CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
CAMERON'S PAWTUXET PHARMACY, INC.

I. PREAMBLE

Cameron's Pawtuxet Pharmacy, Inc. (Cameron's) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Cameron's is entering into a Settlement Agreement with the United States and the State of Rhode Island and Providence Plantations, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM AND SCOPE OF THE CIA

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

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

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

1. "Covered Persons" includes:

    a. all owners, officers, directors, and employees of Cameron's; and

b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Cameron's.

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

2. "Relevant Covered Persons" includes those employees who work in the pharmacy section of Cameron's.

III. CORPORATE INTEGRITY OBLIGATIONS

Cameron's shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Prior to the Effective Date, Cameron's appointed a Compliance Officer and Cameron's shall continue to employ an individual to serve as its Compliance Officer for the term of the CIA. The Compliance Officer is and shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Cameron's, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Cameron's, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Cameron's as well as for any reporting obligations created under this CIA.

Cameron's 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, Cameron's appointed a Compliance Committee, and Cameron's shall maintain a Compliance

Committee during the term of the CIA. The Compliance Committee includes and shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA. The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Cameron's 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.* Within 90 days after the Effective Date, Cameron's shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Cameron's 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 shall, at a minimum, set forth:

a. Cameron's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

b. Cameron's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Cameron's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);

c. the requirement that all of Cameron's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Cameron's suspected violations of any Federal health care program requirements or of Cameron's own Policies and Procedures;

d. the possible consequences to both Cameron's and Covered Persons of failure to comply with Federal health care program requirements and with Cameron's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.E, and Cameron's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by Cameron's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Cameron's 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 30 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 90 days after the Effective Date, Cameron's shall implement written Policies and Procedures regarding the operation of Cameron'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. Cameron's commitment to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program requirements;

c. the proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements; and

d. the proper management and accountability of the prescription drug inventory, including tracking vendor orders, proper storage, periodic inspections, dispensing of prescription drug orders, implementing appropriate drug recall, and tracking adverse drug reactions and medication evaluation use.

Within 90 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 annually (and more frequently, if appropriate), Cameron's 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. Training and Education.

1. *General Training.* Within 90 days after the Effective Date, Cameron's shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Cameron's:

a. CIA requirements; and

b. Cameron's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training annually.

2. *Specific Training.* Within 90 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

a. the Federal health care program requirements regarding the accurate coding and submission of claims;

b. policies, procedures, and other requirements applicable to the management and accountability of the prescription drug inventory;

c. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;

d. the personal obligation of each individual involved with the prescription drug inventory to ensure that the drug inventory is properly managed and dispensed;

e. the applicable reimbursement statutes, regulations, and program requirements and directives;

f. the legal sanctions for violations of the Federal health care program requirements; and

g. examples of proper and improper claims submission practices and drug inventory practices.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. A Cameron's employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least two hours of Specific Training annually.

Training provided to Relevant Covered Persons within 60 days prior to the Effective Date that satisfies the requirements of this Section III.C.2 shall be deemed to meet the initial training requirements of this subsection.

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

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

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

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

D. Management and Accountability of Prescription Drug Inventory.

Within 90 days following the Effective Date of this Agreement, Cameron's shall assess its internal procedures relating to the management and accountability of its prescription drug inventory. If necessary, Cameron's shall establish and implement, or revise, internal procedures so they are reasonably designed to track the receipt, storage, inventory, use, and financial disposition of prescription drugs. As part of the Implementation Report, Cameron's shall describe the general procedures used to track the receipt, storage, use, inventory, and financial disposition of prescription drugs. In addition, Cameron's shall include in each Annual Report a certification by the Compliance Contact that Cameron's has complied with the applicable Federal health care program requirements relating to the management and accountability of prescription drugs and the requirements under this Section III.D.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Cameron's shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Cameron's in assessing and evaluating its billing and coding practices (Claims Review) and prescription drug inventory (Drug Inventory Review), and certain other obligations pursuant to this Agreement and the Settlement Agreement. The applicable requirements relating to the IRO are outlined in Appendix A to this Agreement, which is incorporated by reference.

Each IRO engaged by Cameron's shall have expertise in the billing, coding, reporting, and other requirements of pharmacies and in the general requirements of the Federal health care program(s) from which Cameron's seeks reimbursement. Each IRO shall assess, along with Cameron's, 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 IRO(s) review shall evaluate and analyze Cameron's coding, billing, and claims submission to the Federal health care programs and the reimbursement received (Claims Review), and shall analyze Cameron's management of its prescription drug inventory.

b. *Frequency of Claims Review.* The Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Claims Review.

c. *Frequency of Drug Inventory Review.* The Drug Inventory Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each Drug Inventory Review.

