CORPORATE INTEGRITY AGREEMENT

BETWEEN THE

OFFICE OF INSPECTOR GENERAL

OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES AND

PHARMERICA, INC., AND PHARMERICA DRUG SYSTEMS, INC.

I. PREAMBLE

PharMerica, Inc., PharMerica Drug Systems, Inc., and their subsidiaries that furnish pharmaceutical items and products and related services reimbursable under Medicare, Medicaid or other Federal health care programs to long-term care, assisted living and other like facilities (PharMerica, Inc., PharMerica Drug Systems, Inc. and such subsidiaries being hereafter collectively referred to as "PharMerica") 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, related 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, PharMerica, Inc. and PharMerica Drug Systems, Inc. are entering into a Settlement Agreement with the OIG, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to the Effective Date of this CIA, PharMerica established a voluntary compliance program, which includes a corporate compliance officer ("Compliance Officer"), a corporate compliance committee ("Compliance Committee"), a Code of Ethics & Business Conduct (the "Code of Conduct"), written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program ("Disclosure Program"), an ineligible persons screening program ("Screening Program"), and internal audit and review procedures designed, as represented by PharMerica, to promote compliance with applicable laws, including Federal health care program requirements, and the promotion of ethical business practices. PharMerica shall continue the operation of the compliance program for the duration of the term of the CIA.

II. TERM AND SCOPE OF THE CIA

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

- B. Sections VIII, IX, X, XI, and XII shall expire no later than 120 days after OIG's receipt of: (1) PharMerica's final Annual Report; or (2) any additional materials submitted by PharMerica pursuant to OIG's request, whichever is later.
- C. The scope of this CIA shall be governed by the following definitions:
 - 1. "Covered Persons" means:
 - a. all employees of PharMerica, including but not limited to, the PharMerica CEO and all members of PharMerica management inclusive of senior vice presidents, vice presidents, directors, and managers;
 - b. all contractors, subcontractors and agents engaged by PharMerica to provide pharmaceutical items or services to patients or to perform billing or coding functions;
 - c. all contractors, subcontractors and agents engaged by PharMerica to perform functions related to the marketing of items or services reimbursable by Federal health care programs;
 - d. all contractors, subcontractors and agents engaged by PharMerica to perform functions related to the preparation of claims or other requests for reimbursement for pharmaceutical items or services to patients on behalf of PharMerica; and
 - e. all contractors, subcontractors and agents engaged by PharMerica to provide functions related to the sale or acquisition of entities that engage in Federal health care program business, including but not limited to solicitation of sellers, valuation, due diligence, negotiation, drafting and review of documents related to such transactions, excluding lawyers, accountants and financial advisors except those accountants and financial advisors who are acting as agents of

PharMerica in connection with a Covered Transaction (defined below).

Notwithstanding the above, the term "Covered Persons" does not include part-time or per diem employees, contractors, subcontractors, and agents 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. "Covered Persons" who are entities shall have those obligations with respect to their employees and subcontractors that are set forth in section III.C.7 of the CIA.

- 2. "Arrangements" means every arrangement or transaction that involves directly or indirectly the offer, payment, solicitation, or receipt of anything of value; and is between PharMerica and any actual or potential source of health care business or referrals to PharMerica or any actual or potential recipient of health care business or referrals from PharMerica. For purpose of this definition, the term "source" shall mean any physician, contractor, vendor, or agent, and the term "health care business or referrals" shall include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.
- 3. "Covered Transaction" means any transaction pursuant to which PharMerica acquires or sells any interest in a business unit or entity that furnishes pharmaceutical items or products and related services that are reimbursable by Medicare, Medicaid or other Federal health care programs.
- 4. "Relevant Covered Persons" means a Covered Person who is involved with the development, approval, management, or review of any of PharMerica's Arrangements.

III. CORPORATE INTEGRITY OBLIGATIONS

- A. <u>Compliance Officer and Committee</u>.
 - 1. Compliance Officer. Prior to the Effective Date of this CIA, PharMerica appointed a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer is and

shall remain a member of management of PharMerica, is and shall remain required to make periodic (at least quarterly) reports regarding compliance matters directly to the PharMerica Compliance Committee, and is and shall remain authorized to report on such matters directly to the PharMerica Compliance Committee and the Chief Executive Officer of PharMerica and shall have direct or indirect access to the Board or Directors of PharMerica, Inc.'s parent. The Compliance Officer is not and shall not be the General Counsel or Chief Financial Officer. The Compliance Officer is and shall remain responsible for monitoring the day-to-day compliance activities engaged in by PharMerica as well as for any reporting obligations created under this CIA. The Compliance Officer function outlined in this Section II.A.1 shall continue during the Term of this CIA.

