INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
BACHTHU (THERESA) M. PHAN, RPH AND
LAN APOTHECARY, INC.

I. PREAMBLE

Bachthu (Theresa) M. Phan, RPH ("Theresa Phan") and Lan Apothecary, Inc. hereby enter into this Integrity Agreement (IA) 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). Theresa Phan and Lan Apothecary, Inc. are hereafter collectively referred to as "Lan Apothecary." Contemporaneously with this IA, Lan Apothecary is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE IA

A. The Effective Date of this IA shall be the date on which the final signatory signs this IA. The term of this IA shall be three years from the 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, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Lan Apothecary's final annual report; or (2) any additional materials submitted by Lan Apothecary pursuant to OIG's request, whichever is later.

C. The term "Covered Persons" includes: (1) Lan Apothecary and all owners and employees of Lan Apothecary; and (2) all contractors, agents, and other persons who are involved with the dispensing or compounding of prescription drugs, furnish patient care items or services, or perform billing or coding functions on behalf of Lan Apothecary, except that the employees of any third-party billing company that submits claims to the Federal health care programs on behalf of Lan Apothecary shall not be considered Covered Persons, provided that Lan Apothecary and the third party billing company provide the certifications required by Section III.H.

III. COMPLIANCE PROGRAM REQUIREMENTS

Lan Apothecary shall be responsible for ensuring compliance with the requirements of this IA and shall establish and maintain a compliance program that includes the following elements:

A. Posting of Notice

Within 60 days after the Effective Date, Lan Apothecary shall post in a prominent place accessible to all patients and Covered Persons a notice that provides the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

B. Training and Education

1. *Covered Persons Training*. All Covered Persons shall receive at least three hours of training during the first Reporting Period. Training may be completed in-person or online. These training requirements may be satisfied only by the completion of training courses that are submitted to OIG, prior to registration for the training course, for review and approval.

At a minimum, the required training sessions must include the following topics:

a. the Federal health care program billing, coding and claim submission statutes, regulations, and program requirements and directives relating to dispensing of and billing for prescription drugs by Lan Apothecary;

b. state Board of Pharmacy requirements relating to the dispensing of prescription drugs by Lan Apothecary, including, but not limited to, prescription drug documentation requirements and the accurate receipt, storage, tracking, and dispensing of prescription drugs;

c. the Federal and state health care program requirements relating to the accurate submission of pharmacy claims by Lan Apothecary, including requirements regarding prescription refills, billing, and crediting; and

d. the Federal and state health care program requirements relating to documentation that the prescription drugs were

dispensed and documentation of physician orders for prescription drugs; and

e. the personal obligation of each individual involved in the medical record (including prescription record) documentation and claim submission processes to ensure that medical records (including prescription records) and claims are accurate.

New Covered Persons shall receive at least three hours of training within 90 days after becoming a Covered Person.

The OIG may, in its discretion, require that Lan Apothecary or all Covered Persons complete additional hours of training regarding the topics identified above, or additional topics, in the second or third years of the IA. The OIG shall provide notice to Lan Apothecary of such additional required training at least 180 days prior to the required completion date for such training.

2. *Training Records*. Lan Apothecary shall maintain written documentation (e.g., written or electronic certificates of completion from the training provider) that all Covered Persons required to receive training have in fact completed such training. The documentation shall specify the type of training received, the individual who completed the training, and the date received.

C. Review Procedures

1. *General Description*.

a. *Engagement of Independent Review Organization*. Within 60 days after the Effective Date, Lan Apothecary shall engage an individual or entity, such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.C. The applicable requirements relating to the IRO are outlined in Appendix A to this IA, which is incorporated by reference.

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

c. *Access to Records and Personnel.* Lan Apothecary shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.C and that all records furnished to the IRO are accurate and complete.

2. *Claims Review.* The IRO shall conduct a review of Lan Apothecary's claims submitted to and reimbursed by the Medicare and Medicaid programs, to determine whether Lan Apothecary: (1) dispensed the prescription drugs according to a valid prescription, (2) maintained appropriate documentation of a valid prescription for each drug dispensed (including any prescription refills of such drug), and (3) correctly submitted the claims and received reimbursement for each three-month period during the term of this IA (Quarterly Claims Review). The IRO shall prepare a Quarterly Claims Review Report, as outlined in Appendix B to this IA, which is incorporated by reference. The first three-month period for purposes of the Quarterly Claims Review requirement shall begin 30 days after the Effective Date. Each Quarterly Claims Review Report shall be submitted to OIG within 60 days following the end of the three-month period covered by the Quarterly Claims Review.

3. *Drug Inventory Review*. The IRO shall conduct a review of Lan Apothecary's prescription drug inventory, to determine the accuracy of the inventory and whether the prescription drug inventory test count results match the amount of prescription drugs purchased from vendors, dispensed to Medicare beneficiaries or any state Medicaid recipients, and billed to Medicare or any state Medicaid program for each three-month period during the term of this IA (Quarterly Drug Inventory Review) and shall prepare a Quarterly Drug Inventory Review Report, as outlined in Appendix C to this IA. The first three-month period for purposes of the Quarterly Drug Inventory Review requirement shall begin 30 days after the Effective Date. Each Quarterly Drug Inventory Review Report shall be submitted to OIG within 60 days following the end of the three-month period covered by the Quarterly Drug Inventory Review.