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

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 B to this Agreement, which is incorporated by reference.

a. *Discovery Sample.* The IRO shall randomly select and review a sample of 50 Paid Claims submitted by or on behalf of Cameron's (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at Cameron's office or under Cameron's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix B) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Cameron's should, as appropriate, further analyze any errors identified in the Discovery Sample. Cameron's recognizes that 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 or any other segment of the universe.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO 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, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix B. The Full Sample shall be designed to: (i) 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 (ii) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Cameron's office or under Cameron's control and applicable billing and coding regulations and guidance to determine whether the claim 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, Cameron's 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, if: (i) statistically appropriate and (ii) Cameron's selects the Full Sample Items using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Cameron's to the appropriate Federal health care program payor for appropriate follow-up by that payor.

c. *Systems Review*. If Cameron's Discovery Sample identifies an Error Rate of 5% or greater, Cameron's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall 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. The IRO shall provide 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.I.1 of this Agreement, Cameron's shall 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. Cameron's shall make available to OIG any and all documentation and the associated documentation that reflects the refund of the Overpayment(s) to the payor.

3. Claims Review Report. The IRO shall prepare a report based upon the Claims Review performed (Claims Review Report). Information to be included in the Claims Review Report is described in Appendix B.

4. Drug Inventory Review. The IRO shall randomly select and review a sample of 50 prescription drugs to be test counted. The IRO shall compare the test count results with vendor invoices, order reports, inventory records, computer billing data, and any related transaction and sales data for each select prescription drug to evaluate the accuracy of the inventory. The IRO shall identify any errors and/or potential vulnerabilities with the management and accountability of Cameron's prescription drug inventory and recommend appropriate corrective action to Cameron's. If any error involves an Overpayment, Cameron's shall identify and repay the Overpayment within 30 days to the appropriate payor and in accordance with payor refund policies. Cameron's shall make available to OIG any and all documentation and the associated documentation that reflects the refund of the Overpayment(s) to the payor.

5. Drug Inventory Review Report. The IRO shall prepare a report summarizing the findings of the Drug Inventory Review (Drug Inventory Review Report), including any errors, vulnerabilities with the management and accountability of Cameron's prescription drug inventory, and/or recommended corrective actions.

6. Validation Review. In the event OIG has reason to believe that: (a) Cameron's Claims Review or Drug Inventory Review fails to conform to the requirements of this Agreement; or (b) the IRO's findings, Claims Review results, or Drug Inventory Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Drug Inventory Review complied with the requirements of the Agreement and/or whether the findings, Claims Review results, or Drug Inventory Review results are inaccurate (Validation Review). Cameron's shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Cameron's final Annual Report must be initiated no later than one year after Cameron's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Cameron's 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, Cameron's may request a meeting with OIG to: (a) discuss the results of any Claims Review or Drug Inventory Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review or Drug Inventory Review or to correct the inaccuracy of the Claims Review or Drug Inventory Review; and/or (c) propose alternatives to the proposed Validation Review. Cameron's 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 Claims Review or Drug Inventory Review issues with Cameron's 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.

7. Independence/Objectivity Certification. The IRO shall include in its report(s) to Cameron's 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 Claims Review and Drug Inventory Review and that it has concluded that it is, in fact, independent and/or objective.

F. Disclosure Program.

Cameron's shall maintain a Disclosure Program that includes a mechanism (e.g., 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 Cameron'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. Cameron's shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

G. Ineligible Persons.

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov).

c. "Screened Persons" include prospective and current owners, officers, directors, employees, contractors, and agents of Cameron's.

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

a. Cameron's 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. Cameron's shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Cameron's 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) Cameron's to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If Cameron's has actual notice that a Screened Person has become an Ineligible Person, Cameron's shall remove such person from responsibility for, or involvement with, Cameron'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 Cameron's 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, Cameron's 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. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Cameron's shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Cameron's conducted or brought by a governmental entity or its agents involving an allegation that Cameron's 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. Cameron's 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. Definition of Overpayments. For purposes of this CIA, an "Overpayment" shall mean the amount of money Cameron's 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, Cameron's identifies or learns of any Overpayment, Cameron's shall notify the payor (e.g., Medicaid contractor) 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, Cameron's 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, Cameron's 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

C 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. Definition of Reportable Event. 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 Cameron's determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Cameron's shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. 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 all of the information on the Overpayment Refund Form, as well as:

(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 Cameron's actions taken to correct the Reportable Event; and

iv. any further steps Cameron's 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, Cameron's 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, Cameron's 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, Medicaid Provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicaid number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Cameron's 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 Cameron's Code of Conduct required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2 and Section III.D, including procedures on the management and accountability of prescription drugs;

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;

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 general procedures used to track the receipt, storage, use, inventory, and financial disposition of prescription drugs required under Section III.D.