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

2. Compliance Committee. Prior to the Effective Date of this CIA PharMerica appointed a Compliance Committee. The Compliance Committee includes and shall continue to include the Compliance Officer and members of senior management responsible for finance, clinical, human resources, legal, sales and operations. The Compliance Committee supports the Compliance Officer in fulfilling his/her responsibilities (e.g., assists in the analysis of the organization's risk areas and oversees monitoring of internal and external audits and investigations). The Compliance Committee function outlined in this Section II.A.2 shall continue during the Term of this CIA.

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

B. Written Standards.

1. Code of Conduct. Prior to the Effective Date of this CIA, PharMerica adopted and distributed the Code of Conduct to all Covered Persons who are employees and the personnel file of each Covered Person who is an employee contains a written certification that he or she has

received, read, understood, and shall abide by the Code of Conduct. PharMerica shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct reflects:

- a. a commitment to full compliance with all federal, state and local laws and regulations (which includes Federal health care program requirements);
- b. the requirement that all of PharMerica's officers, directors, and employees shall be expected to comply with all federal, state and local laws and regulations (which includes Federal health care program requirements);
- c. the requirement that all of PharMerica's officers and employees shall be expected to report to the Compliance Officer, or other appropriate individual designated by PharMerica, suspected violations of the Code of Conduct or any Federal, state and local laws and regulations (which includes Federal health care program requirements);
- d. the possible consequences to both PharMerica and individuals of failure to comply with Federal health care program requirements and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.F, and PharMerica's commitment to non-retaliation.

Covered Persons who are not employees and new Covered Persons shall receive the Code of Conduct and shall complete the form of certification currently used for Covered Persons who are employees within the later of 120 days after the Effective Date or 30 days after becoming a Covered Person.

PharMerica shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 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 30 days after the distribution of the revised

Code of Conduct.

- 2. Policies and Procedures. Within 120 days after the Effective Date, PharMerica shall implement written Policies and Procedures regarding the operation of PharMerica's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:
 - a. the subjects relating to the Code of Conduct identified in Section III.B.1;
 - b. the expectation that all Covered Persons shall comply with the Code of Conduct, the Policies and Procedures required under this Section, and this CIA; and
 - c. 42 U.S.C. § 1320a-7b(b) ("Anti-Kickback Statute") and related regulations and guidance; business or financial arrangements or contracts that may violate the Anti-Kickback Statute; and the applicability of the Anti-Kickback statute to Covered Transactions as that term is defined in Section II.C.3.

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

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

C. <u>Training and Education</u>.

1. General Training. Within 120 days after the Effective Date, PharMerica shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain the CIA requirements and PharMerica's Compliance Program (including the Code of Conduct) as supplemented by this CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming employed or engaged, or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person who is an employee shall receive at least one hour of General Training per fiscal year of PharMerica beginning on October 1, 2005.

- 2. Anti-Kickback Training. Within 120 days after the Effective Date, each Relevant Covered Person shall receive no less than two hours of training addressing:
 - a. Arrangements that potentially implicate the Anti-Kickback Statute and related regulations and guidance;
 - b. the policies, procedures and other requirements relating to Arrangements and the Anti-Kickback Statute, including the "Covered Transactions Procedures" (as defined in, and required by, Section III.D.1);
 - c. the personal obligation of each Relevant Covered Person to know the applicable legal requirements and PharMerica's the policies and procedures;
 - d. the legal sanctions under the Anti-Kickback Statute; and
 - e. examples of violations of the Anti-Kickback Statute.

New Relevant Covered Persons shall receive this training within 30 days after becoming employed or engaged, or within 120 days after the Effective Date, whichever is later. A PharMerica employee who has completed the Anti-Kickback Training shall review the work of a new Relevant Covered Person on a Covered Transaction until such time as the new Relevant Covered Person completes his or her Anti-Kickback Training.

