt of a duly delivered Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If Medi Mart is excluded under the provisions of this CIA, Medi Mart may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

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

a. a failure to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.H;

b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A of this CIA;

c. a failure to respond to a duly delivered Demand letter concerning the payment of Stipulated Penalties in accordance with section X.B above; or

d. a failure to retain and use an Independent Review Organization for review purposes in accordance with section III.E.

D. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to the Companies or to Medi Mart of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, the Companies and/or Medi Mart 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. § 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.22. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within fifteen (15) days of the date of the Companies' receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date of Medi Mart's 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 the Companies were in full and timely compliance with the obligations of this CIA for which the OIG demands payment; (b) the period of noncompliance; and (c) with respect to a stipulated penalty imposed under § X.A.5., whether the non-compliance was continuing on the date of the Demand Letter and whether, if the alleged failure to comply could not be cured within the 10-day period, (i) the Companies have taken steps to cure the failure to comply, (ii) the Companies are pursuing such action with due diligence, and (iii) the Companies have provided to OIG a reasonable timetable for curing the failure to comply. The Companies shall have the burden of proving full and timely compliance and the steps taken to cure the noncompliance, if any. Stipulated Penalties shall become due and payable to the OIG twenty (20) days after the final level of review in favor of the OIG available

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under this CIA or the expiration of any time frame within which to seek such review.

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 the Companies were in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) whether, if the alleged material breach cannot be cured within the 35 day period, (i) the Companies have taken action to cure the material breach, (ii) the Companies are pursuing such action with due diligence, and (iii) the Companies have provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. Medi Mart's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Medi Mart upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that Medi Mart may request review of the ALJ decision by the DAB.

XI. EFFECTIVE AND BINDING AGREEMENT

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

A. This CIA shall be binding on Medi Mart, any purchaser of substantially all of its stock, any entity surviving a merger or created as a result of a consolidation with Medi Mart, or any purchaser of substantially all of Medi Mart's assets that includes the purchaser's acceptance of the assignment of Medi Mart's Part B billing number.

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA or the date on which the final signature is obtained on the Related Settlement Agreement, whichever is later;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and

D. The undersigned signatories of the Companies 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.

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ON BEHALF OF THE COMPANIES

XVIII B Medi Mart, Inc.

6/8/01
DATE

By: _____
Its: Treasurer

McKesson Red Line HealthCare Corporation

6/8/01
DATE

By: _____
Its: Treasurer

Carrie Valiant

6/18/01
DATE

Carrie Valiant
EPSTEIN BECKER & GREEN, P.C.

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

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

8/6/07
DATE

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date:_____
Contractor Deposit Control #_____ Date of Deposit: _____
Contractor Contact Name:_____Phone #_____
Contractor Address:_____
Contractor Fax:_____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME_____
ADDRESS_____
PROVIDER/PHYSICIAN/SUPPLIER #_____CHECK NUMBER#_____
CONTACT PERSON:_____PHONE #_____
AMOUNT OF CHECK $_____ CHECK DATE_____

REFUND INFORMATION

For each Claim, provide the following:
Patient Name_____HIC #_____
Medicare Claim Number_____Claim Amount Refunded $_____
Reason Code for Claim Adjustment:_____ (Select reason code from list below. Use one reaso
n per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment:*_____

For Institutional Facilities Only:
Cost Report Year(s) _____
(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)
For OIG Reporting Requirements:
Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

Billing/Clerical Error	MSP/Other Payer Involvement	Miscellaneous
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp.(Including Black Lung	16 - Medical Necessity
05 - Modifier Added/Removed	12 - Veterans Administration	17 - Other (Please Specify)
06 - Billed in Error		_____
07 - Corrected CPT Code		

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AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND MEDI MART, INC.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Medi Mart, Inc. ("Medi Mart") entered into a Corporate Integrity Agreement ("CIA") on August 6, 2001.

A. Pursuant to section XI.C. of Medi Mart's CIA, modifications to the CIA may be made with the prior written consent of both the OIG and Medi Mart. Therefore, the OIG and Medi Mart hereby agree that Medi Mart's CIA will be amended as follows:

Section III.E., Review Procedures of the CIA is hereby superceded by the attached new section III.E., Review Procedures and Appendix A.

The attached Appendix A is hereby added to Medi Mart's CIA.

B. The OIG and Medi Mart agree that all other sections of Medi Mart's CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and Medi Mart.

C. The undersigned Medi Mart signatory represent and warrant that he is authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

D. The effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF THE COMPANIES

XVIII B Medi Mart, Inc.