4. *Independence and Objectivity Certification*. Prior to performing the first Quarterly Claims Review, and annually thereafter, the IRO shall submit to Lan Apothecary a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.C and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this IA. The IRO's certification shall include a summary of all current and prior engagements between Lan Apothecary and the IRO.

D. Ineligible Persons

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

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

i. is currently excluded from participation in any Federal health care program; or

ii. has been convicted of (a) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (b) a criminal offense relating to neglect or abuse of patients; (c) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health care program); or (d) a felony criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov).

2. *Screening Requirements*. Lan Apothecary shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Lan Apothecary shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Lan Apothecary shall screen all current Covered Persons against the Exclusion List within 30 days after the Effective Date and on a monthly basis thereafter.

c. Lan Apothecary shall require all Covered Persons to disclose immediately if they become an Ineligible Person.

Lan Apothecary shall maintain documentation in order to demonstrate that Lan Apothecary: (1) has checked the Exclusion List (i.e., a print screen of the search results) and determined that its Covered Persons are not Ineligible Persons; and (2) has required its Covered Persons to disclose if they are an Ineligible Person.

Nothing in this Section III.D affects Lan Apothecary's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. Lan Apothecary understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Lan Apothecary may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Lan Apothecary meets the requirements of Section III.D.

3. *Removal Requirement*. If Lan Apothecary has actual notice that a Covered Person has become an Ineligible Person, Lan Apothecary shall remove such Covered Person from responsibility for, or involvement with, Lan Apothecary's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions*. If Lan Apothecary has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Lan Apothecary shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

E. Notification of Government Investigation or Legal Proceeding

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

F. Overpayments

1. *Definition of Overpayments*. An "Overpayment" means any funds that Lan Apothecary receives or retains under any Federal health care program to which Lan Apothecary, after applicable reconciliation, is not entitled under such Federal health care program.

2. *Repayment of Overpayments*. If, at any time, Lan Apothecary identifies any Overpayment, Lan Apothecary shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) in accordance with 42 U.S.C. § 1320a-7k(d) and any applicable regulations and guidance from the Centers for Medicare and Medicaid Services (CMS). Lan Apothecary should follow the payor's policies regarding the form of notification and the repayment process for any Overpayment refunds. Any questions regarding the repayment process should be directed to the payor.

G. Reportable Events

1. *Definition of Reportable Event*. For purposes of this IA, a "Reportable Event" means anything that involves:

a. a substantial Overpayment;

b. 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;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.D.1.a; or

d. the filing of a bankruptcy petition by Lan Apothecary.

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

2. *Reporting of Reportable Events*. If Lan Apothecary determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Lan Apothecary shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.G.1.a and III.G.1.b.* For Reportable Events under Section III.G.1.a and b, the report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;

c. the Federal health care programs affected by the Reportable Event;

d. a description of the steps taken by Lan Apothecary to identify and quantify any Overpayments; and

e. a description of Lan Apothecary's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, Lan Apothecary shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and CMS guidance and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.G.1.c.* For Reportable Events under Section III.G.1.c, the report to OIG shall include:

a. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Persons employment or contractual relationship;

c. a description of the Exclusion List screening that Lan Apothecary completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Ineligible Person was identified; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.G.1.d.* If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Lan Apothecary to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Lan Apothecary identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Lan Apothecary is not required by this Section III.G to submit the Reportable Event to CMS through the SRDP.

H. Third Party Billing

If, prior to the Effective Date or at any time during the term of this IA Lan Apothecary contracts with a third party billing company to submit claims to the Federal health care programs on behalf of Lan Apothecary, Lan Apothecary must certify to OIG that it does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company.

Lan Apothecary also shall obtain (as applicable) a certification from any third party billing company that the company: (1) has a policy of not employing any person

who is excluded from participation in any Federal health care program to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (2) screens its prospective and current employees against the Exclusion List; and (3) provides training in the applicable requirements of the Federal health care programs to those employees involved in the preparation and submission of claims to Federal health care programs.

If applicable, a copy of these certifications shall be included in Lan Apothecary's Implementation Report and each Annual Report required by Section V below.

IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS; NEW EMPLOYMENT OR CONTRACTUAL ARRANGEMENT

A. Sales or Purchase of a Location or Business

In the event that, after the Effective Date, Theresa Phan or Lan Apothecary, Inc. propose to (a) sell any or all of their locations or businesses that are subject to this IA (whether through a sale of assets, a sale of stock, or other type of transaction), or (b) purchase or establish a new location or business related to the furnishing of items or services that may be reimbursed by any Federal health care program, the IA shall be binding on the purchaser of any such location or business and any new location or business (and all Covered Persons at each new location or business) shall be subject to the requirements of this IA, unless otherwise determined and agreed to in writing by OIG. Theresa Phan and Lan Apothecary, Inc. shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or proposed purchase, Theresa Phan and Lan Apothecary, Inc. wish to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the IA, Theresa Phan and Lan Apothecary, Inc. must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the location or business to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the proposed purchaser.