After receiving the initial Anti-Kickback Training described in this Section, each Relevant Covered Person shall receive at least one hour of Anti-Kickback Training per fiscal year of PharMerica beginning on October 1, 2005.

- 3. Certification. Each individual who is required to attend training pursuant to this Section III.C shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.
- 4. Qualifications of Trainer. Persons providing the training required by this Section III.C shall be knowledgeable about the subject area.
- 5. Update of Training. PharMerica shall at least once per fiscal year of PharMerica review the training programs developed to satisfy the requirements of this Section III.C, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits, the Covered Transactions Procedures, and any other relevant information.
- 6. Training Methods. PharMerica may provide the training required under this CIA through videotape, DVD, appropriate computer-based training approaches or other comparable methods not involving in-person training. If PharMerica chooses to provide training pursuant to any such method, it shall make available at reasonable times appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.
- 7. Entities. Where a Covered Person or Relevant Covered Person is an entity, the General Training obligations under this CIA shall be met so long as the training is provided to a member of management of the entity. PharMerica shall require the entity to take reasonable steps to apprise its employees and other personnel regarding the content of the training. In addition PharMerica shall require such entities to do the following:
 - a. agree to abide by the Code of Conduct or adopt its own Code of Conduct addressing substantially all of the requirements of Section III..B.1;
 - b. distribute the following materials to its employees and subcontractors working on PharMerica matters: (1) PharMerica or its own Code of Conduct; (2) copies of relevant PharMerica policies and procedures relating to the work of the entity; and (3)

- information about PharMerica's Disclosure Program (including the hotline number);
- c. provide, either directly or through PharMerica, Anti-Kickback Training (as described in Section III.C.2) to its employees and subcontractors to the extent they are involved with the development, approval, management, or review of any of PharMerica's Arrangements;
- d. certify to PharMerica that all employees and subcontractors working on PharMerica matters have: (1) been screened to exclude Ineligible Persons in accordance with the requirements of Section III.G of the CIA; (2) received a copy of PharMerica's Code of Conduct or its own Code of Conduct, copies of relevant PharMerica policies and procedures, and information about PharMerica's Disclosure Program (including the hotline number); and (3) to the extent applicable, received Anti-Kickback training.

D. <u>Compliance with the Anti-Kickback Statute</u>.

- 1. Covered Transactions Procedures. Within 120 days after the Effective Date, PharMerica shall create procedures reasonably designed to ensure that Covered Transactions entered into from and after 120 days after the Effective Date do not violate the Anti-Kickback Statute, taking into account the related regulations and guidance ("Covered Transactions Procedures"). These Covered Transactions Procedures shall apply to Covered Transactions entered into 120 days from and after the Effective Date and shall include the following:
 - a. creating and maintaining a database of all Covered Transactions containing, at minimum (i) the name(s) of the acquiring and selling party(ies), (ii) the type of transaction (e.g., stock or asset acquisition), (iii) the purchase price, (iv) the name of the individual that provided the "Management Representation" as required by III.D.1.c, (v) the name of counsel who conducted the legal review required by Section III.D.1.d and the date the "Completion Memo" required by such Section was prepared by such counsel, (vi) the date of the closing of the Covered Transaction, and (vii) the file number for the Covered Transaction, as required by Section III.D.1.e ("Covered Transactions Database");

- b. requiring that the agreement governing the Covered Transaction and all related arrangements between the parties thereto be set forth in writing and signed by, as applicable, PharMerica and the other parties thereto;
- c. requiring that a written representation be obtained from the most senior member of PharMerica management involved in the Covered Transaction that the entirety of the arrangement between the parties to the Covered Transaction is reflected in written agreements and documents that were supplied to counsel conducting the review required by Section III.D.1.d ("Management Representation");
- d. establishing and implementing a written review and approval process that includes but is not limited to a legal review by counsel with expertise in the Anti-Kickback Statute and the creation of appropriate documentation of all such reviews and approvals, the purpose of which is to ensure that no Covered Transaction is consummated until such counsel has prepared a written memorandum ("Completion Memo") attesting to (i) the general completion of such review and approval process, (ii) the receipt of the Management Representation, and (iii) the completion of counsel's own review of the Covered Transaction under Federal health care program requirements;
- e. assuring that PharMerica maintains a complete file (and assigns a number to such file permitting ready retrieval) for each Covered Transaction, which file shall contain, at minimum (i) all of the written agreements and documents required by Section III.D.1.b, (ii) the Management Representation, and (iii) the Completion Memo;
- f. requiring that the Compliance Officer review the Covered Transactions Database, Covered Transaction review and approval process required by Section III.D.1.d, and other Covered Transactions Procedures on at least a quarterly basis and provide a report on the results of such review to the Compliance Committee; and
- g. implementing an effective response when violations of the Anti-Kickback Statute are discovered; such effective response may

include disclosure of the violation to the OIG, unwinding the Arrangement, and repaying any associated Overpayments pursuant to Section III.I (Reporting) when appropriate.

