INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ANTIM PATEL, RPH AND
JAI SHRI KRISHNA LLC D/B/A PENNMARK PHARMACY

I. PREAMBLE

Antim Patel, RPH ("Patel") and Jai Shri Krishna LLC d/b/a Pennmark Pharmacy 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). This IA applies to Antim Patel, RPH, Jai Shri Krishna LLC d/b/a Pennmark Pharmacy, and any entity in which Antim Patel, RPH or Jai Shri Krishna LLC d/b/a Pennmark Pharmacy have an ownership or control interest at any time during the term of the IA, as defined in 42 U.S.C. § 1320a-3(a)(3), and any other Covered Persons as defined in Section II.C. Antim Patel, RPH and Jai Shri Krishna LLC d/b/a Pennmark Pharmacy are hereafter collectively referred to as "JSK." Contemporaneously with this IA, JSK is entering into a Settlement Agreement with the United States.

II. EFFECTIVE DATE, TERM, AND DEFINITIONS

A. Effective Date. The "Effective Date" of this IA shall be the signature date of the final signatory to this IA.

B. Term. The term of this IA shall be three years from the Effective Date, except that Sections VII and X shall continue for 120 days after OIG's receipt of: (1) JSK's final Annual Report or (2) any additional documentation relating to the final Annual Report requested by OIG, whichever is later. In addition, if OIG issues a Stipulated Penalties Demand Letter pursuant to Section X.C.1 or a Notice of Material Breach and Intent to Exclude pursuant to Section X.E.2 prior to the expiration of the 120 day period, then Section X shall remain in effect until the Stipulated Penalties Review described in Section X.E.2 or the Exclusion Review described in Section X.E.3 is completed, and JSK complies with the decision.

C. Definitions.

1. "Covered Persons" means: (a) JSK and all owners and employees of JSK; (b) 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 JSK, except that the employees of any third-party billing company that submits claims to the Federal health care programs on behalf of JSK shall not be considered Covered Persons, provided that JSK and the third party billing company provide the

certifications required by Section III.H; and (c) all employees of any entity in which Antim Patel, RPH or Jai Shri Krishna LLC d/b/a Pennmark Pharmacy have an ownership or control interest at any time during the term of this IA (as defined in 42 U.S.C. § 1320a-3(a)(3)) and contractors, agents, or other persons who provide patient care items or services or who perform billing or coding functions on behalf of such entity.

2. "Exclusion Lists" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available at http://www.oig.hhs.gov) and state Medicaid program exclusion lists that are publicly available.

3. "Ineligible Person" means an individual or entity who: (a) is currently excluded from participation in any Federal health care program; or (b) has been convicted of: (i) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (ii) a criminal offense relating to neglect or abuse of patients; (iii) 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 (iv) 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.

4. "Overpayment" means any funds that JSK receives or retains under any Federal health care program to which JSK, after applicable reconciliation, is not entitled under such Federal health care program.

5. "Reportable Event" means: (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 criminal penalties or civil monetary penalties under Section 1128A or 1128B of the Social Security Act (the "Act") or exclusion under Section 1128 of the Act may be authorized; (c) the employment of or contracting with a Covered Person who is an Ineligible Person; or (d) the filing of a bankruptcy petition by JSK.

6. "Reporting Period" means each one-year period during the term of this IA, beginning with the one-year period following the Effective Date.

III. COMPLIANCE PROGRAM REQUIREMENTS

JSK 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, JSK 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 JSK;

b. state Board of Pharmacy requirements relating to the dispensing of prescription drugs by JSK, 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 JSK, 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 JSK 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 JSK of such additional required training at least 180 days prior to the required completion date for such training.

2. *Training Records*. JSK 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 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, JSK shall engage an individual or entity (the "Independent Review Organization" or "IRO"), that meets the qualifications and requirements outlined in Appendix A to this IA, which is incorporated by reference, to perform the reviews described in this Section III.C.

b. *Retention of Records*. The IRO and JSK shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and JSK) related to the reviews described in this Section III.C.

c. *Access to Records and Personnel.* JSK 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. *Pharmacy Claims Review.* The IRO shall review JSK's claims submitted to and reimbursed by the Medicare program, to determine whether JSK: (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 coded, submitted, and reimbursed (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this IA, which is incorporated by reference.