4/18/02
DATE

By: _____

Its: _____

McKesson Red Line HealthCare Corporation

4/18/02
DATE

By: _____

Its: Vice President

Carrie Valiant 4/24/02

Carrie Valiant
EPSTEIN BECKER & GREEN, P.C.

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

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

4/16/07
DATE

E. Review Procedures.

1. *General Description.*

a. Annual Internal Review. Medi Mart's annual review will be conducted by its internal audit team, which shall perform reviews to assess and evaluate its billing and coding practices to the Medicare program, its collection of co-payments and deductibles, its procedures for identifying and refunding overpayments (including amounts in Payor Credit Reserve) (the "Claims Review"). Those individuals involved in conducting the Claims Review shall have expertise in the billing, coding, reporting, and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Medicare program. For purposes of the Claims Review, Medi Mart shall not be held responsible for the adequacy of documentation in nursing home patient records.

b. Retention of Independent Review Organization. Within 120 days of the effective date of this CIA, Medi Mart shall retain an entity such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist Medi Mart in its compliance obligations pursuant to this CIA and the Settlement Agreement. From time to time, and during the term of this CIA, Medi Mart shall have the right, in its sole discretion, to select new or alternate IROs. Each IRO retained by Medi Mart shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Medicare program. Each IRO shall assess, along with Medi Mart, whether it can perform the IRO engagement in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO review shall analyze Medi Mart's compliance with the obligations assumed under this CIA and Settlement Agreement ("Compliance Review")

c. Future CMS and/or OIG Guidance. In those instances where Medi Mart has sought guidance from the Centers for Medicare and Medicaid Services ("CMS") and/or OIG as appropriate, and can document that such clarification has been sought, the Medi Mart internal audit team and the IRO shall include such information in its report. Further, for purposes of

compliance with this CIA, once CMS and/or OIG has issued guidance or clarification to Medi Mart specifically or to the supplier community generally, if such guidance requires modification of Medi Mart's procedures, Medi Mart shall be permitted a reasonable period of time up to ninety (90) days to bring its procedures into compliance with any such CMS or OIG guidance or clarification. This ninety day period for Medi Mart to alter its procedures for compliance with CMS or OIG guidance or clarification, if necessary, shall not affect Medi Mart's obligation to submit claims in accordance with such guidance or clarification upon its effective date nor shall it affect the effective date of such guidance for Federal health care program purposes.

d. IRO Verification Review. An independent review organization shall be engaged by Medi Mart to conduct a verification review of 20% of the Discovery Sample. If a Full Sample Review is necessary, the IRO shall be required to review either 10% or a 40 unit sample (whichever is greater). The IRO shall validate the sampling units from the Discovery Sample and the Full Sample, if applicable, from the current year's internal review to validate Medi Mart's internal billing review sample and findings. Included with Medi Mart's Annual Report to the OIG, the IRO shall furnish a report and its work papers to OIG of its findings regarding the validity of Medi Mart's internal billing review sample and related findings.

e. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the Effective Date of this CIA. Medi Mart shall perform all components of each annual Claims Review.

f. Frequency of Compliance Review. The Compliance Review shall be performed by the IRO for the first and third years of the CIA beginning with the Effective Date of this CIA.

g. Frequency of Verification Review. The Verification Review shall be performed by the IRO for the first and third year of the CIA beginning with the Effective Date of this CIA.

h. Retention of Records. The IRO and Medi Mart shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged

between the IRO and Medi Mart) related to the reviews in accordance with the Document and Record Retention Requirements set forth in Section VIII of this CIA.

2. *Claims Review*. The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

a. Discovery Sample. The Medi Mart internal audit team shall randomly select and review one sample of 50 Paid Claims submitted by or on behalf of Medi Mart encompassing the following six strata: (1) urological supply claims, (2) ostomy supply claims, (3) enteral nutrition therapy supply claims, (4) tracheostomy care supply claims, (5) surgical dressings claims, and (6) blood glucose monitors and testing supplies. The Paid Claims shall be reviewed based on the supporting documentation available at Medi Mart or under Medi Mart's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

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

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, Medi Mart's internal audit team shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.E.2.a, Medi Mart's internal audit team shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a

90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines in effect at the time the Full Sample is drawn. The Paid Claims shall be reviewed based on supporting documentation available at Medi Mart or under Medi Mart's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, Medi Mart may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Medi Mart to the appropriate Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If Medi Mart's internal audit team Discovery Sample identifies an Error Rate of 5% or greater, Medi Mart's internal audit team shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, Medi Mart's internal audit team should perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. Medi Mart's internal audit team shall internally document its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with section III.H.1 of the CIA, Medi Mart agrees to repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Medi Mart agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

3. *Claims Review Report.* Medi Mart's internal audit team shall prepare a report based upon the Claims Review performed (the "Claims Review Report"). Information to be included in the Claims Review Report is detailed in Appendix A.