B. New Employment or Contractual Arrangement

At least 30 days prior to Theresa Phan becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by any Federal health care program, Theresa Phan shall notify OIG of her plan to become an employee or contractor and must provide OIG with the name, location, status (employee or contractor) and an explanation of Theresa Phan's responsibilities with respect to such potential employer or contractor. In addition, prior to Theresa Phan becoming an

employee or contractor with another party related to the furnishing of items or services that may be reimbursed by any Federal health care program, Theresa Phan shall notify that party of this IA. This notification shall include a copy of the IA and a statement indicating the remaining term of the IA. The IA shall continue to apply to Theresa Phan following the start of the new employment or contractual relationship, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION REPORT, IRO REPORTS AND ANNUAL REPORTS

A. Implementation Report

Within 90 days after the Effective Date,Lan Apothecary shall submit a written report to OIG summarizing the status of its implementation of the requirements of this IA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. a copy of the notice required by Section III.A, a description of where the notice is posted, and the date the notice was posted;

2. the following information regarding the IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this IA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Lan Apothecary that includes a summary of all current and prior engagements between Lan Apothecary and the IRO;

3. a copy of the search result print screens demonstrating that Lan Apothecary has screened all Covered Persons against the Exclusion List, as required by Section III.D, within 30 days of the Effective Date;

4. a copy of any certifications from Lan Apothecary and the third-party billing company required by Section III.H (if applicable);

5. a list of all of Lan Apothecary's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and each location's Medicare and state Medicaid program provider number(s), and/or supplier number(s); and

6. a certification by Theresa Phan and Lan Apothecary, Inc. that: (a) they have reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of their knowledge, except as otherwise described in the Implementation Report, Theresa Phan and Lan Apothecary

are in compliance with all of the requirements of this IA; (c) they have reviewed the Implementation Report and have made a reasonable inquiry regarding its content and believe that the information is accurate and truthful; and (d) they understand that the certification is being provided to and relied upon by the United States

B. IRO Reports

Within 60 days following the end of each three-month period during the term of this IA, Lan Apothecary shall provide to OIG a copy of the Pharmacy Quarterly Claims Review Report and the Quarterly Drug Inventory Review Report prepared by the IRO for each Pharmacy Quarterly Claims Review and the Quarterly Drug Inventory Review Report performed, along with Lan Apothecary's response and corrective action plan related to any recommendations made by the IRO, including Lan Apothecary's determination of whether the CMS overpayment rule requires the repayment of an extrapolated Overpayment (as defined in Appendix B and Appendix C), in the Pharmacy Quarterly Claims Review Report and the Quarterly Drug Inventory Review Report. Each Pharmacy Quarterly Claims Review Report and the Quarterly Drug Inventory Review Report shall include the information specified in Appendix B and Appendix C to this IA.

C. Annual Reports

Lan Apothecary shall submit to OIG a report on its compliance with the IA requirements for each of the three Reporting Periods (Annual Report). Each Annual Report shall, at a minimum, include:

1. (in the first Annual Report) the following information regarding the training required by Section III.B during the first reporting period (and any additional hours of training required for the second and third reporting periods): a copy of the training program registration for each Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program. A copy of all training materials shall be made available to OIG upon request;

2. a certification from the IRO regarding its professional independence and objectivity with respect to Lan Apothecary, including a summary of all current and prior engagements between Lan Apothecary and the IRO;

3. a copy of the search result print screens demonstrating that Lan Apothecary screened all prospective and current Covered Persons against the Exclusion List, as required by Section III.D;

4. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.E. 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;

5. a report of the aggregate Overpayments that have been returned to the Federal health care programs during the Reporting Period. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

6. a summary of Reportable Events (as defined in Section III.G) identified during the Reporting Period;

7. a copy of any certifications from Lan Apothecary and the third-party billing company required by Section III.H (if applicable);

8. a summary of any audits conducted during the applicable Reporting Period by any Medicare or state Medicaid program contractor, and Medicare Part D plan or Medicare Part D plan subcontractor, or any government entity or contractor, involving a review of Federal health care program claims, and Lan Apothecary's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

9. a description of all changes to the most recently provided list of Lan Apothecary's locations (including addresses) as required by Section V.A.5; and

10. a certification signed by Lan Apothecary that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Annual Report, Lan Apothecary is in compliance with all of the requirements of this IA; (c) he or she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful; and (d) he or she understands that the certification is being provided to and relied upon by the United States.

The first Annual Report shall be received by OIG no later than 60 days[1] 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.

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[1] *Do not extend the deadline for the submission of the Annual Report without first consulting with the Team 4 Deputy. If a longer deadline is requested, you should ask for the reason(s) for the request.*

D. Designation of Information

Lan Apothecary 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. Lan Apothecary 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 IA 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, SW
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Lan Apothecary:

Theresa Phan
Lan Apothecary, Inc.907 S 11th Street
Philadelphia, PA 19147
Telephone: (215) 923-1469
Facsimile: (215) 925-3884
Email Address: lanapothecary@aol.com

Unless otherwise specified, all notifications and reports required by this IA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Lan Apothecary may be required to provide OIG with an additional copy of each notification or report required by this IA in OIG's requested format (electronic or paper).