3. *Drug Inventory Review*. The IRO shall conduct a review of JSK'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, and billed to Medicare 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*. The IRO shall include in its report(s) to JSK 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 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 JSK and the IRO.

D. Ineligible Persons

1. *Screening Requirements*. JSK shall:

a. screen all prospective Covered Persons against the Exclusion Lists 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. screen all Covered Persons against the Exclusion Lists within 30 days after the Effective Date and on a monthly basis thereafter; and

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

JSK shall maintain documentation demonstrating that JSK: (1) has checked the Exclusion Lists (i.e., a screen print 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.

2. *Removal Requirement*. If JSK has actual notice that a Covered Person has become an Ineligible Person, JSK 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). Items or services furnished by excluded persons are not payable by Federal health care programs and JSK may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether JSK meets the requirements of Section III.D.

E. Notification of Government Investigation or Legal Proceeding. JSK shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that JSK has committed a crime or has engaged in fraudulent activities, within 30 days of JSK receiving notice of such investigation or legal proceeding. This notification shall include a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Within 30 days after resolution of the matter, JSK shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

F. Overpayments. JSK shall repay any identified 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). JSK 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. JSK shall notify OIG, in writing, within 30 days after determining that a Reportable Event exists, as follows:

1. *Substantial Overpayment.* 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 individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

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

   c. a description of the steps taken by JSK to identify and quantify the Overpayment; and

   d. a description of JSK's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the substantial Overpayment, JSK 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 documentation of the repayment.

2. *Probable Violation of Law.* 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 individuals and entities 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;

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

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

e. a description of JSK'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, JSK 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 documentation of the repayment.

3. *Ineligible Person.* 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 Person's employment or contractual relationship;

c. a description of the Exclusion Lists screening that JSK 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.

4. *Bankruptcy.* The report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

5. *Reportable Events Involving the Stark Law*. Any Reportable Event that involves solely a probable violation of the Stark Law should be submitted by JSK to CMS through the self-referral disclosure protocol (SRDP), with a copy to OIG. However, if JSK identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then JSK is not required by this Section III.G to submit the Reportable Event to CMS through the SRDP, but shall provide OIG with a copy of the repayment documentation.

H. Third Party Billing. If, prior to the Effective Date or at any time during the term of this IA JSK contracts with a third party billing company to submit claims to the Federal health care programs on behalf of JSK, JSK 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.

JSK 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 Lists; 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 JSK's Implementation Report and each Annual Report required by Section V below.

IV. SUCCESSOR LIABILITY; NEW EMPLOYMENT OR CONTRACTUAL ARRANGEMENT

A. Sales or Purchase of a Location or Business

If, after the Effective Date, Patel or Jai Shri Krishna LLC d/b/a Pennmark Pharmacy propose to (1) 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 (2) 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. Patel and Jai Shri Krishna LLC d/b/a Pennmark Pharmacy shall notify OIG, in writing, of such sale or purchase within 30 days following the closing of the transaction and shall notify OIG, in writing, within 30 days of establishing such new location or business.

If Patel or Jai Shri Krishna LLC d/b/a Pennmark Pharmacy wish to obtain a determination by OIG that a proposed purchaser or proposed acquisition will not be subject to the IA requirements, Patel or Jai Shri Krishna LLC d/b/a Pennmark Pharmacy must notify OIG in writing at least 30 days in advance of the proposed sale or purchase. 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 Patel 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, Patel shall notify OIG of his plan to become an employee or contractor and provide OIG with the name, location, status (employee or contractor) and an explanation of Patel's responsibilities with respect to such potential employer or contractor. In addition, prior to Patel 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, Patel 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 Patel 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, JSK shall submit a written report (Implementation Report) to OIG that includes, at a minimum, the following information:

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 JSK that includes a summary of all current and prior engagements between JSK and the IRO;

3. a copy of the search result screens prints demonstrating that JSK has screened all Covered Persons against the Exclusion Lists, as required by Section III.D;

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

5. a list of all of JSK's locations (including 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. certifications signed by Patel and Jai Shri Krishna LLC d/b/a Pennmark Pharmacy 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 Implementation Report, JSK is in compliance with all of the requirements of this IA;

   c. he or she has reviewed the Implementation 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.

