# CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND CITY PHARMACY, INC. AND CITY PHARMACY KAPAHULU, INC.

#### I. PREAMBLE

City Pharmacy, Inc. and City Pharmacy Kapahulu, Inc. (collectively referred to as "CP") hereby enter into this Corporate Integrity Agreement ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its subsidiaries, pharmacists, pharmacy technicians, employees, contractors and agents, and all other persons employed or engaged by CP to provide pharmacy services or prepare and/or submit claims for pharmacy services to any Federal health care programs ("Covered Persons") 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 Agreement, CP is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

# II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by CP under this Agreement shall be five years from the effective date of this Agreement. The effective date of this Agreement shall be the date on which the final signatory of this Agreement executes this Agreement.

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by CP pursuant to OIG's request.

#### III. CORPORATE INTEGRITY OBLIGATIONS

CP hereby agrees to establish a Compliance Program that, at minimum, includes the following elements:

#### A. Compliance Contact

Within 30 days of execution of this Agreement, CP shall designate a person to be the Compliance Contact for purposes of developing and implementing policies, procedures and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements. In addition, the Compliance Contact is responsible for responding to questions and concerns from Covered Persons and the OIG regarding compliance with the Agreement obligations. The name and phone number of the Compliance Contact shall be included in the Implementation Report. In the event a new Compliance Contact is appointed during the term of this Agreement, CP shall notify the OIG, in writing, within 15 days of such a change.

#### B. Posting of Notice

Within the first 30 days following the effective date of this Agreement, at all pharmacy locations CP shall post in a prominent place accessible to all customers and Covered Persons a notice detailing its commitment to comply with all Federal health care program requirements in the conduct of its business. This notice shall include a means (i.e., telephone number, address, etc.) by which instances of misconduct may be reported anonymously. A copy of this notice shall be included in the Implementation Report.

#### C. Written Policies and Procedures

Within 90 days of the effective date of this Agreement, CP agrees to develop, implement, and make available to all Covered Persons written policies that address the following:

- 1. CP's commitment to operate its business in full compliance with all Federal health care program requirements;
- 2. The proper procedures for the honest and accurate submission of claims in accordance with Federal health care program requirements;
- 3. The proper documentation of services and billing information and the

retention of such information in a readily retrievable form;

- 4. The requirement that all of its Covered Persons shall be expected to report to the Compliance Contact suspected violations of any Federal health care program requirement or CP's own Policies and Procedures. Any Covered Person who makes an inquiry regarding compliance with Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect.
- 5. The requirement that CP not hire, employ or engage as contractors any Ineligible Person. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, debarred 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 related to the provision of health care items or services, but has not yet been excluded, debarred, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, CP shall check all prospective employees and contractors prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <a href="http://www.hhs.gov/oig">http://www.hhs.gov/oig</a>) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <a href="http://epls.arnet.gov">http://epls.arnet.gov</a>) and, as appropriate, the state list of exclusions from Medicaid or Medical Assistance programs.
- 6. The commitment of CP 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.
- 7. CP will not bill in excess of federally-established upper limit prices for drugs that are available from multiple sources.
- 8. CP will not bill Medicaid for brand name drugs which have a generic equivalent that have been approved by the State of Hawaii for substitution unless a physician has ordered that the brand name drug product is medically necessary.

At least annually (and more frequently if appropriate), CP shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any

revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions are related to those Policies and Procedures.

Within 90 days of the effective date of the Agreement and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and will abide by CP's Policies and Procedures. New Covered Persons shall review the Policies and Procedures and shall complete the required certification within two weeks after becoming a Covered Person or within 90 days of the effective date of the Agreement, whichever is later.

Copies of the written policies and procedures shall be included in the Implementation Report. Copies of any written policies and procedures that are subsequently revised shall be included in the Annual Report.

#### D. Training and Certification

Within 90 days following the effective date of this Agreement and at least once each year thereafter, Covered Persons involved in the preparation or submission of claims for reimbursement from any Federal health care program shall receive at least 4 hours of training from an individual or entity, other than CP or a Covered Person. The training shall be conducted by individuals with expertise in the relevant subject areas, <u>e.g.</u>, preparation or submission of claims to Federal health care programs for the types of services provided by CP.