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 conduct interviews, examine or request copies of Lan Apothecary's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Lan Apothecary's locations for the purpose of verifying and evaluating: (a) Lan Apothecary's compliance with the terms of this IA and (b) Lan Apothecary's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Lan Apothecary to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview Lan Apothecary and any of Lan Apothecary's employees or contractors 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. Lan Apothecary shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Lan Apothecary's employees and contractors may elect to be interviewed with or without a representative of Lan Apothecary present.

VIII. DOCUMENT AND RECORD RETENTION

Lan Apothecary shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this IA for four years (or longer if otherwise required by law) from the Effective Date.

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 Lan Apothecary prior to any release by OIG of information submitted by Lan Apothecary pursuant to its requirements under this IA and identified upon submission by Lan Apothecary as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Lan Apothecary shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties

OIG may assess:

1. A Stipulated Penalty of up to $1,000 for each day Lan Apothecary fails to comply with Section III.A;

2. A Stipulated Penalty of up to $1,000 for each day Lan Apothecary fails to comply with Section III.B;

3. A Stipulated Penalty of up to $1,000 for each day Lan Apothecary fails to comply with Section III.C;

4. A Stipulated Penalty of up to $1,000 for each day Lan Apothecary fails to comply with Section III.D;

5. A Stipulated Penalty of up to $1,000 for each day Lan Apothecary fails to comply with Section III.E;

6. A Stipulated Penalty of up to $1,000 for each day Lan Apothecary fails to comply with Section III.F;

7. A Stipulated Penalty of up to $1,000 for each day Lan Apothecary fails to comply with Section III.G;

8. A Stipulated Penalty of up to $1,000 for each day Lan Apothecary fails to comply with Section III.H (if applicable);

9. A Stipulated Penalty of up to $1,000 for each day Lan Apothecary fails to comply with Section IV;

10. A Stipulated Penalty of up to $1,000 for each day Lan Apothecary fails to comply with Section V;

11. A Stipulated Penalty of up to $1,000 for each day Lan Apothecary fails to comply with Section VII;

12. A Stipulated Penalty of up to $1,000 for each day Lan Apothecary fails to comply with Section VIII; or

13. A Stipulated Penalty of up to $50,000 for each false certification submitted by or on behalf of Lan Apothecary under this IA.

B. Timely Written Requests for Extensions

Lan Apothecary 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 IA. 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 Lan Apothecary fails to meet the revised deadline set by OIG. 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 Lan Apothecary 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*. If OIG determines that a bases for Stipulated Penalties under Section X.A exists, OIG shall notify Lan Apothecary of: (a) Lan Apothecary's failure to comply; and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter*. Within 15 business days after the date of the Demand Letter, Lan Apothecary shall either: (a) 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.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

D. Exclusion for Material Breach of this IA

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

a. failure to comply with any of the requirements of this IA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C;

b. failure to comply with Section III.C;

d. failure to comply with Section III.G;

e. failure to comply with Section V;

f. failure to respond to a Demand Letter for Stipulated Penalties in accordance with Section X.C;

g. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Lan Apothecary to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or

h. failure to come into compliance with a requirement for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this IA by Lan Apothecary constitutes an independent basis for Lan Apothecary's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than three years for each material breach. Upon a preliminary determination by OIG that Lan Apothecary has materially breached this IA, OIG shall notify Lan Apothecary of: (a) Lan Apothecary's material breach; and (b) OIG's intent to exclude Lan Apothecary. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice*. Lan Apothecary shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter*. If OIG determines that exclusion is warranted, OIG shall notify Lan Apothecary in writing of its determination to exclude Lan Apothecary. (This letter shall be referred to 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. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by Lan Apothecary, including administrative and management services, except as stated in regulations found at 42 C.F.R. 1001.1901(c). Reinstatement to program participation is not automatic. At the end of the period of exclusion, Lan Apothecary 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 issuing a Demand Letter or Exclusion Letter, and as an agreed-upon remedy for the resolution of disputes arising under this IA, Lan Apothecary 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. 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 DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this IA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 10 days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter; and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

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 IA shall be: (a) whether Lan Apothecary was in full and timely compliance with the requirements of this IA for which OIG demands payment; and (b) the period of noncompliance. Lan Apothecary shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Lan Apothecary has breach this IA and orders Lan Apothecary to pay Stipulated Penalties, Lan Apothecary must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless Lan Apothecary properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, Lan Apothecary must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 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 IA shall be whether Lan Apothecary was in material breach of this IA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. 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. Lan Apothecary shall waive its right to any notice by OIG of the exclusion if a decision upholding the

exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Lan Apothecary, Lan Apothecary shall be reinstated effective on the date of the 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. The parties to this IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA and Lan Apothecary agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XI. EFFECTIVE AND BINDING AGREEMENT

Lan Apothecary and OIG agree as follows:

A. This IA shall become final and binding on the date the final signature is obtained on the IA.

B. This IA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this IA.

C. OIG may agree to a suspension of Lan Apothecary's requirements under this IA based on a certification by Lan Apothecary that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If Lan Apothecary is relieved of its IA requirements, Lan Apothecary shall be required to notify OIG in writing at least 30 days in advance if Lan Apothecary plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the IA will be reactivated or modified.