4. *Compliance Review.* The IRO shall conduct a review of Medi Mart's compliance activities. The Compliance Review shall consist of a review of Medi Mart's compliance with the obligations set forth in each section of this CIA.

5. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include the IRO's findings and supporting rationale regarding Medi Mart's compliance with the terms of each section of the CIA, as applicable.

6. *Validation Review.* In the event the OIG has reason to believe that: (a) Medi Mart's Claims Review, Compliance Review, or Verification Review fails to conform to the requirements of this CIA; or (b) the Claims Review, Compliance Review, or Verification Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review, Compliance Review, or Verification Review complied with the requirements of the CIA and/or the findings are inaccurate ("Validation Review"). Medi Mart agrees to pay for the reasonable cost of any such validation review performed by the OIG or any of its designated agents so long as it is within the scope of (a) or (b) above, and initiated within one year after (1) Medi Mart's final Annual Report is filed and (2) any additional information requested by the OIG is received by the OIG related to that final Annual Report.

Prior to initiating a Validation Review, the OIG shall notify Medi Mart of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, Medi Mart may request a meeting with the OIG to discuss the results of any Claims Review or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Compliance Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the Validation Review. Medi Mart agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review or Compliance Review issues with Medi Mart 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 the OIG.

7. *Independence Certification.* The IRO shall include in its report(s) to Medi Mart a certification or sworn affidavit that it has evaluated its professional independence with regard to the Verification Review and Compliance Review and that it has concluded that it is, in fact, independent.

APPENDIX A

A. Claims Review.

1. **Definitions.** For the purposes of the Claims Review, the following definitions shall be used:

a. Overpayment: The amount of money Medi Mart has received in excess of the amount due and payable under Medicare program requirements.

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).

c. Paid Claim: A code or line item submitted by Medi Mart and for which Medi Mart has received reimbursement from the Medicare program.

d. Population: All Items for which Medi Mart has submitted a code or line item and for which Medi Mart has received reimbursement from the Medicare program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

e. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample. For years 1 and 3, the following payment errors should be included in calculating the error rate: (i) all payment errors identified by Medi Mart and not verified by the IRO; (ii) all payment errors identified by the IRO and not identified by Medi Mart; and (iii) all payment errors identified by Medi Mart and verified by the IRO.

2. **Other Requirements.**

a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which Medi Mart cannot produce documentation sufficient to support the Paid Claim shall be considered an error and either (a) the total reimbursement received by Medi Mart, or (b) the difference between what should have been claimed by Medi Mart based on what the documentation supports and what actually was paid, for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample.

B. **Claims Review Report.** The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. **Claims Review Methodology.**

a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review.

b. Claims Review Population. A description of the Population subject to the Claims Review.

c. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

d. Sampling Frame. A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Source of Data. A description of the documentation relied upon by Medi Mart's internal audit team when performing the Claims Review or the documentation relied upon by the IRO when performing the Verification Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

2. **Statistical Sampling Documentation.**

a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.

b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by Medi Mart's internal audit team and the IRO.

c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.

d. A description or identification of the statistical sampling software package used to conduct the sampling.

3. **Claims Review Findings.**

a. Narrative Results.

i. A description of Medi Mart's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of Medi Mart's internal audit team and its IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net

Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.

b. Quantitative Results.

i. Total number and percentage of instances in which Medi Mart's internal audit team and its IRO determined that the Paid Claims submitted by Medi Mart ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.

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

iii. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

iv. For each Discovery and Full Sample: (i) the number of Items the IRO verified; (ii) the number of instances in which the IRO disagreed with Medi Mart's payment determinations; and (iii) the dollars associated with the difference between the IRO's and Medi Mart's payment determinations.

v. Error Rate in the sample, as defined in section A.1.e of this Appendix

vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor (80% of Medicare allowed amount), correct procedure code (as determined by Medi Mart's internal audit team and its IRO), correct allowed amount (80% of Medicare allowed amount - as determined by Medi Mart's internal audit team and its IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment A to this Appendix.)

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

5. **Credentials.** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.

Attachment A

Medicare Claim Review Results

Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed (80% of Medicare Allowed Amount)	Correct Procedure Code (Internal audit team &/or IRO determined)	Correct Allowed Amt Reimbursed (80% of Medicare Allowed Amount) (Internal audit team &/or IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt