

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
OLIVE STREET PHARMACY, LLC**

I. PREAMBLE

Olive Street Pharmacy, LLC (Provider) hereby enters 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). Contemporaneously with this IA, Provider 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) Provider’s final annual report; or (2) any additional materials submitted by Provider pursuant to OIG’s request, whichever is later.

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

III. COMPLIANCE PROGRAM REQUIREMENTS

Provider shall establish and maintain a compliance program that includes the following elements:

A. Compliance Contact

Within 90 days after the Effective Date, Provider shall designate a Compliance Contact and shall maintain a Compliance Contact for the term of the IA. The Compliance Contact shall be responsible for: (1) monitoring Provider's day-to-day compliance activities, (2) meeting any reporting requirements created under this IA, and (3) responding to questions and concerns from OIG regarding Provider's compliance with the IA. The Compliance Contact shall make periodic (at least quarterly) reports regarding compliance matters to the Provider. Written documentation of the Compliance Contact's reports to the Provider shall be made available to OIG upon request. The Compliance Contact shall not have any responsibilities that involve acting in any capacity as legal counsel or supervising legal functions for Provider and any non-compliance job responsibilities shall not involve billing, coding, or claim submission (or oversight for those functions) for Provider.

Provider shall report to OIG, in writing, any changes in the identity or job responsibilities of the Compliance Contact, or any actions or changes that would affect the Compliance Contact's ability to perform the duties necessary to meet the requirements in this IA, within five business days after such a change.

B. Policies and Procedures

Within 90 days after the Effective Date, Provider shall develop and implement written policies and procedures regarding appropriate billing and medical record documentation for compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this IA, Provider shall enforce its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

The Policies and Procedures shall be made available to all Covered Persons.

At least annually (and more frequently, if appropriate), Provider shall assess and update, as necessary, the Policies and Procedures. Any revised or new Policies and

Procedures shall be made available to all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. Posting of Notice

Within 90 days after the Effective Date, Provider shall post in a prominent place accessible to all patients and Covered Persons a notice that provides the name and phone number of the Compliance Officer and 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.

D. Training and Education

1. *Covered Persons Training.* All Covered Persons shall receive at least three hours of training during the first Reporting Period. Any individuals who become Covered Persons after the Effective Date and during the term of this IA shall receive at least three hours of training within 90 days of becoming a Covered Person.

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 the items or services furnished by Provider;
- b. the Federal health care program medical record documentation requirements relating to items or services furnished by Provider; and
- c. the personal obligation of each individual involved in the medical record (including prescription record) documentation and claims submission processes to ensure that medical records and claims are accurate.

The OIG may, in its discretion, require that 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 Provider of such additional required training at least 180 days prior to the required completion date for such training.

2. *Training Records.* Provider 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.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Provider 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.E. 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 Provider shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Provider) related to the reviews.
- c. *Access to Records and Personnel.* Provider shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E and that all records furnished to the IRO are accurate and complete.

2. *Claims Review.* The IRO shall conduct a review of Provider’s claims submitted to and reimbursed by the Medicare and Medicaid programs to determine whether: (1) the prescription drugs furnished by provider were dispensed according to a valid prescription, (2) Provider maintained appropriate documentation of a valid prescription for each drug dispensed including any prescription refills, (3) the claims were correctly submitted and reimbursed for each three-month period during the term of this IA (Quarterly Claims Review), and (4) 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. *Independence and Objectivity Certification.* Prior to performing the first Quarterly Claims Review, and annually thereafter, the IRO shall submit to Provider a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E 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 Provider and the IRO.

F. 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.* Provider shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Provider 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. Provider shall screen all current Covered Persons against the Exclusion List within 30 days after the Effective Date and on a monthly basis thereafter.
- c. Provider shall require all Covered Persons to immediately disclose immediately if they become an Ineligible Person.

Provider shall maintain documentation in order to demonstrate that Provider: (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.F affects Provider’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. Provider understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Provider may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Provider meets the requirements of Section III.F.

3. *Removal Requirement.* If Provider has actual notice that a Covered Person has become an Ineligible Person, Provider shall remove such Covered Person from responsibility for, or involvement with, Provider’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 Provider 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, Provider 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.

G. Notification of Government Investigation or Legal Proceeding

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

H. Overpayments

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

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, Provider shall develop and implement written policies and procedures regarding the identification, quantification and repayment of Overpayments received from any Federal health care program.

3. *Repayment of Overpayments.* If, at any time, Provider identifies any Overpayment, Provider shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and guidance from the Centers for Medicare and Medicaid Services (CMS). Provider 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.

I. 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.F.1.a; or
- d. the filing of a bankruptcy petition by Provider.

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

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

3. *Reportable Events under Section III.I.1.a. and III.I.1.b.* For Reportable Events under Section III.I.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 Provider to identify and quantify any Overpayments; and
- e. a description of Provider'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, Provider shall repay the Overpayment, 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 and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.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 Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that Provider 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.I.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 Provider to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Provider identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Provider is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP.