D. All requirements and remedies set forth in this IA are in addition to and do not affect: (1) Lan Apothecary's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

E. The undersigned Lan Apothecary signatory represents and warrants that she is authorized to execute this IA. The undersigned OIG signatories represent that they are signing this IA in their official capacity and that they are authorized to execute this IA.

F. This IA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same IA. Electronically transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this IA.

ON BEHALF OF LAN APOTHECARY

___/Bachthu Phan/_____ ____11/19/21_____
BACHTHU (THERESA) M. PHAN, RPH DATE
Individually and on behalf of
Lan Apothecary, Inc.

___/David Rubin/_____ ____11/19/21_____
DAVID RUBIN, ESQ. DATE
Counsel for Bachthu (Theresa) M. Phan, RPH
and Lan Apothecary, Inc.

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

/Lisa M. Re/ 12/10/2021

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

/Katie R. Fink/ 12/10/2021

KATIE R. FINK
Senior Counsel
Affirmative Litigation Branch
Office of Inspector General
U. S. Department of Health and Human Services

DATE

APPENDIX A
INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Lan Apothecary 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 objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.2 of the IA or any additional information submitted by Lan Apothecary in response to a request by OIG, whichever is later, OIG will notify Lan Apothecary if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Lan Apothecary may continue to engage the IRO.

2. If Lan Apothecary engages a new IRO during the term of the IA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Lan Apothecary shall submit the information identified in Section V.A.2 of the IA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information, or any additional information submitted by Lan Apothecary at the request of OIG, whichever is later, OIG will notify Lan Apothecary if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Lan Apothecary may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Quarterly Claims Review who have expertise in the Medicare Part D and state Medicaid program requirements and state Board of Pharmacy requirements applicable to the claims being reviewed and the dispensing and billing for prescription drugs;

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

3. assign individuals to conduct the coding review portions of the Quarterly Claims Review who have expertise in pharmacy billing for prescription drugs;

4. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professional acting within their scope of practice and specialized expertise) to make the medical necessity determinations required by the Quarterly Claims Review; and

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

C. IRO Responsibilities

The IRO shall:

1. perform each Quarterly Claims Review in accordance with the specific requirements of the IA;

2. follow all applicable Medicare and state Medicaid program rules and reimbursement guidelines and State Board of Pharmacy requirements in making assessments in the Claims Review;

3. request clarification from the appropriate authority (e.g., Medicare contractor), if in doubt of the application of a particular Medicare or state Medicaid program policy or regulation;

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 and Appendix C to the IA.

D. Lan Apothecary Responsibilities

Lan Apothecary shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in Section III.C of this IA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform each Quarterly Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

1. Lan Apothecary *and IRO*. If Lan Apothecary terminates its IRO or if the IRO withdraws from the engagement during the term of the IA, Lan Apothecary must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG no later than 30 days after termination or withdrawal. Lan Apothecary must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Lan Apothecary in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Lan Apothecary shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Lan Apothecary regarding its IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Lan Apothecary in writing that Lan Apothecary shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Lan Apothecary must engage a new IRO within 60 days of receipt of OIG's written notice. The final determination as to whether or not to require Lan Apothecary to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B
PHARMACY QUARTERLY CLAIMS REVIEW

A. Quarterly Claims Review. The IRO shall conduct a review of Lan Apothecary's claims submitted to and reimbursed by the Medicare and Medicaid programs, to determine whether: (1) the prescription drugs furnished by Lan Apothecary were dispensed according to a valid prescription, (2) Lan Apothecary maintained appropriate documentation of a valid prescription for each drug dispensed (including any refills of such drug), and (3) whether the claims were correctly submitted and reimbursed, for each three-month period during the term of this IA (Quarterly Claims Review) and prepare a report for each Quarterly Claims Review performed. The first three-month period shall begin 30 days following the Effective Date of this IA.

1. *Definitions*. For the purposes of this Appendix B, the following definitions shall be used:

a. Overpayment: The amount of money Lan Apothecary has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix B.

b. Paid Claim: A claim for a prescription drug furnished by Lan Apothecary and submitted by Lan Apothecary and for which Lan Apothecary has received reimbursement from the Medicare program or a state Medicaid program.

c. Population: The Population shall be defined as all Paid Claims during the three-month period covered by the Quarterly Claims Review.