2. Records Retention and Access. PharMerica shall retain and make available to OIG, upon request, the Covered Transactions Database and all supporting documentation of the Covered Transactions subject to Section and, to the extent available, all non-privileged communications related to such Covered Transactions.

E. Review Procedures.

- 1. General Description.
 - a. Engagement of Independent Review Organization. Within 90 days after the Effective Date, PharMerica shall engage an individual or entity (or entities), such as an accounting, auditing, law or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a review to assist PharMerica in assessing its compliance with the obligations pursuant to this CIA set forth in Section III.D ("Covered Transactions Review"). The IRO engaged by PharMerica to perform the Covered Transactions Review shall have familiarity with the Anti-Kickback Statute and Federal health care program requirements.

Each IRO shall assess, along with PharMerica, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The engagement of the IRO for the Covered Transactions Review shall not be deemed to create an attorney-client relationship between PharMerica and the IRO.

- b. Frequency of Covered Transactions Review. The Covered Transactions Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Covered Transactions Review.
- c. Retention of Records. The IRO and PharMerica shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those

exchanged between the IRO and PharMerica) related to the Covered Transactions Reviews.

- d. Responsibilities and Liabilities. Nothing in this Section III.E affects PharMerica's responsibilities for or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.
- 2. Covered Transactions Review. The IRO shall perform a review to assess whether PharMerica is complying with the Covered Transactions Procedure required by Section III.D.1 for each Covered Transaction consummated from and after 120 days after the Effective Date. The IRO's assessment shall include (a) verifying that the Covered Transaction is listed in the Covered Transaction Database and that the required information for the Covered Transaction is reflected in the Covered Transaction Database; (b) verifying the receipt of the Management Representation prior to the consummation of the Covered Transaction; (c) verifying that the Covered Transaction was subject to the contract review and approval process (including a legal review), that such review and approval process was appropriately documented and that a Completion Memo was prepared prior to the consummation of the Covered Transaction; (d) verifying that PharMerica maintains a complete file (and assigns a number to such file permitting ready retrieval) for the Covered Transaction; and (e) verifying that the Compliance Officer is reviewing the Covered Transactions Database, contract review and approval process and satisfaction of the other requirements of the Covered Transactions Procedure, on a quarterly or more frequent basis, and reporting the results of such review to the Compliance Committee.
- 3. Covered Transactions Review Report. The IRO shall prepare a report based upon the Covered Transactions Review performed ("Covered Transactions Review Report"). The Covered Transactions Review Report shall include the IRO's findings with respect to (a) whether PharMerica has generally implemented the Covered Transactions Procedures described in Section III.D.1; and (b) specific findings as to whether PharMerica has complied with the Covered Transactions Procedures for each Covered Transaction reviewed by the IRO in accordance with Section III.E.2.
- 4. Validation Review. In the event OIG has reason to believe that: (a) PharMerica's Covered Transactions Procedure fails to conform to the

requirements of this CIA; or (b) the IRO's findings or Covered Transactions Review Report are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Covered Transactions Review complied with the requirements of the CIA and/or the findings or Covered Transactions Review Report are inaccurate ("Validation Review"). PharMerica shall pay for the reasonable cost of any Validation Review performed by OIG or any of its designated agents. Any Validation Review must be initiated no later than one year after PharMerica's final submission (as described in Section II of this CIA) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify PharMerica 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, PharMerica may request a meeting with OIG to: (a) discuss the results of any Covered Transactions Review or Covered Transactions Review Report; (b) present any additional information to clarify the results of the Covered Transactions Review or to correct the inaccuracy of the Covered Transactions Review Report; and/or (c) propose alternatives to the proposed Validation Review. PharMerica 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 Covered Transactions Review issues with PharMerica 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.

5. Independence/Objectivity Certification. The IRO shall include in its report(s) to PharMerica 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 Covered Transactions Review and that it has concluded that it is, in fact, independent and/or objective.

F. <u>Disclosure Program.</u>

Prior to the Effective Date of this CIA, PharMerica established a Disclosure Program that includes a toll-free compliance telephone line to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with PharMerica'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. PharMerica 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). PharMerica shall continue the Disclosure Program during the Term of the CIA as set forth in this Section III.F.

The Disclosure Program emphasizes a non-retribution, non-retaliation policy, and includes a reporting mechanism for anonymous communications for which appropriate confidentiality is maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) gathers all relevant information from the disclosing individual. The Compliance Officer (or designee) makes 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 permits a determination of the appropriateness of the alleged improper practice and provides an opportunity for taking corrective action, PharMerica conducts an internal review of the allegations set forth in the disclosure and ensures that proper follow-up is conducted.

The Compliance Officer (or designee) maintains a confidential disclosure log, which includes 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 written request but only as to those log entries that relate to allegations received concerning Federal health care programs or any alleged patient harm or abuse resulting from PharMerica's practices. At such time as PharMerica makes the confidential disclosure log available for review by the OIG as specified above, it will also report to the OIG the following information (but only as it relates to those log entries other than those for Federal health care program allegations or patient harm allegations): the total number of disclosures received and included in the confidential disclosure log for such period, the general categories into which the disclosures fell (including, at a minimum, the following categories: human resources, loss prevention, controlled substance issues), the number of disclosures in each category, and a general description of how PharMerica followed up on the disclosures in each category. When PharMerica provides access to the confidential disclosure log to the OIG as specified in this Section, it shall provide the log to the OIG upon request and as soon as practicable, but not later than 10 business days from the date of the OIG request.

G. <u>Ineligible Persons</u>.

- 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 non-procurement programs; or
 - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
 - b. "Exclusion Lists" include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov); and
 - ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov).
 - c. "Screened Persons" include officers, directors, employees, contractors, and agents of PharMerica (excluding employees, subcontractors or agents of any such contractors or agents).
- 2. Screening Requirements. PharMerica shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.
 - a. PharMerica 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. PharMerica shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. PharMerica 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) PharMerica to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person (including employees, subcontractors, and agents of any contractors or agents of PharMerica).

- 3. Removal Requirement. If PharMerica has actual notice that a Screened Person has become an Ineligible Person, PharMerica shall remove such person from responsibility for, or involvement with, PharMerica'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 PharMerica 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, PharMerica 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.

H. <u>Notification of Government Investigation or Legal Proceedings</u>.

Within 30 days after discovery, PharMerica shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to PharMerica conducted or brought by a governmental entity or its agents, involving an allegation that PharMerica 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. PharMerica 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.

I. Reporting.

1. Overpayments.

- a. <u>Definition of Overpayments</u>. For purposes of this CIA, an "Overpayment" shall mean the amount of money PharMerica has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Reporting of Overpayments. If, at any time, PharMerica identifies or learns of any Overpayment, PharMerica shall notify the payor (e.g., Medicaid fiscal agent) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, PharMerica shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, PharMerica shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and for Medicare contractors, shall include the information contained on the Overpayment Refund Form provided as Appendix A to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events.

a. <u>Definition of Reportable Event</u>. For purposes of this CIA, a "Reportable Event" means anything that involves:

- i. a substantial Overpayment; or
- ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

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

- b. Reporting of Reportable Events. If PharMerica determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, PharMerica shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include all of the information on the Overpayment Refund Form as well as the following information:
 - i. if the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.I.1 and shall include:
 - (A) the payor's name, address, and contact person to whom the Overpayment was sent; and
 - (B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;
 - ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
 - iii. a description of PharMerica's actions taken to correct the Reportable Event; and
 - iv. any further steps PharMerica 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, PharMerica changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, PharMerica 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, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. <u>IMPLEMENTATION AND ANNUAL REPORTS</u>

- A. <u>Implementation Report</u>. Within 150 days after the Effective Date, PharMerica shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA ("Implementation Report"). The Implementation Report shall, at a minimum, include:
 - 1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
 - 2. the names and positions of the members of the Compliance Committee required by Section III.A;
 - 3. a copy of PharMerica's Code of Conduct as provided in Section III.B.1;
 - 4. a copy of all Policies and Procedures required by Section III.B.2;
 - 5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
 - 6. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the

topics covered, the length of sessions and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