B. IRO Reports for the Quarterly Drug Inventory Review

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

C. Annual Reports. JSK shall submit to OIG a written report (Annual Report) for each of the three Reporting Periods that includes, at a minimum, the following information:

1. (in the first Annual Report) the following information regarding the training required by Section III.B during the first Reporting Period (and in the second and third Annual Reports, any additional hours of training required for the second and third Reporting Periods):

   a. a copy of the training program registration for each Covered Person who completed the training;

   b. the title of the training course;

   c. the name of the individual or entity that provided the training;

   d. the location, date, and length of the training; and

   e. a brochure or other documentation that describes the content of the training program. (A copy of all training materials shall be made available to OIG upon request.)

2. a complete copy of all reports prepared pursuant to Section III.C and JSK's response to the reports, along with corrective action plan(s) related to any issues raised by the report and documentation of JSK's refund of the Estimated Overpayment (as defined in Appendix B and Appendix C to this IA);

3. a certification from the IRO regarding its professional independence and objectivity with respect to JSK that includes a summary of all current and prior engagements between JSK and the IRO;

4. a copy of the search result screen prints demonstrating that JSK screened all prospective and current Covered Persons against the Exclusion Lists, as required by Section III.D;

5. a summary of any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.E that includes a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

6. 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;

7. a summary of Reportable Events required to have been reported pursuant to Section III.G during the Reporting Period;

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

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

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

11. certifications signed by Patel and Jai Shri Krishna LLC d/b/a Pennmark Pharmacy 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, JSK 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 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.

D. Designation of Information. JSK shall clearly identify any portions of its submissions that they believe 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. JSK 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

All notifications and reports required under this IA shall be submitted using the following contact information:

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 5628
330 Independence Avenue, SW
Washington, DC 20201
Telephone: (202) 619-2078
Email Address: officeofcounsel@oig.hhs.gov

JSK:

Antim Patel, RPH
Jai Shri Krishna LLC d/b/a Pennmark Pharmacy
1735 South Street, FL 1
Philadelphia, PA 19146
Telephone: (215) 735-1200
Facsimile: (215) 735-0455
Email Address: pennmarkrs@gmail.com

Unless otherwise requested by OIG, all notifications and reports required by this IA shall be submitted electronically. OIG shall notify JSK in writing of any changes to the OIG contact information listed above. JSK shall notify OIG in writing within two business days of any changes to the JSK contact information listed above.

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 and/or request copies of or copy JSK's books, records, and other documents and supporting materials, and conduct on-site reviews of any of JSK's locations, for the purpose of evaluating: (a) JSK's compliance with the terms of this IA and (b) JSK's compliance with the requirements of the Federal health care

programs. The documentation described above shall be made available by JSK to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. For purposes of this provision, OIG or its duly authorized representative(s) may interview JSK and any of JSK'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. JSK shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. JSK's employees and contractors may elect to be interviewed with or without a representative of JSK present.

VIII. DOCUMENT AND RECORD RETENTION

JSK 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 JSK prior to any release by OIG of information submitted by JSK pursuant to its requirements under this IA and identified upon submission by JSK as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, JSK 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 JSK fails to comply with Section III.A;

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

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

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

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

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

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

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

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

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

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

12. A Stipulated Penalty of up to $1,000 for each day JSK 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 JSK under this IA.

B. Timely Written Requests for Extensions. JSK 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 JSK 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 JSK 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 basis for Stipulated Penalties under Section X.A exists, OIG shall notify JSK of: (a) JSK'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, JSK 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.