J. Third Party Billing

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

Provider 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 Provider's Implementation Report and each Annual Report required by Section V below.

IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS

In the event that, after the Effective Date, Provider proposes to (a) sell any or all of its locations or businesses that are subject to this IA (whether through a sale of assets, 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. Provider 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, Provider wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the IA, Provider 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 prospective purchaser.

V. IMPLEMENTATION REPORT, IRO REPORTS, AND ANNUAL REPORTS

A. Implementation Report

Within 90 days after the Effective Date, Provider 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. the name, address, phone number, and position description of the Compliance Contact required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Contact may have;
2. a list of the Policies and Procedures required by Section III.B.;
3. a copy of the notice required by Section III.C, a description of where the notice is posted, and the date the notice was posted;
4. 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 Provider that includes a summary of all current and prior engagements between Provider and the IRO;

5. a copy of the search result print screens demonstrating that Provider has screened all Covered Persons against the Exclusion List as required by Section III.F within 30 days of the Effective Date;

6. a copy of Provider's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.H;

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

8. a list of all of Provider'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

9. a certification by the Compliance Contact 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, Provider 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 this 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, Provider shall provide to OIG a copy of the Quarterly Claims Review Report prepared by the IRO for each Quarterly Claims Review performed, along with Provider's response and corrective action plan related to any recommendations made by the IRO in the Quarterly Claims Review Report. Each Quarterly Claims Review Report shall include the information specified in Appendix B to this IA.

C. Annual Reports

Provider 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 include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Contact described in Section III.A;
2. a list of any new or revised Policies and Procedures developed during the Reporting Period;
3. (in the first Annual Report) the following information regarding the training required by Section III.D: 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 describes the content of the training program. A copy of all training materials shall be made available to OIG upon request;
4. a certification from the IRO regarding its professional independence and objectivity with respect to Provider that includes a summary of all current and prior engagements between Provider and the IRO;
5. a copy of the search result print screens demonstrating that Provider screened all prospective and current Covered Persons against the Exclusion List, as required by Section III.F;
6. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
7. a description of any changes to the Overpayment policies and procedures required by Section III.H, including the reasons for such changes;
8. 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;
9. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;
10. a copy of any certifications from Provider and the third party billing company required by Section III.J (if applicable);

11. a summary of any audits conducted during the applicable Reporting Period by any Medicare or state Medicaid program contractor, any 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 Provider's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

12. a description of all changes to the most recently provided list of Provider's locations (including addresses) as required by Section V.A.8; and

13. a certification signed by Provider's Compliance Contact 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, Provider 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 this 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

Provider 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. Provider 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

Provider:

Alexander Shlafshiteyn
Olive Street Pharmacy
10420 Old Olive Street Road, Ste. 103
Creve Coeur, MO 63141
shlafik@hotmail.com
314-504-0404

and

Steven E. Holtshouser, Esq.
Husch Blackwell
190 Carondelet Ave., 6th Floor
St. Louis, MO 63105
Steve.holtshouser@huschblackwell.com
314-345-6269

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

VIII. DOCUMENT AND RECORD RETENTION

Provider 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 Provider prior to any release by OIG of information submitted by Provider pursuant to its requirements under this IA and identified upon submission by Provider as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Provider 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 Provider fails to comply with Section III.A;
2. A Stipulated Penalty of up to \$1,000 for each day Provider fails to comply with Section III.B;
3. A Stipulated Penalty of up to \$1,000 for each day Provider fails to comply with Section III.C;
4. A Stipulated Penalty of up to \$1,000 for each day Provider fails to comply with Section III.D;
5. A Stipulated Penalty of up to \$1,000 for each day Provider fails to comply with Section III.E;
6. A Stipulated Penalty of up to \$1,000 for each day Provider fails to comply with Section III.F;
7. A Stipulated Penalty of up to \$1,000 for each day Provider fails to comply with Section III.G;
8. A Stipulated Penalty of up to \$1,000 for each day Provider fails to comply with Section III.H;
9. A Stipulated Penalty of up to \$1,000 for each day Provider fails to comply with Section III.I;
10. A Stipulated Penalty of up to \$1,000 for each day Provider fails to comply with Section III.J (if applicable);
11. A Stipulated Penalty of up to \$1,000 for each day Provider fails to comply with Section IV;
12. A Stipulated Penalty of up to \$1,000 for each day Provider fails to comply with Section V;

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

14. A Stipulated Penalty of up to \$1,000 for each day Provider fails to comply with Section VIII; or

15. A Stipulated Penalty of up to \$50,000 for each false certification or false statement made to OIG by or on behalf of Provider under this IA.

B. Timely Written Requests for Extensions

Provider 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 Provider 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 Provider 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 Provider of: (a) Provider'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, Provider 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.A;
 - c. failure to comply with Section III.E;
 - d. failure to comply with Section III.I;
 - 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 Provider 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 Provider constitutes an independent basis for Provider'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 Provider has materially breached this IA, OIG shall notify Provider of: (a) Provider's material breach; and (b) OIG's intent to exclude Provider. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice.* Provider 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 Provider in writing of its determination to exclude Provider. (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 Provider, 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, Provider 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, Provider 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 15 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 Provider was in full and timely compliance with the requirements of this IA for which OIG demands payment; and (b) the period of noncompliance. Provider shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG’s determination that Provider has breached this IA and orders Provider to pay Stipulated Penalties, Provider 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 Provider 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, Provider 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 Provider 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. Provider 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 Provider, Provider 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 Provider 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

Provider 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 Provider's requirements under this IA based on a certification by Provider 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 Provider is relieved of its IA requirements, Provider

shall be required to notify OIG in writing at least 30 days in advance if Provider 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) Provider'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 Provider signatories represent and warrant that they are 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 Provider

OLIVE STREET PHARMACY, LLC

/Alexander Shlafshteyn/

BY: _____
ALEXANDER SHLAFSHTEYN
Manager

9/28/21

DATE: _____

BY: /Steven E. Holtshouser/

STEVEN E. HOLTSHOUSER
Husch Blackwell LLP
Counsel for Olive Street Pharmacy, LLC

DATE: 9-27-21

BY: /Matthew Eddy/

MATTHEW J. EDDY
Lashly & Baer, P.C.
Counsel for Olive Street Pharmacy, LLC

DATE: 9-27-21

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

/Lisa M. Re/

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

9/30/21

DATE

/Nancy W. Brown/

NANCY W. BROWN
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

9.30.2021

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Provider 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.4 of the IA or any additional information submitted by Provider in response to a request by OIG, whichever is later, OIG will notify Provider if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Provider may continue to engage the IRO.

2. If Provider 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, Provider shall submit the information identified in Section V.A.4 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 Provider at the request of OIG, whichever is later, OIG will notify Provider if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Provider 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 requirements and state Medicaid program requirements and state Board of Pharmacy requirements applicable to 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; and

4. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professionals 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, as well as applicable 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 inquiries in a prompt, objective, and factual manner; and

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

D. Provider Responsibilities

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

E. IRO Independence and Objectivity

The IRO must perform the 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. *Provider and IRO.* If Provider terminates its IRO or if the IRO withdraws from the engagement during the term of the IA, Provider 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. Provider 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 Provider in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Provider 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 Provider regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Provider in writing that Provider shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Provider must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Provider to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

QUARTERLY CLAIMS REVIEW

A. Quarterly Claims Review. The IRO shall conduct a review of Provider's claims submitted to and reimbursed by the Medicare and Medicaid programs, to determine whether: (1) the prescription drugs furnished by Provider were dispensed according to a valid prescription, (2) Provider maintained appropriate documentation of a valid prescription for each drug dispensed (including any refills of such drug), and (3) whether the claims were correctly coded, billed, 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 Provider 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 Provider and submitted by Provider and for which Provider 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 Provider 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. Provider shall provide the IRO with a list of all Provider'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 Provider's office or under Provider's control and applicable Medicare and state Medicaid program requirements and applicable State Board of Pharmacy requirements to determine whether each prescription was dispensed according to a valid prescription, whether documentation of the prescription (including any refills) is maintained and appropriately documented, whether the claim was correctly submitted, and reimbursed. For each Paid Claim reviewed, the IRO should verify that Provider maintained documentation of: (1) the prescription order for the drug dispensed; (2) the delivery of the drug; and (3) any required steps to initiate and process a prescription refill.
- 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.* Provider 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 Provider determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Provider shall repay that amount at the mean

point estimate as calculated by the IRO. Provider 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 Provider 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., medical records, physician orders, including drug prescriptions), 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), Medicare contractor manual 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 Provider 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 Provider 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) Provider's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing, and (b) a description of controls in place to ensure that all items and services 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. 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 Provider (Submitted Claim) differed from what should have been the correct claim (Correct Claim) and in which such difference resulted in an Overpayment to Provider.

- ii. Total number and percentage of instances in which the IRO determined that Provider did not maintain adequate documentation of a prescription drug (or refill) for which a Paid Claim was submitted and in which such documentation errors resulted in an Overpayment to Provider.
 - iii. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items or services that were not medically necessary and resulted in an Overpayment to Provider.
 - iv. 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, date of service, national drug code submitted, quantity prescribed, quantity dispensed, quantity billed, amount reimbursed by payor, correct amount reimbursed (as determined by IRO), and any dollar difference between allowed amount reimbursed by payor and the correct amount reimbursed (as determined by the IRO).
- c. Recommendations. The IRO's report shall include any recommendations for improvements to Provider's billing and coding system or to Provider's controls for ensuring that all items and services billed to Medicare or a state Medicaid program are

medically necessary and appropriately documented, 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 Provider cannot produce documentation shall be considered an error and the total reimbursement received by Provider 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).