2. *Quarterly Claims Sample.*

a. Within 15 days following the end of each three-month period during the term of the IA, the IRO shall randomly select a sample of 30 Paid Claims submitted by or on behalf of Lan Apothecary during the preceding three-month period (Quarterly Claims Sample). The sample must be selected through the use of OIG's Office of Audit Services' Statistical Sampling Software, also known as RAT-STATS, which is currently available at https://oig.hhs.gov/compliance/rat-stats/index.asp.

b. Lan Apothecary shall provide the IRO with a list of all Lan Apothecary's Paid Claims for the three-month period covered by the Quarterly Claims Sample. The IRO should number each Paid Claim in the Population sequentially prior to generating the random numbers used to select the Quarterly Claims Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the 30 Paid Claims in the Population that will be subject to review by the IRO.

c. The randomly selected 30 Paid Claims shall be reviewed by the IRO based on the supporting documentation available at Lan Apothecary's location or under Lan Apothecary's control and applicable Medicare and state Medicaid program requirements and applicable State Board of Pharmacy requirements to determine whether (i) each prescription drug furnished was dispensed according to a valid prescription, (ii) Lan Apothecary maintained appropriate documentation of a valid prescription for each prescription drug dispensed (including any refills), (iii) any prior authorization required by the payor was obtained, (iv) all cost sharing amounts were collected or waived in accordance with applicable payor requirements, and (v) the claim was correctly submitted and reimbursed.

d. The IRO shall prepare a written report of its findings from the Quarterly Claims Sample, as described in Section C below (Quarterly Claims Review Report). The Quarterly Claims Review Report shall be submitted to the OIG within 60 days following the end of the three-month period covered by each Quarterly Claims Review.

3. *Repayment of Identified Overpayments.* Lan Apothecary shall repay within 60 days any Overpayments identified by the IRO in the Quarterly Claims Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance (the "CMS overpayment rule"). If Lan Apothecary determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Lan Apothecary shall repay that amount at the mean point estimate as calculated by the IRO. Lan Apothecary shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Quarterly Claims Review Sample (and any related work papers) received from Lan Apothecary to the appropriate Medicare or state Medicaid program contractor for appropriate follow up by that payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report for each Quarterly Claims Review performed (Quarterly Claims Review Report). The following information shall be included in each Quarterly Claims Review Report.

1. *Claims Review Methodology*.

a. Claims Review Population. A description of the Population subject to the Quarterly Claims Review.

b. Source of Data. A description of (1) the process used to identify claims in the Population, and (2) the specific documentation relied upon by the IRO when performing the Quarterly Claims Review (e.g., electronic or hard copy prescriptions, physician orders, State pharmacy laws or regulations regarding the dispensing and handling of prescription drugs, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), and Medicare contractor or State Medicaid program manuals or bulletins (including issue and date), other policies, regulations, or directives).

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

d. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in each Quarterly Claims Sample and Lan Apothecary shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Quarterly Claims Sample. If the IRO accepts any supplemental documentation or materials from Lan Apothecary after the IRO has completed its initial review of the Quarterly Claims Sample (Supplemental Materials), the IRO shall identify in the Quarterly Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Quarterly Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Statistical Sampling Documentation*. A copy of the printout of the random numbers generated by the "Random Numbers" function of RAT-STATS used by the IRO to select the Quarterly Claims Sample.

3. *Claims Review Findings*.

a. Narrative Results.

i. For the first Quarterly Claims Review Report only, a description of (a) Lan Apothecary's claim submission system(s), including the identification, by position description, of the personnel involved in claim submission, and (b) a description of controls in place to ensure that all prescription drugs billed to Medicare or a state Medicaid program by Provider are dispensed and billed in accordance with a valid prescription, that documentation of the prescription (including any refills) is maintained, and that the claims are correctly submitted and reimbursed including compliance with any prior authorization requirements and requirements relating to the collection or appropriate waiver of cost-sharing amounts. Subsequent Quarterly Claims Review Reports should describe any significant changes to items (a) and (b) or, if no significant changes were made, state that the systems and controls remain the same as described in the prior Quarterly Claims Review Report.

ii. A narrative explanation of the results of the Quarterly Claims Sample, including reasons for errors, patterns noted, etc.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Lan Apothecary were not supported by valid prescriptions or did not otherwise meet all Medicare and State Medicaid program requirements (including but not limited to any prior authorization requirements) and in which such errors resulted in an Overpayment to Provider.

ii. Total number and percentage of instances in which the IRO determined that Lan Apothecary failed to collect or inappropriately waived any cost-sharing amounts.

iii. Total dollar amount of all Overpayments in the Quarterly Claims Review Sample.

v. Total dollar amount of Paid Claims included in the Quarterly Claims Review Sample.

vi. Error Rate in the Quarterly Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in the Quarterly Claims Review Sample by the total dollar amount associated with the Paid Claims in the Quarterly Claims Review Sample.

vii. An estimate of the actual Overpayment in the Population at the mean point estimate.

viii. A spreadsheet of the Quarterly Claims Sample results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, prescription fill date, National Drug Code (NDC) submitted, quantity prescribed, quantity dispensed, quantity billed, amount reimbursed by payor, correct amount reimbursed (as determined by IRO), and any dollar difference between the amount reimbursed by the payor and the correct amount reimbursed (as determined by the IRO).

c. Recommendations. The IRO's report shall include any recommendations for improvements to Lan Apothecary's claim submission system(s) or to Lan Apothecary's controls for ensuring that all prescription drugs billed to Medicare or a state Medicaid program are dispensed and billed in accordance with a valid prescription and otherwise meet all Medicare and state Medicaid program requirements, including any preauthorization requirements and requirements relating to the collection of cost-sharing amounts, that documentation of the prescription (including any refills) is maintained, and that the claims are correctly submitted and reimbursed, based on the findings of the Quarterly Claims Review.

d. Credentials. The names and credentials of the individuals who: (1) designed the review methodology utilized for the Quarterly Claims Review and (2) performed the Quarterly Claims Review.

