

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
GREGORY H. BALOTIN**

I. PREAMBLE

Gregory H. Balotin (Balotin) 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). The compliance program requirements in this IA apply to Balotin and any entity in which he has 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 which submits claims for items or services to any Federal health care program (hereinafter referred to as an “Owned or Controlled Entity”).¹ Contemporaneously with this IA, Balotin 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) Balotin’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 Balotin complies with the decision.

C. Definitions.

¹ As of the Effective Date of this IA, the only known entity in which Balotin has an ownership or control interest is SPRX, Inc., a compounding and retail pharmacy.

1. “Covered Persons” means: (a) Balotin and all employees of Balotin; (b) all owners and employees of any Owned or Controlled Entity; and (c) all contractors who furnish patient care items or services, who are involved in compounding or dispensing prescription drugs, medications, and/or creams, or who perform billing or coding functions on behalf of Balotin, except that the employees of any third-party billing company that submits claims to the Federal health care programs on behalf of Balotin or any Owned or Controlled Entity shall not be considered Covered Persons, provided that Balotin and the third party billing company provide the certifications required by Section III.H.

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 Balotin or any Owned or Controlled Entity receives or retains under any Federal health care program to which Balotin or to which any Owned or Controlled Entity, after applicable reconciliation, is not entitled under such Federal health care program.

5. “Reportable Event” means: (a) a substantial Overpayment; (b) a matter involving Balotin or any Owned or Controlled Entity 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 Balotin.

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

Balotin 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, Balotin and any Owned or Controlled Entity 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 the items or services and prescriptions, including compounded medications and creams, furnished by Balotin and any Owned or Controlled Entity, and the collection or waiver of cost-sharing for items or services and prescriptions, including compounded medications and creams, furnished by Balotin and any Owned or Controlled Entity;
- b. the Federal health care program medical record documentation requirements relating to items or services and prescriptions, including compounded medications and creams, furnished by Balotin and any Owned or Controlled Entity;
- c. the personal obligation of each individual involved in the medical record documentation and claim submission processes to ensure that medical records and claims are accurate; and
- d. applicable Medicare requirements, U.S. Food and Drug Administration (FDA) requirements, and state pharmacy law requirements regarding compounded medications and creams and their ingredients.

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 Balotin 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 Balotin of such additional required training at least 180 days prior to the required completion date for such training.

2. *Training Records.* Balotin 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, Balotin 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 Balotin shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and Balotin related to the reviews described in this Section III.C.

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

2. *Claims Review.* The IRO shall review prescription drug claims submitted by or on behalf of Balotin and any Owned or Controlled Entity and reimbursed by the Medicare program, to determine whether: (1) the prescription drugs, including compounded medications and creams, furnished by Balotin or any Owned or Controlled Entity were dispensed according

to a valid prescription;² (2) each prescription drug³ recommended by Balotin or any Owned or Controlled Entity, including a compounded medication or cream, and all ingredients of such drug were being used for a medically accepted and FDA-approved indication and were medically reasonable and necessary for the medical condition for which the drug was prescribed; (3) each verbal order authorizing a prescription drug, including a compounded medication or cream, met all requirements under state law for verbal orders of prescription drugs; (4) all ingredients in each prescription for compounded medications or creams were authorized by the prescriber; (5) each request to a prescriber to authorize a change to a prescription, including a prescription for a compounded medication or cream, was truthful, accurate, and complete as to the reason for the requested change; (6) Balotin and any Owned or Controlled Entity maintained appropriate documentation of a valid prescription for each drug, including each compounded medication and cream, dispensed (including any refills of such prescription); (7) any prior authorization required by the payor was properly obtained in accordance with payor requirements; (8) Balotin and/or any Owned or Controlled Entity appropriately collected or appropriately waived cost-sharing amounts; and (9) the claims were correctly billed 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. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Balotin 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 Balotin or any Owned or Controlled Entity and the IRO.

D. Ineligible Persons.

1. *Screening Requirements.* Balotin and any Owned or Controlled Entity shall:

² A "valid prescription" shall be defined as "a prescription or compounded prescription written by a licensed prescriber, transmitted by any valid and lawful means of transmission, determined to be medically necessary for the patient by the patient's prescriber, prescribed in the normal course of a valid patient-prescriber relationship, and meeting all requirements for a valid prescription under state and federal law."