New Covered Persons who provide pharmacy services or prepare and/or submit claims for pharmacy services to any Federal health care programs shall receive the training described above within 30 days after becoming a Covered Person or within 90 days of the effective date of this Agreement, whichever is later. The training for New Covered Persons may either be provided internally by a qualified Covered Persons who has completed the required annual training and is proficient with the training material or externally by a qualified individual or entity. Until they have received the requisite training, such New Covered Persons shall work under the direct supervision of a Covered Person who has received such training.

At a minimum, the annual and new employee training sessions shall cover the following topics:

- 1. Federal health care program requirements related to the proper submission of accurate bills for items provided to Federal health care program patients;
- 2. The written Policies and Procedures developed pursuant to Section III.C., above;
- 3. The legal sanctions for improper billing or other violations of the Federal health care program requirements;
- 4. Examples of proper and improper billing practices; and
- 5. Federal health care program requirements related to billing generic and brand name drugs.

Each Covered Person shall annually certify in writing that he or she has received the required training. The certification shall specify the type of training received and the date received. CP shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

#### E. Annual Review Procedures

- 1. Retention of Independent Review Organization. Within 90 days of the effective date of this Agreement, CP shall retain a person or entity, such as a nurse reviewer, an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a systems review to assess CP's billing and coding practices ("Systems Engagement"). The Independent Review Organization retained by CP shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this Agreement and in the Federal health care program requirements. The IRO shall assess, along with CP, whether it can perform the IRO engagement in a professionally independent fashion, taking into account any other business relationships or other engagements that may exist.
- 2. Frequency of the Systems Engagement. The Systems Engagement shall be performed at least annually and shall cover each of the one-year periods beginning with the effective date of this Agreement. The IRO shall perform all components of each

annual Systems Engagement and prepare the required reports in accordance with the procedures set forth in this section.

- 3. Systems Review. The IRO shall review CP's billing and coding systems and/or operations (the "Systems Review"). The Systems Review shall consist of a thorough review of the following:
  - i. CP's billing systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the operation of the billing system, safeguards to ensure proper claim submission and billing, and procedures to correct inaccurate billing); and
  - ii. CP's coding systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the process by which claims are coded, safeguards to ensure proper coding, and procedures to correct inaccurate coding).
  - 4. *Systems Review Report*. The IRO shall prepare a report based upon each Systems Review performed ("Systems Review Report"). The Systems Review Report shall include the IRO's findings and supporting rationale regarding:
    - i. the strengths and weaknesses in CP's billing systems and/or operations;
    - ii. the strengths and weaknesses in CP's coding systems and/or operations; and
    - iii. any recommendations the IRO may have to improve any of these systems, operations, and processes.
- 5. Independence Certification. Within 120 days from the effective date of this Agreement, the IRO shall provide to CP a certification or sworn affadavit that it has evaluated its professional independence with regard to the Systems Review and that it has concluded that it is, in fact, independent. Such certification shall be included in CP's Implementation Report submission.

6. Validation Review. In the event the OIG has reason to believe that: (a) CP's Systems Review fails to conform to the requirements of this Agreement; or (b) the findings or System Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Systems Engagement complies with the requirements of the Agreement and/or the findings are inaccurate. CP agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the CP's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify CP of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, CP may request a meeting with the OIG to discuss the results of any Engagement submissions; present any additional or relevant information to clarify the results of the Engagements or to correct the inaccuracy of the Systems Review; and/or propose alternatives to the proposed Validation Review. CP agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Systems Engagement issues with Provider prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

# F. Reporting of Overpayments and Material Deficiencies

### 1. Overpayments

- a. Definition of Overpayments. For purposes of this Agreement, an "overpayment" shall mean the amount of money CP has received in excess of the amount due and payable under any Federal health care program requirements. CP may not subtract any underpayments for purposes of determining the amount of relevant "overpayments" for purposes of reporting under this Agreement.
- b. Reporting of Overpayments. If, at any time, CP identifies or learns of any overpayments, CP shall notify the payor within 30 days of identification of the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, CP shall repay

the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, CP 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 contractor should be done in accordance with the contractor policies.