8. a description of the Disclosure Program required by Section III.F;

9. 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 Cameron's and the IRO; and (d) the proposed start and completion dates of the Claims Review and Drug Inventory Review;

10. a certification from the IRO regarding its professional independence and/or objectivity with respect to Cameron's;

11. a description of the process by which Cameron's fulfills the requirements of Section III.G regarding Ineligible Persons;

12. 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;

13. a list of all of Cameron'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 Medicaid Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicaid contractor to which Cameron's currently submits claims;

14. a description of Cameron's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

15. the certifications required by Section V.C.

B. Annual Reports. Cameron's shall submit to OIG annually a report with respect to the status of, and findings regarding, Cameron's compliance activities for each of the 5 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) and copies of any compliance-related Policies and Procedures;

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 certification by the Compliance Officer that Cameron's has complied with the applicable Federal health care program requirements relating to the management and accountability of prescription drugs and the requirements under Section III.D.

6. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter (if applicable);

7. Cameron's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

8. summary and description of any and all current and prior engagements and agreements between Cameron's and the IRO, if different from what was submitted as part of the Implementation Report;

9. a certification from the IRO regarding its professional independence and/or objectivity with respect to Cameron's;

10. 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;

11. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down by the applicable Federal health care program (e.g., Medicaid). 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;

12. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

13. any changes to the process by which Cameron's fulfills the requirements of Section III.G regarding Ineligible Persons;

14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by Cameron's 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 relating to items or services furnished, ordered or prescribed by an Ineligible Person;

15. 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;

16. a description of all changes to the most recently provided list of Cameron's locations (including addresses) as required by Section V.A.13; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicaid Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicaid contractor to which Cameron's currently submits claims; and

17. 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. Certifications. 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, Cameron's is in compliance with all of the requirements of this CIA;

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; and

3. Cameron's has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

D. Designation of Information. Cameron's 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. Cameron's 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

Cameron's:

Stephen Mesnick
Cameron's Pawtuxet Pharmacy
2206 Broad Street
Cranston, RI 02905
Telephone: 401.781.1313
Facsimile: 401.781.4309

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 Cameron's

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

VIII. DOCUMENT AND RECORD RETENTION

Cameron's shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for 6 years (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 Cameron's prior to any release by OIG of information submitted by Cameron's pursuant to its obligations under this CIA and identified upon submission by Cameron's as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Cameron's shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Cameron's is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Cameron's 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 Cameron's fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures, including procedures on the management and accountability of the prescription drug inventory;

e. the training of Covered Persons;

f. a Disclosure Program;

g. Ineligible Persons screening and removal requirements; and

h. Notification of Government investigations or legal proceedings.

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

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Cameron's 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 Cameron's fails to submit the annual Claims Review Report and Drug Inventory Review Report in accordance with the requirements of Section III.E and Appendix B.

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

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

B. Timely Written Requests for Extensions. Cameron's 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 Cameron's 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 Cameron's 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 Cameron's 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 Cameron's of: (a) Cameron's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Cameron's shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Cameron's elects to request

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

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

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

D. Exclusion for Material Breach of this CIA.

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

a. a failure by Cameron's 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;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Cameron's constitutes an independent basis for Cameron's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Cameron's has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Cameron's of: (a) Cameron'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.* Cameron's 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. Cameron's 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) Cameron's has begun to take action to cure the material breach; (ii) Cameron's is pursuing such action with due diligence; and (iii) Cameron's has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Cameron's fails to satisfy the requirements of Section X.D.3, OIG may exclude Cameron's from participation in the Federal health care programs. OIG shall notify Cameron's in writing of its determination to exclude Cameron's (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 Cameron'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, Cameron's may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Cameron's of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Cameron's shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after

receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Cameron's was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Cameron's 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 Cameron's to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Cameron's 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 Cameron's 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) Cameron's had begun to take action to cure the material breach within that period; (ii) Cameron's has pursued and is pursuing such action with due diligence; and (iii) Cameron's provided to OIG within that period a reasonable timetable for curing the material breach and Cameron's 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 Cameron's, only after a DAB decision in favor of OIG. Cameron's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Cameron's 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 Cameron's 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. Cameron's 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 Cameron's, Cameron's shall be reinstated effective on the date of the original exclusion.