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, unless such Stipulated Penalty was overturned by an ALJ on appeal pursuant to the procedures described in Section X.E below;

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. a false statement or false certification made to OIG by or on behalf of JSK under this IA;

h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering JSK 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

i. 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 JSK constitutes an independent basis for JSK'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 JSK has materially breached this IA, OIG shall notify JSK of: (a) JSK's material breach and (b) OIG's intent to exclude JSK. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice*. JSK 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 JSK in writing of its determination to exclude JSK. (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 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 JSK, including administrative and management services, except as stated in regulations found at 42 C.F.R. 1001.1901(c). The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, JSK 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, JSK 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 JSK was in full and timely compliance with the requirements of this IA for which OIG demands payment and (b) the period of noncompliance. JSK shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that JSK has breached this IA and orders JSK to pay Stipulated Penalties, JSK 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 JSK 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, JSK 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 JSK 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. JSK shall waive its right to any notice of such exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of JSK, JSK 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 JSK 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

JSK and OIG agree as follows:

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

B. All requirements and remedies set forth in this IA are in addition to and do not affect: (1) JSK'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.

C. The undersigned JSK signatory represents and warrants that he 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.

D. 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 ANTIM PATEL, RPH AND
JAI SHRI KRISHNA LLC D/B/A PENNMARK PHARMACY

/Antim Patel/ 12-20-2023
ANTIM PATEL, RPH DATE
Individually and on behalf of
Jai Shri Krishna LLC d/b/a Pennmark Pharmacy

/Satish Poondi/ 12/21/2023
SATISH POONDI, ESQ. DATE
Counsel for Antim Patel, RPH and
Jai Shri Krishna LLC d/b/a Pennmark Pharmacy

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

/Susan Gillin/ 12/20/2023
LISA M. RE DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

/Katie R. Fink/ 1/7/2024
KATIE R. FINK DATE
Senior Counsel
Affirmative Litigation Branch
Office of Inspector General
U. S. Department of Health and Human Services

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. JSK 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 JSK in response to a request by OIG, whichever is later, OIG will notify JSK if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, JSK may continue to engage the IRO.

2. If JSK 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, JSK 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 JSK at the request of OIG, whichever is later, OIG will notify JSK if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, JSK may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review and Quarterly Drug Inventory Review and who have expertise in the Federal health care 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 Claims Review sample and Quarterly Drug Inventory Review sample who are knowledgeable about the appropriate statistical sampling techniques; and

3. 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 Claims Review and Quarterly Drug Inventory Review in accordance with the specific requirements of the IA;

2. follow all applicable Federal health care program rules and reimbursement guidelines and State Board of Pharmacy requirements in making assessments in the Claims Review and Quarterly Drug Inventory Review;

3. request clarification from the applicable Federal health care program if in doubt of the application of a particular 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. JSK Responsibilities

JSK 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 Claims Review and Quarterly Drug Inventory 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. JSK *and IRO*. If JSK terminates its IRO or if the IRO withdraws from the engagement during the term of the IA, JSK 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. JSK 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 JSK in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. JSK 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 JSK regarding its IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify JSK in writing that JSK shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. JSK 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 JSK to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B
PHARMACY CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review for each of the three Reporting Periods.

1. *Definitions*.

a. "Paid Claim" means a prescription drug claim submitted by JSK and for which JSK has received reimbursement from the Medicare program.

b. "Population" means all Paid Claims during the 12-month period covered by the Claims Review. In OIG's discretion, OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed and shall notify JSK and the IRO of its selection of the Population at least 30 days prior to the end of each Reporting Period. JSK, or its IRO on behalf of JSK, may submit proposals identifying suggestions for the subset(s) of Paid Claims to be reviewed at least 90 days prior to the end of each Reporting Period. In connection with limiting the Population, OIG may consider (1) proposals submitted by JSK or its IRO, (2) information furnished to OIG regarding the results of JSK's internal risk assessment and internal auditing, or (3) other information obtained by OIG. The determination of whether, and in what manner, to limit the Population shall be made at the sole discretion of OIG.

c. "Overpayment" means the amount of money JSK has received for any Paid Claim in excess of the amount due and payable under Medicare program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix B.

d. "Error Rate" means the percentage of net Overpayments identified in the Claims Review Sample. The net Overpayment shall be calculated by subtracting all underpayments identified in the Claims Review Sample from all Overpayments identified in the Claims Review Sample. The Error Rate is calculated by dividing the net Overpayment by the total dollar amount associated with the Paid Claims in the Claims Review Sample.