C. Other Requirements. The following requirements apply to any Quarterly Claims Review performed pursuant to this Appendix B.

1. *Paid Claims without Supporting Documentation*. Any Paid Claim for which Lan Apothecary cannot produce documentation shall be considered an error and the total reimbursement received by Lan Apothecary for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

2. *Use of First Samples Drawn*. For the purposes of all samples discussed in this Appendix, the Paid Claims selected in each first sample 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 sample).

APPENDIX C
QUARTERLY DRUG INVENTORY REVIEW

A. Quarterly Drug Inventory Review. The IRO shall conduct a review of Lan Apothecary's prescription drug inventory, to determine the accuracy of the inventory and whether the prescription drug inventory test count results match the amount of prescription drugs purchased from vendors, dispensed to Medicare beneficiaries or any state Medicaid recipients, and billed to Medicare or any state Medicaid program for each three-month period during the term of this IA (Quarterly Drug Inventory Review) and shall prepare a Quarterly Drug Inventory Review Report, as outlined in Appendix B to this IA. The first three-month period for purposes of the Quarterly Drug Inventory Review requirement shall begin 30 days after the Effective Date.

1. *Definitions*. For the purposes of the Quarterly Drug Inventory Review and Quarterly Drug Inventory Review Report in this Appendix B, the following definitions shall be used:

   a. Overpayment: The amount of money Lan Apothecary has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements, as determined by the IRO in connection with the Quarterly Claims Review or Quarterly Drug Inventory Review performed under this Appendix B.

   b. Drug Population: The Drug Population shall be defined as all prescription drugs in Lan Apothecary's inventory for which Lan Apothecary has received reimbursement from the Medicare program or a state Medicaid program during the three-month period covered by the Quarterly Drug Inventory Review.

2. *Quarterly Drug Inventory Sample*.

   a. Within 15 days following the end of each three-month period during the term of the IA, the IRO shall randomly select a sample of 30 prescription drugs for which Lan Apothecary has received reimbursement from the Medicare program or any state Medicaid program during the preceding three-month period (Quarterly Drug Inventory Sample). The sample must be selected through the use of OIG's Office of
   Audit Services' Statistical Sampling Software, also known as RAT-STATS, which is currently available at
   https://oig.hhs.gov/compliance/rat-stats/index.asp.

b. Lan Apothecary shall provide the IRO with a list of all of prescription drugs in Lan Apothecary's inventory for the three-month period covered by the Quarterly Drug Inventory Sample. The IRO should number each prescription drug in the Drug Population sequentially prior to generating the random numbers used to select the Quarterly Drug Inventory Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the 30 prescription drugs in the Drug Population that will be subject to review by the IRO.

c. The randomly selected 30 prescription drugs shall be test counted by the IRO and the IRO shall compare the test count results with supporting documentation, including, but not limited to, vendor invoices, order reports, inventory records, dispensing records, billing and claims data, and any related transaction and sales data for each selected prescription drug, available at Lan Apothecary's office or under Lan Apothecary's control to determine the accuracy of the inventory and whether the prescription drug inventory test count results match the amount of prescription drugs purchased from vendors, dispensed to Medicare beneficiaries or any state Medicaid recipients, and billed to Medicare or any state Medicaid program.

d. The IRO shall prepare a written report of its findings from the Quarterly Drug Inventory Sample, as described in Section E below (Quarterly Drug Inventory Review Report). The Quarterly Drug Inventory Review Report shall be submitted to OIG within 60 days following the end of the three-month period covered by each Quarterly Claims Review.

3. *Repayment of Identified Overpayments.* Lan Apothecary shall repay within 60 days any Overpayments identified by the IRO in the Quarterly Drug Inventory Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. §§ 401.301-305 (and any applicable CMS guidance) (the "CMS overpayment rule"). If Lan Apothecary determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Lan Apothecary shall repay that amount at the mean point estimate as calculated by the IRO. Lan Apothecary shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Quarterly Claims Review Sample (and any related work papers) received from Lan Apothecary to the appropriate Medicare or state Medicaid program contractor for appropriate follow up by that payor.

B. Drug Inventory Review Report. The IRO shall prepare a Drug Inventory Review Report for each Quarterly Drug Inventory Review performed (Quarterly Drug Inventory Review Report). The following information shall be included in each Quarterly Drug Inventory Review Report.

1. *Prescription Drug Review Methodology*.

a. Drug Review Population. A description of the Drug Population subject to the Quarterly Drug Inventory Review.

b. Source of Data. A description of (1) the process used to identify prescription drugs in the Drug Population, and (2) the specific documentation relied upon by the IRO when performing the Quarterly Drug Inventory Review (e.g., vendor invoices; order reports; inventory records; dispensing records; billing and claims data; any related transaction and sales data for each selected prescription drug; medical records; CMS program memoranda (including title and issuance number); Medicare contractor manual or bulletins (including issue and date); federal or state statues, regulations, or written directives relating to the management and accountability of prescription drugs; other policies, regulations, or directives).

c. Review Protocol. A narrative description of how the Quarterly Drug Inventory Review was conducted and what was evaluated.

d. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the prescription drugs in each Quarterly Drug Inventory Sample and Lan Apothecary shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Quarterly Drug Inventory Sample. If the IRO accepts any supplemental documentation or materials from Lan Apothecary after the IRO has completed its initial review of the Quarterly Drug Inventory Sample (Supplemental Materials), the IRO shall identify in the Quarterly Drug Inventory Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Quarterly Drug Inventory Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Statistical Sampling Documentation*. A copy of the printout of the random numbers generated by the "Random Numbers" function of RAT-STATS used by the IRO to select the Quarterly Drug Inventory Sample.