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

XI. EFFECTIVE AND BINDING AGREEMENT

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

A. This CIA shall be binding on the successors, assigns, and transferees of Cameron's;

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 Cameron's obligations under the CIA in the event of Cameron's cessation of participation in Federal health care programs. If Cameron's withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, Cameron's shall notify OIG at least 30 days in advance of Cameron'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 Cameron's signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF CAMERON'S PAWTUXET PHARMACY, INC.

Mona Albanese

Mona Albanese
President

3-23-05

DATE

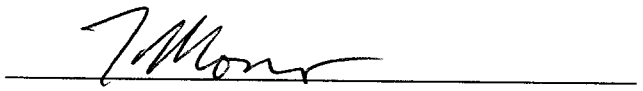
Lawrence W. Vernaglia

Lawrence W. Vernaglia
Counsel for Cameron's Pawtuxet Pharmacy, Inc.

3/28/05

DATE

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



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

3/28/05
DATE

APPENDIX A
INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement.

Cameron's shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Cameron's if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Cameron's may continue to engage the IRO.

If Cameron's engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Cameron's shall submit the information identified in Section V.A.8 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Cameron's if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Cameron's may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Claims Review engagement who have expertise in the billing, coding, reporting, and other requirements of pharmacies and in the general requirements of the Federal health care program(s) from which Cameron's seeks reimbursement;

2. assign individuals to conduct the Drug Inventory Review engagement who have expertise in the proper management and accountability of the prescription drug inventory and other requirements of pharmacies and in the general requirements of the Federal health care program(s) from which Cameron's seeks reimbursement

3. assign individuals to design and select the Claims Review and Drug Inventory Review sample who are knowledgeable about the appropriate statistical sampling techniques;

4. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification (e.g., CCA, CCS, CCS-P, CPC,

RRA, etc.) and who have maintained this certification (e.g., completed applicable continuing education requirements); and

5. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Claim Review and Drug Inventory Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare, Medicaid, and other Federal health care program rules and reimbursement guidelines in making assessments in the Claims Review and Drug Inventory Review;

3. if in doubt of the application of a particular Medicare, Medicaid, and other Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. IRO Independence/Objectivity.

The IRO must perform the Claims 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 engagements that may exist between the IRO and Cameron's.

E. IRO Removal/Termination.

1. *Provider.* If Cameron's terminates its IRO during the course of the engagement, Cameron's must submit a notice explaining its reasons to OIG no later than 30 days after termination. Cameron's must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as

described in Paragraph C, OIG may, at its sole discretion, require Cameron's to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Cameron's to engage a new IRO, OIG shall notify Cameron's of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Cameron's may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Cameron's shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Cameron's prior to requiring Cameron's to terminate the IRO. However, the final determination as to whether or not to require Cameron's to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B
CLAIMS REVIEW

A. Claims Review.

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

a. Overpayment: The amount of money Cameron's has received in excess of the amount due and payable under any Federal health care 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 Cameron's and for which Cameron's has received reimbursement from Medicaid, Medicaid, or any other Federal health care program.

d. Population: For the first Reporting Period, the Population shall be defined as all Items for which a code or line item has been submitted by or on behalf of Cameron's and for which Cameron's has received reimbursement from Medicare, Medicaid, or any other Federal health care programs (i.e., Paid Claim) during the 12-month period covered by the first Claims Review.

For the remaining Reporting Periods, the Population shall be defined as all Items for which Cameron's has received reimbursement from Medicare, Medicaid, or any other Federal health care programs (i.e., 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 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.

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 Cameron's cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Cameron's for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Replacement Sampling. Considering the Population shall consist only of Paid Claims and that Items with missing documentation cannot be replaced, there is no need to utilize alternate or replacement sampling units.

c. 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 (i.e., 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 specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, prescriptions, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicaid contractor manual or bulletins (including issue and date), 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 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 select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings.*

a. Narrative Results.

i. A description of Cameron'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 the 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).

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Cameron's (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 Cameron's.

iii. Total dollar amount of all Overpayments in the sample.

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

v. Error Rate in the sample.

vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 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 1

Claim Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt

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/SUPPLIERNAME_____
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 reason 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
01 - Corrected Date of Service
02 - Duplicate
03 - Corrected CPT Code
04 - Not Our Patient(s)
05 - Modifier Added/Removed
06 - Billed in Error
07 - Corrected CPT Code

MSP/Other Payer Involvement
08 - MSP Group Health Plan Insurance
09 - MSP No Fault Insurance
10 - MSP Liability Insurance
11 - MSP, Workers Comp.(Including Black Lung
12 - Veterans Administration

Miscellaneous
13 - Insufficient Documentation
14 - Patient Enrolled in an HMO
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify)
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