³ A "prescription drug recommended by Balotin or any Owned or Controlled Entity" shall be defined as "(i) a drug, including a compounded medication or cream, listed on a pre-printed prescription pad distributed by Balotin or any Owned or Controlled Entity, (ii) a drug, including a compounded medication or cream, recommended verbally or in writing by Balotin or any Owned or Controlled Entity, or (iii) a request for changes or modifications to an existing prescription for a drug, including a compounded medication or cream, made either verbally or in writing by Balotin or any Owned or Controlled Entity."

- 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.

Balotin shall maintain documentation demonstrating that Balotin and any Owned or Controlled Entity: (1) have checked the Exclusion Lists (i.e., a screen print of the search results) and determined that their Covered Persons are not Ineligible Persons and (2) have required their Covered Persons to disclose if they are an Ineligible Person.

2. *Removal Requirement.* If Balotin has actual notice that a Covered Person has become an Ineligible Person, Balotin 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 Balotin or any Owned or Controlled Entity may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Balotin or any Owned or Controlled Entity meets the requirements of Section III.D.

E. Notification of Government Investigation or Legal Proceeding. Balotin shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that Balotin or any Owned or Controlled Entity has committed a crime or has engaged in fraudulent activities, within 30 days of Balotin or any Owned or Controlled Entity 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, Balotin shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

F. Overpayments. Balotin 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). Balotin 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. Balotin shall notify OIG, in writing, within 30 days after determining that a Reportable Event exists with respect to Balotin or any Owned or Controlled Entity, 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 Balotin to identify and quantify the Overpayment; and
 - d. a description of Balotin's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the substantial Overpayment, Balotin or 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 Balotin to identify and quantify any Overpayments; and
- e. a description of Balotin'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, Balotin 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 Balotin 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 Balotin to CMS through the self-referral disclosure protocol (SRDP), with a copy to OIG. However, if Balotin identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Balotin 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 Balotin or any Owned or Controlled Entity contracts with a third party billing company to submit claims to the Federal health care programs on behalf of Balotin or any Owned or Controlled Entity, Balotin must certify to OIG that he 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.

Balotin 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 Balotin'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, Balotin proposes to (1) sell any or all of his 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. Balotin 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 Balotin wishes to obtain a determination by OIG that a proposed purchaser or proposed acquisition will not be subject to the IA requirements, Balotin 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 Balotin 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, Balotin 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 Balotin's responsibilities with respect to such potential employer or contractor. In addition, prior to Balotin 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, Balotin 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 Balotin following the start of the new employment or contractual relationship, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION REPORT AND ANNUAL REPORTS

A. **Implementation Report.** Within 90 days after the Effective Date, Balotin 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 Balotin that includes a summary of all current and prior engagements between Balotin and the IRO;
3. a copy of the search result screen prints demonstrating that Balotin has screened all Covered Persons against the Exclusion Lists, as required by Section III.D;
4. a copy of any certifications from Balotin and the third-party billing company required by Section III.H (if applicable);
5. a list of all of Balotin's and any Owned or Controlled Entity 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. a certification by Balotin that:
 - a. he has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference;

- b. to the best of his knowledge, except as otherwise described in the Implementation Report, Balotin is in compliance with all of the requirements of this IA;
- c. he 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 understands that the certification is being provided to and relied upon by the United States.

B. Annual Reports. Balotin 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 Balotin's response to the reports, along with corrective action plan(s) related to any issues raised by the report and documentation of Balotin's refund of the Estimated Overpayment (as defined in Appendix B to this IA);

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

4. a copy of the search result screen prints demonstrating that Balotin 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 Balotin 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 submitted by Balotin and any Owned or Controlled Entity, and Balotin'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 Balotin's and any Owned or Controlled Entity's locations (including mailing addresses) as required by Section V.A.5; and

11. a certification signed by Balotin that:

- a. he has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference;
- b. to the best of his knowledge, except as otherwise described in the Annual Report, Balotin is in compliance with all of the requirements of this IA;
- c. he 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 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.