- 7. a description of the Covered Transactions Database required by Section III.D.1.a;
- 8. a description of the tracking and monitoring procedures and other Covered Transactions Procedures required by Section III.D.1;
- 9. a description of the Disclosure Program required by Section III.F;
- 10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between PharMerica and the IRO; and (d) the proposed start and completion dates of the Covered Transactions Review;
- 11. a certification from the IRO regarding its professional independence and/or objectivity with respect to PharMerica;
- 12. a description of the process by which PharMerica fulfills the requirements of Section III.G regarding Ineligible Persons;
- 13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
- 14. a list of all of PharMerica's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s),

and/or supplier number(s); and the name and address of each Medicare contractor to which PharMerica currently submits claims;

- 15. a listing of the PharMerica, Inc. and PharMerica Drug Systems, Inc. subsidiaries that furnish pharmaceutical items and products and related services reimburseable under Medicare, Medicaid, or other Federal health care programs to long-term care, assisted living and other like facilities; and
- 16. the certifications required by Section V.C.
- B. <u>Annual Reports</u>. PharMerica shall submit to OIG annually a report with respect to the status of, and findings regarding, PharMerica's compliance activities for each of the Reporting Periods ("Annual Report").

Each Annual Report shall include, at a minimum:

- 1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
- 2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);
- 3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
- 4. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

- 5. a description of any changes to the Covered Transactions Database required by Section III.D.1.a;
- 6. a description of any changes to the tracking and monitoring procedures and other Covered Transactions procedures required by Section III.D.1;
- 7. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter (if applicable);
- 8. PharMerica's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;
- 9. a summary and description of any and all current and prior engagements and agreements between PharMerica and the IRO, if different from what was submitted as part of the Implementation Report;
- 10. a certification from the IRO regarding its professional independence and/or objectivity with respect to PharMerica;
- 11. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
- 12. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;
- 13. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; (b) allege abuse or neglect of patients; or (c) involve allegations of conduct that may involve illegal remuneration or inappropriate referrals in violation of the Anti-Kickback Statute;

- 14. any changes to the process by which PharMerica fulfills the requirements of Section III.G regarding Ineligible Persons;
- 15. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by PharMerica in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
- 16. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
- 17. a description of all changes to the most recently provided list of PharMerica's locations (including addresses) as required by Section V.A.15; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare provider number(s), provider identification number(s); and the name and address of each Medicare contractor to which PharMerica currently submits claims; and
- 18. the certifications required by Section V.C.

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

- C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:
 - 1. to the best of his or her knowledge, except as otherwise described in the applicable report, PharMerica 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. <u>Designation of Information</u>. PharMerica 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. PharMerica 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

PharMerica:

Paul D. Ross, Rph
Executive Director, Compliance and Regulatory Affairs/
PharMerica Corporate Compliance Officer
3625 Queen Palm Drive
Tampa, FL 33619
Telephone: (813) 318-6152
Facsimile: (813) 318-6733

Facsimile: (813) 318-6733 Email: Pross@Pharmerica.com

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

VIII. DOCUMENT AND RECORD RETENTION

PharMerica shall maintain for inspection all documents and records relating 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 PharMerica prior to any release by OIG of information submitted by PharMerica pursuant to its obligations under this CIA and identified upon submission by PharMerica as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, PharMerica shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. <u>Breach and Default Provisions</u>