#### 2. Material Deficiencies.

- a. Definition of Material Deficiency. For purposes of this Agreement, a "Material Deficiency" means anything that involves:
  - (i) a substantial overpayment;
  - (ii) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or
  - (iii) a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances that present an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

- b. Reporting of Material Deficiencies. If CP determines, by any means, that there is a Material Deficiency, CP shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:
  - (i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the

notification to the payor required in section III.F.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) on which the overpayment was repaid/refunded;
- (ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- (iii) a description of CP's actions taken to correct the Material Deficiency; and
- (iv) any further steps CP plans to take to address the Material Deficiency and prevent it from recurring.

# G. Notification of Government Investigations or Legal Proceedings

Within 30 days of discovery, CP shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that CP 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. CP shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

#### IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, of the effective date of this Agreement, CP changes locations or purchases or establishes a new business related to the furnishing of items or services that may be reimbursed by Federal health care programs, CP shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new

operation(s), phone number, fax number, Medicaid provider or supplier number(s) (if any), and the corresponding contractor's name and address that has issued each Medicaid provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this Agreement (e.g., completing certifications and undergoing training).

#### V. REPORTS

#### A. Implementation Report

Within 120 days after the effective date of this Agreement, CP shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement. This report, known as the "Implementation Report," shall include:

- 1. The name and phone number of CP's Compliance Contact;
- 2. A copy of the notice CP posted in its locations as described in Section III.B and a description of where and when the notice has been posted;
- 3. A copy of the written policies and procedures required by section III.C. of this Agreement;
- 4. A certification signed by the Compliance Contact attesting that the Policies and Procedures are being implemented and have been made available to all Covered Persons;
- 5. A description of the training required by Section.III.D., including a summary of the topics covered and a schedule of when the training session(s) were held;
- 6. A certification signed by the Compliance Contact attesting that all employees have completed the initial training required by Section III.D. and have executed the required certifications;
- 7. The name and qualifications of the IRO CP has retained to conduct the Systems Engagement and the proposed start and completion dates of the first annual review;

- 8. A certification from the IRO regarding its professional independence from CP;
- 9. A list of all CP'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 identification number(s) and the contractor's name and address that issued each provider identification number; and
- 10. A certification from the Compliance Contact stating that he has reviewed the Implementation Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

#### B. Annual Reports

CP shall submit to OIG Annual Reports with respect to the status of and findings regarding CP's compliance activities for each of the five one-year periods beginning on the effective date of the Agreement. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). The first Annual Report shall be received by the OIG no later than one year and 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.

#### Each Annual Report shall include:

- 1. If revisions were made to the written policies and procedures developed pursuant to section III.C. of this Agreement, a copy of any policies and procedures that were revised;
- 2. A certification by the Compliance Contact that all Covered Persons have executed the annual Policies and Procedures certification required by section III.C.;
- 3. A schedule, topic outline and copies of the training materials for the training programs attended in accordance with section III.D. of this Agreement;

- 4. A certification signed by the Compliance Contact certifying that he is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in section III.D. of this Agreement;
- 5. A complete copy of all reports prepared pursuant to the IRO's Systems Engagement, including the Systems Review Report, along with a copy of the IRO's engagement letter;
- 6. CP's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO;
- 7. A summary/description of all engagements between CP and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting;
- 8. A summary of any Material Deficiencies (as defined in III.F.) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
- 9. A summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
- 10. A certification signed by the Compliance Contact certifying that all prospective employees and contractors are being screened against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs; and
- 11. A certification signed by the Compliance Contact certifying that he has reviewed the Annual Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

#### VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the following:

If to the OIG:

Civil Recoveries Branch - Compliance Unit Office of Counsel to the Inspector General

Office of Inspector General

U.S. Department of Health and Human Services

330 Independence Avenue, SW Cohen Building, Room 5527 Washington, DC 20201

Ph. 202.619.2078 Fax 202.205.0604

If to CP:

Carl Murdick

City Pharmacy Kapahulu

750 Palani Avenue

Honolulu, Hawaii 96816-1188

Ph. 808.739.1188 Fax 808.735.6545

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

#### VIII. DOCUMENT AND RECORD RETENTION

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

#### IX. <u>DISCLOSURES</u>

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify CP prior to any release by OIG of information submitted by CP pursuant to its obligations under this Agreement and identified upon submission by CP as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, CP shall have the rights set forth at 45 C.F.R. § 5.65(d). CP shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

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

Full and timely compliance by CP shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by CP.

## A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, CP and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

- 1. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day CP:
  - a. Fails to have in place a Compliance Contact as required in section

#### III.A;

- b. Fails to post the notice required in section III.B;
- c. Fails to have in place the Policies and Procedures required in section III.C;
- d. Or each applicable Covered Person fails to attend the training required by section III.D. of the Agreement within the time frames required in that section;
- e. Fails to retain an IRO within the time frame required in section III.E.1, or annually submit the IRO's Systems Review Report as required in section III.E; or
- f. Fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.
- 2. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day CP employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, CP's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which CP can demonstrate that CP did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.C.5) as to the status of the person).
- 3. A Stipulated Penalty of \$750 for each day CP fails to grant access to the information or documentation as required in section VII of this Agreement. (This Stipulated Penalty shall begin to accrue on the date CP fails to grant access.)
- 4. A Stipulated Penalty of \$750 for each day CP fails to comply fully and adequately with any obligation of this Agreement. In its notice to CP, OIG shall state the specific grounds for its determination that CP has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the CP must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to CP of the failure to comply.) A Stipulated Penalty as described in this

paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-3 of this section.

#### B. Timely Written Requests for Extensions

CP 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 Agreement. 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 CP 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 CP 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 CP 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 CP of: (a) CP's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").
- 2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, CP shall respond by either: (a) curing the breach to OIG's satisfaction, notifying OIG of his corrective actions, and paying the applicable Stipulated Penalties; or (b) sending in writing to OIG a request for 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 CP elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until CP 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 Agreement 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 CP has materially breached this Agreement, 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 Agreement

- 1. Definition of Material Breach. A material breach of this Agreement means:
  - a. a failure by CP to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.F;
  - b. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in section X.A;
  - c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C; or
  - d. a failure to retain and use an Independent Review Organization in accordance with section III.E.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by CP constitutes an independent basis for CP's exclusion from participation in the Federal health care programs. Upon a determination by OIG that CP has materially breached this Agreement and that exclusion should be imposed, OIG shall notify CP of: (a) CP'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. CP 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. CP is in compliance with the obligations of the Agreement cited by the 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) CP has begun to take action to cure the material breach; (ii) CP is pursuing such action with due diligence; and (iii) CP has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If at the conclusion of the 30-day period, CP fails to satisfy the requirements of section X.D.3, OIG may exclude CP from participation in the Federal health care programs. OIG will notify CP in writing of its determination to exclude CP (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, CP wishes to apply for reinstatement, CP must submit 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 CP of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, CP 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 Agreement. 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 of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.
- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether CP was in full and timely compliance with the obligations of this Agreement for which

IN WITNESS WHEREOF, the parties hereto affix their signatures:

#### CITY PHARMACY, INC. AND CITY PHARMACY KAPAHULU, INC.

5/16/01	Cheriana C. Kam Pres
Date	City Pharmaey, Inc.
	966 Kaheka Street
	Honolulu, Hawaii 96814
~ (1) (0)	Gerpiner C. Kam Pre
5//0/01	Janua C. Van Me
Date	City Pharmacy Kapahulu, Inc.
	City Pharmacy Kapahulu
	750 Palani Avenue
	Honolulu, Hawaii 96816-1188
<u>\$ /10/81</u> Date	Counsel for City Pharmacy, Inc. and City Pharmacy Kapahulu, Inc.

# OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Date

5/23/01

Lewis Morris, Esquire

Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human
Services