C. Designation of Information. Balotin shall clearly identify any portions of his submissions that he 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. Balotin 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 5527
330 Independence Avenue, SW
Washington, DC 20201
Telephone: (202) 619-2078
Email Address: officeofcounsel@oig.hhs.gov

Balotin:

Gregory H. Balotin
24640 Harbour View Drive
Ponte Vedra Beach, FL 32082
Telephone: (904) 534-2130
Email Address: gbalotin@gmail.com

Unless otherwise requested by OIG, all notifications and reports required by this IA shall be submitted electronically. OIG shall notify Balotin in writing of any changes to the OIG contact information listed above. Balotin shall notify OIG in writing within two business days of any changes to the Balotin 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 Balotin's and any Owned or Controlled Entity's books, records, and other documents and supporting materials, and conduct on-site reviews of any of Balotin's and any Owned or Controlled Entity's locations, for the purpose of evaluating: (a) Balotin's and any Owned or Controlled Entity's compliance with the terms of this IA and (b) Balotin's and any Owned or Controlled Entity's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Balotin and any Owned or Controlled Entity 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 Balotin and any of Balotin's or any Owned or Controlled Entity'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. Balotin shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Balotin's and any Owned or Controlled Entity's employees and contractors may elect to be interviewed with or without a representative of Balotin present.

VIII. DOCUMENT AND RECORD RETENTION

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

B. Timely Written Requests for Extensions. Balotin 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 Balotin 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 Balotin 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 Balotin of: (a) Balotin's and/or any Owned or Controlled Entity'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, Balotin 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 Balotin under this IA;
- h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Balotin 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 Balotin and/or any Owned or Controlled Entity constitutes an independent basis for Balotin's and/or any Owned or Controlled Entity'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 Balotin and/or any Owned or Controlled Entity has materially breached this IA, OIG shall notify Balotin of: (a) Balotin's and/or any Owned or Controlled Entity's material breach and (b) OIG's intent to exclude Balotin and/or any Owned or Controlled Entity. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice.* Balotin 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 Balotin in writing of its determination to exclude Balotin and/or any Owned or Controlled Entity. (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 Balotin and/or any Owned or Controlled Entity, 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, Balotin and/or any Owned or Controlled Entity 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, Balotin and/or any Owned or Controlled Entity 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 Balotin and/or any Owned or Controlled Entity was in full and timely compliance with the requirements of this IA for which OIG demands payment and (b) the period of noncompliance. Balotin and/or any Owned or Controlled Entity shall have the burden of proving their full and timely compliance. If the ALJ upholds the OIG's determination that Balotin and/or any Owned or Controlled Entity has breached this IA and orders Balotin to pay Stipulated Penalties, Balotin and/or any Owned or Controlled Entity 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 Balotin 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, Balotin and/or any Owned or Controlled Entity 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 Balotin and/or any Owned or Controlled Entity 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. Balotin and/or any Owned or Controlled Entity shall waive their 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 Balotin and/or any Owned or

Controlled Entity, Balotin and/or any Owned or Controlled Entity 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 Balotin or Balotin on behalf of any Owned or Controlled Entity 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

Balotin 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) Balotin's and any Owned or Controlled Entity'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 Balotin 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 GREGORY H. BALOTIN

/Gregory Balotin/
GREGORY H. BALOTIN

6/9/23
DATE

/Adam P. Schwartz/
ADAM P. SCHWARTZ
Carlton Fields
Counsel for Gregory H. Balotin

June 14, 2023
DATE

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

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

2023.06.14
DATE

/John O'Brien/
JOHN W. O'BRIEN
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

2023.06.14
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

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

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

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the Federal health care program requirements and State Board of Pharmacy requirements applicable to the claims being reviewed;

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

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements);

4. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professional acting within their scope of practice and specialized expertise) to review and ensure that all ingredients in each prescription for a compounded medication or cream were authorized by the prescriber and for each

prescription drug, including a compounded medication or cream, recommended¹ by Balotin or any Owned or Controlled Entity, to determine whether all ingredients of a prescribed compounded medication and cream are being used for medically accepted and FDA-approved indications for the medical condition for which they are prescribed; 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 Claims Review in accordance with the specific requirements of the IA;

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

3. request clarification from the applicable Federal health care program or State Pharmacy Board if in doubt of the application of a particular 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. Balotin Responsibilities

Balotin 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 in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

¹ A “prescription drug recommended by Balotin or any Owned or Controlled Entity” shall be defined as “(i) a drug, including a compounded medication or cream, listed on a pre-printed prescription pad distributed by Balotin or any Owned or Controlled Entity, (ii) a drug, including a compounded medication or cream, recommended verbally or in writing by Balotin or any Owned or Controlled Entity, or (iii) a request for changes or modifications to an existing prescription for a drug, including a compounded medication or cream, made either verbally or in writing by Balotin or any Owned or Controlled Entity.”