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

- A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, PharMerica 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 PharMerica fails to establish and implement any of the following obligations as described in Section III:
 - a. a Compliance Officer;
 - b. a Compliance Committee;
 - c. the Code of Conduct;
 - d. written Policies and Procedures;
 - e. the training of Covered Persons;
 - f. the Covered Transactions Procedures described in Section III.D.1.;
 - g. a Disclosure Program;
 - h. Ineligible Persons screening and removal requirements; and
 - i. 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 PharMerica fails to engage an IRO, as required in Section III.E.
 - 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 PharMerica 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 \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day PharMerica fails to submit the annual Covered Transactions Review Report (and any other required Review Report) in accordance with the requirements of Section III.E.
- 5. A Stipulated Penalty of \$1,500 for each day PharMerica fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date PharMerica fails to grant access.)
- 6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of PharMerica as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.
- 7. A Stipulated Penalty of \$1,000 for each day PharMerica fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to PharMerica, stating the specific grounds for its determination that PharMerica has failed to comply fully and adequately with the CIA obligation(s) at issue and steps PharMerica shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 20 days after PharMerica receives this notice from OIG of the failure to comply provided PharMerica does not cure such failure within such 20-day period.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.
- B. <u>Timely Written Requests for Extensions</u>. PharMerica 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 PharMerica 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 PharMerica 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 PharMerica 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 PharMerica of: (a) PharMerica'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 20 days after the receipt of the Demand Letter, PharMerica 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 IX.E. In the event PharMerica elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until PharMerica 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.
- 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 V.
- 4. Independence from Material Breach Determination. Except as set forth in Section X.D.1.b, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that PharMerica 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. <u>Exclusion for Material Breach of this CIA</u>.

- 1. Definition of Material Breach. A material breach of this CIA
- means:
- a. a failure by PharMerica to report a Reportable Event, take

corrective action, and make the appropriate refunds, as required in Section III.I;

- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A; or
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by PharMerica constitutes an independent basis for PharMerica's exclusion from participation in the Federal health care programs. Upon a determination by OIG that PharMerica has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify PharMerica of: (a) PharMerica'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. PharMerica 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. PharMerica 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) PharMerica has begun to take action to cure the material breach; (ii) PharMerica is pursuing such action with due diligence; and (iii) PharMerica has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If, at the conclusion of the 30-day period, PharMerica fails to satisfy the requirements of Section X.D.3, OIG may exclude PharMerica from participation in the Federal health care programs. OIG shall notify PharMerica in writing of its determination to exclude PharMerica(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 PharMerica'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, PharMerica 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. <u>Dispute</u> Resolution

- Review Rights. Upon OIG's delivery to PharMerica of its Demand 1. Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, PharMerica 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.
- Stipulated Penalties Review. Notwithstanding any provision of Title 2. 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 PharMerica was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. PharMerica 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 PharMerica to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless PharMerica 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 PharMerica 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) PharMerica had begun to take action to cure the material breach within that period; (ii) PharMerica has pursued and is pursuing such action with due diligence; and (iii) PharMerica provided to OIG within that period a reasonable timetable for curing the material breach and PharMerica 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 PharMerica, only after a DAB decision in favor of OIG. PharMerica's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude PharMerica 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 PharMerica 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. PharMerica 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 PharMerica, PharMerica 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. <u>EFFECTIVE AND BINDING AGREEMENT</u>

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

- A. This CIA shall be binding on the successors, assigns, and transferees of PharMerica, Inc. and PharMerica Drug Systems, Inc.;
- 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. OIG may agree to a suspension of PharMerica's obligations under the CIA in the event of PharMerica's cessation of participation in Federal health care programs. If PharMerica withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, PharMerica shall notify OIG at least 30 days in advance of PharMerica's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.
- E. The undersigned signatories of PharMerica, Inc. and PharMerica Drug Systems, Inc. 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 PHARMERICA, INC. AND PHARMERICA DRUG SYSTEMS, INC.

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3-29-05

WILLIAM SHIELDS

President and C.E.O.

PharMerica, Inc. and PharMerica Drug Systems, Inc.

RICHARD GREENHALL, Esq.

Counsel

PharMerica, Inc. and PharMerica Drug Systems, Inc.

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

DATE

OVERPAYMENT REFUND

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Contractor #		Name:			Phone
Contractor Address:					
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For Institutional Facilities Only Cost Report Year(s)	<u>y</u> :							
(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 Integrit	y Agreement with OIG?	Yes	No					
Reason Codes:								
Billing/Clerical Error	MSP/Other Payer Involven	nent Miscell	aneous					
01 - Corrected Date of Service	08 - MSP Group Healt	h Plan Insurance	13 -					
Insufficient Documentation	1							
02 - Duplicate	09 - MSP No Fault Insuran	ce 14	- Patient					
Enrolled in an HMO								
03 - Corrected CPT Code	10 - MSP Liability Ins	urance	15 -					
Services Not Rendered								
04 - Not Our Patient(s)	11 - MSP, Workers Comp.	(Including 16	- Medical					
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05 - Modifier Added/Removed	Black Lung	17	- Other					
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