3. *Drug Inventory Review Findings*.

a. Narrative Results.

i. For the first Quarterly Drug Inventory Review Report only, a description of (a) Lan Apothecary's prescription drugs inventory system(s), including the identification, by position description, of the personnel involved the management and accountability of prescription drugs, and (b) a description of controls in place to ensure the accurate receipt, storage, inventory, use, financial disposition, and documentation of prescription drugs billed to Medicare or a state Medicaid program by Lan Apothecary. Subsequent Quarterly Drug Inventory Review Reports should describe any significant changes to items (a) and (b) or, if no significant changes were made, state that the systems and controls remain the same as described in the prior Quarterly Drug Inventory Review Report.

ii. A narrative explanation of the results of the Quarterly Drug Inventory Sample, including reasons for errors, patterns noted, etc.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the prescription drug inventory test counts differed from the amount of prescription drugs purchased from vendors, dispensed to Medicare beneficiaries or any state Medicaid recipients, or billed to Medicare or any state

Medicaid program and in which such difference(s) resulted in an Overpayment to Lan Apothecary.

ii. Total dollar amount of all Overpayments in the Quarterly Drug Inventory Review Sample.

iii. Total dollar amount of prescription drugs included in the Quarterly Drug Inventory Review Sample.

vi. Error Rate in the Quarterly Drug Inventory Review Sample. The Error Rate shall be calculated by dividing the Overpayment in the Quarterly Claims Review Sample by the total dollar amount associated with the prescription drugs in Lan Apothecary's inventory for which Lan Apothecary has received reimbursement from the Medicare program or a state Medicaid program in the Quarterly Claims Review Sample.

v. An estimate of the actual Overpayment in the Drug Population at the mean point estimate.

vi. A spreadsheet of the Quarterly Drug Inventory Sample results that includes, but is not limited to, the following information for each prescription drug:

- name of the prescription drug;
- dosage form (e.g., tablet, capsule, injectable);
- product number;
- strength of the prescription drug;
- the prescription drug inventory test count on the date prior to the first day of three-month period (Beginning Test Count);
- the prescription drug inventory test count on the last day of the three-month period the drug (Ending Test Count)
- the quantity of the prescription drug purchased from vendors (Vendor Count);
- the quantity of the prescription drug dispensed to all patients of Lan Apothecary Pharmacy (Total Dispensed Count);
- the quantity of the prescription drug dispensed to Medicare beneficiaries or any state Medicaid recipients (Federal Dispensed Count);
- the quantity of the prescription drug billed to any payor source (Total Billed Count);
- the quantity of the prescription drug billed to Medicare beneficiaries or any state Medicaid recipients (Federal Billed Count);
- the quantity difference between the Beginning Test Count plus the Vendor Count minus the Ending Test Count

(Total Inventory Change);
- the difference between the Total Inventory Change and the Total Dispensed Count; and
- the Error Rate for the prescription drug, calculated by dividing any Overpayment for the prescription drug by the total dollar amount associated with the prescription drug in Lan Apothecary's inventory for which Lan Apothecary has received reimbursement from the Medicare program or a state Medicaid program.

c. Recommendations. The IRO's report shall include any recommendations for improvements to Lan Apothecary's prescription drug inventory system or to Lan Apothecary's controls for ensuring that all prescription drugs billed to Medicare or a state Medicaid program are dispensed and appropriately and accurately documented, received, stored, inventoried, and tracked, based on the findings of the Quarterly Drug Inventory Review. The IRO's report shall identify any errors and potential vulnerabilities with the management and accountability of Lan Apothecary's prescription drug inventory system and recommend appropriate corrective action to Lan Apothecary.

d. Credentials. The names and credentials of the individuals who: (1) designed the review methodology utilized for the Quarterly Drug Inventory Review and (2) performed the Quarterly Drug Inventory Review.

C. Other Requirements for the Quarterly Drug Inventory Review. The following requirements apply to any Quarterly Drug Inventory Review performed pursuant to this Appendix C.

1. *Prescription Drugs without Supporting Documentation*. Any prescription drug in the Drug Population for which Lan Apothecary cannot produce documentation shall be considered an error and the total reimbursement received by Lan Apothecary for such prescription drugs in the Drug Population shall be deemed an Overpayment. Replacement sampling for prescription drugs in the Drug Population with missing documentation is not permitted.

2. *Use of First Samples Drawn*. For the purposes of all samples for the Quarterly Drug Inventory Review discussed in this Appendix, the prescription drugs selected in each first sample 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 sample).