2. *Claims Review Sample.* The IRO shall select a random sample of 100 Paid Claims (Claims Review Sample). The IRO shall review the Paid Claims based on JSK's documentation, applicable Medicare program requirements, and applicable State Board of Pharmacy requirements to determine whether (i) each prescription drug was dispensed according to a valid prescription, (ii) JSK maintained appropriate documentation of a valid prescription for each prescription drug dispensed (including any refills), (iii) any prior authorization required by the payor was properly obtained in accordance with payor requirements, (iv) all cost-sharing

amounts were collected or appropriately waived, and (v) the claim was correctly submitted and reimbursed.

3. *Other Requirements.*

a. Supplemental Materials. The IRO shall request all documentation required for its review of the Paid Claims in the Claims Review Sample and JSK shall furnish such documentation to the IRO prior to the IRO initiating its review of the Claims Review Sample. If the IRO accepts any supplemental documentation from JSK after the IRO has completed its initial review of the Claims Review Sample (Supplemental Materials), the IRO shall include the following in the Claims Review Report: (i) a description of the Supplemental Materials, (ii) the date the Supplemental Materials were accepted, (iii) the IRO's reason(s) for accepting the Supplemental Materials, and (iv) the relative weight the IRO gave to the Supplemental Materials in its review.

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

c. Use of First Samples Drawn. The first set of Paid Claims selected shall be used for the Claims Review Sample (i.e., it is not permissible to generate more than one list of random samples and then select one for use).

4. *Repayment of Estimated Overpayment.* The findings of the Claims Review shall be used by the IRO to estimate the actual Overpayment in the Population with the point estimate and a two-sided 90% confidence interval. Within 60 days of receipt of the Claims Review Report, JSK shall repay the lower limit of the two-sided 90% confidence interval (Estimated Overpayment) to the Centers for Medicare and Medicaid Services (CMS). Documentation of JSK's refund of the Estimated Overpayment to CMS shall be submitted to OIG with JSK's Annual Report. OIG, in its sole discretion, may refer the findings of the Claims Review Sample to CMS for appropriate follow up.

B. Claims Review Report. The IRO shall prepare a Claims Review Report for each Claims Review that includes the following information:

1. *Claims Review Methodology.*

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

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

c. Source of Data. A description of (1) the process used to identify Paid Claims in the Population and (2) the specific documentation and other information relied on by the IRO when performing the 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 manuals or bulletins (including issue and date), other policies, regulations, or directives).

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

e. Supplemental Materials. A description of any Supplemental Materials as required by A.3.a., above.

2. *Statistical Sampling Documentation.*

a. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

b. A description or identification of the statistical sampling software package used by the IRO.

3. *Claims Review Findings.*

a. Narrative Results.

i. A description of JSK's claim submission system(s), including the identification, by position description, of the personnel involved in claims submission.

ii. A description of controls in place at JSK: (a) to ensure that all prescription drugs billed to the Medicare program 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 (b) relating to the collection or appropriate waiver of cost-sharing amounts.

iii. A narrative explanation of the results of the IRO's review of the Claims Review, including an explanation of all errors identified by the IRO.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by JSK were not supported by valid prescriptions or did not otherwise meet all applicable Medicare program requirements (including, but not limited to any prior authorization requirements).

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

iii. Total dollar amount of Paid Claims included in the Claims Review Sample and the net Overpayment associated with the Claims Review Sample.

iv. Error Rate in the Claims Review Sample.

v. An estimate of the actual Overpayment in the Population with the point estimate and a two-sided 90% confidence interval.

vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim:

1. Federal health care program billed;
2. Beneficiary health insurance claim number;
3. Prescription fill date;
4. National Drug Code (NDC) submitted;
5. Quantity prescribed;
6. Quantity dispensed;
7. Quantity billed;
8. Quantity reimbursed;
9. Amount reimbursed by payor;
10. Correct amount reimbursed (as determined by the IRO); and
11. The dollar difference between the amount reimbursed by the payor and the correct amount reimbursed.

c. Recommendations. The IRO's report shall include any recommendations for improvements to JSK's claim submission system or to JSK's controls for ensuring: (1) that all prescription drugs billed to the Medicare program are dispensed and billed in accordance with a valid prescription and otherwise meet all Medicare program requirements, including any preauthorization requirements; (2) that documentation of the prescription (including any refills) is maintained, and that the claims are correctly

submitted and reimbursed; and (3) that cost-sharing amounts are collected or appropriately waived.

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

APPENDIX C
QUARTERLY DRUG INVENTORY REVIEW

A. Quarterly Drug Inventory Review. The IRO shall conduct a review of JSK'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 C, the following definitions shall be used:

a. "Overpayment" means the amount of money JSK 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 Drug Inventory Review performed under this Appendix C.

b. "Drug Population" means all prescription drugs in JSK's inventory for which JSK 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 JSK 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. JSK shall provide the IRO with a list of all of prescription drugs in JSK'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 JSK's office or under JSK'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 Drug Inventory Review.

3. *Other Requirements.*

a. 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 JSK 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 JSK after the IRO has completed its initial review of the Quarterly Drug Inventory Sample (Supplemental Materials), the IRO shall include the following in the Quarterly Drug Inventory Review Report: (i) a description of the Supplemental Materials, (ii) the date the Supplemental Materials were accepted, (iii) the IRO's reason(s) for accepting the Supplemental Materials, and (iv) the relative weight the IRO gave to the Supplemental Materials in its review.

b. Prescription Drugs without Supporting Documentation. Any prescription drug in the Drug Population for which JSK cannot produce documentation, including purchasing or dispensing records, shall be considered an error and the total reimbursement received by JSK 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.

c. 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).

4. *Repayment of Estimated Overpayments.* The findings of the Quarterly Drug Inventory Review shall be used by the IRO to estimate the actual Overpayment in the Population with the point estimate and a two-sided 90% confidence interval. Within 60 days of receipt of the Claims Review Report, JSK shall repay the lower limit of the two-sided 90% confidence interval (Estimated Overpayment) to the applicable payor(s). Documentation of JSK's refund of the Estimated Overpayment to the applicable payor(s) shall be submitted to OIG with JSK's Annual Report. OIG, in its sole discretion, may refer the findings of the Claims Review Sample to the applicable payor(s) for appropriate follow up.

B. Drug Inventory Review Report. The IRO shall prepare a Drug Inventory Review Report for each Quarterly Drug Inventory Review that includes the following information:

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.

2. *Statistical Sampling Documentation*.

   a. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

   b. A description or identification of the statistical sampling software package used by the IRO.

3. *Drug Inventory Review Findings.*

a. Narrative Results.

i. For the first Quarterly Drug Inventory Review Report only, a description of (a) JSK'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 JSK. 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 IRO's review Quarterly Drug Inventory Review, including an explanation of all errors identified and patterns noted by the IRO.

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 JSK.

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 Drug Inventory Review Sample by the total dollar amount associated with the prescription drugs in JSK's inventory for which JSK has received reimbursement from the Medicare program or a state Medicaid program in the Quarterly Drug Inventory Review Sample.

v. An estimate of the actual Overpayment in the Drug Population with the point estimate and a two-sided 90% confidence interval.

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 the three-month period (Beginning Test Count);
- the prescription drug inventory test count on the last day of the three-month period (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 JSK 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 JSK's inventory for which JSK has received reimbursement from the Medicare program or a state Medicaid program.

b. Recommendations. The IRO's report shall include any recommendations for improvements to JSK's prescription drug inventory system or to JSK'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 JSK's prescription drug inventory system and recommend appropriate corrective action to JSK.

4. *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.