F. IRO Removal/Termination

1. *Balotin and IRO.* If Balotin terminates his IRO or if the IRO withdraws from the engagement during the term of the IA, Balotin must submit a notice explaining (a) his 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. Balotin 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 Balotin in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Balotin 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 Balotin regarding his IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Balotin in writing that Balotin shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Balotin 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 Balotin 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, including a claim for a compounded medication or cream, submitted by or on behalf of Balotin or any Owned or Controlled Entity and for which Balotin or any Owned or Controlled Entity 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 Balotin and the IRO of its selection of the Population at least 30 days prior to the end of each Reporting Period. Balotin, or his IRO on behalf of Balotin, 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 Balotin or his IRO, (2) information furnished to OIG regarding the results of Balotin’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 Balotin or any Owned or Controlled Entity 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 Balotin’s or any Owned or Controlled Entity’s documentation, applicable Medicare program requirements, and applicable State Board of Pharmacy requirements to determine whether (i) each prescription

drug, including a compounded medication or cream, was dispensed according to a valid prescription;¹ (ii) each prescription drug recommended² by Balotin or any Owned or Controlled Entity, including a compounded medication or cream, and all ingredients of such drug are being used for a medically accepted and FDA-approved indication and are medically reasonable and necessary for the medical condition for which the drug is prescribed; (iii) each verbal order authorizing a prescription drug, including a compounded medication or cream, met all requirements under state law for verbal orders of prescription drugs; (iv) all ingredients in each prescription for compounded medication or cream were authorized by the prescriber; (v) each request to a prescriber to authorize a change to a prescription, including a prescription for a compounded medication or cream, was truthful, accurate, and complete as to the reason for the requested change; (vi) Balotin or any Owned or Controlled Entity maintained appropriate documentation of a valid prescription for each prescription drug, including each compounded medication or cream, dispensed (including any refills); (vii) any prior authorization required by the payor was properly obtained in accordance with payor requirements; (viii) all cost-sharing amounts were appropriately collected or appropriately waived; and (ix) 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 Balotin 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 Balotin 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 Balotin or any Owned or Controlled Entity cannot produce documentation shall be considered an error and the total reimbursement received by Balotin or any Owned or Controlled Entity for such Paid

¹ A "valid prescription" shall be defined as "a prescription or compounded prescription written by a licensed prescriber, transmitted by any valid and lawful means of transmission, determined to be medically necessary for the patient by the patient's prescriber, prescribed in the normal course of a valid patient-prescriber relationship, and meeting all requirements for a valid prescription under state and federal law."

² Throughout Appendix B, a "prescription drug recommended by Balotin or any Owned or Controlled Entity" shall be defined as "(i) a drug, including a compounded medication or cream, listed on a pre-printed prescription pad distributed by Balotin or any Owned or Controlled Entity, (ii) a drug, including a compounded medication or cream, recommended verbally or in writing by Balotin or any Owned or Controlled Entity, or (iii) a request for changes or modifications to an existing prescription for a drug, including a compounded medication or cream, made either verbally or in writing by Balotin or any Owned or Controlled Entity."

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, Balotin 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 Balotin's refund of the Estimated Overpayment to CMS shall be submitted to OIG with Balotin'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 Balotin’s and any Owned or Controlled Entity’s claim submission system(s), including the identification, by position description, of the personnel involved in claims submission.
 - ii. A description of controls put into place by Balotin and at any Owned or Controlled Entity to ensure that: (a) all prescription drugs, including compounded medications and creams, billed to the Medicare program are dispensed and billed in accordance with a valid prescription; (b) all prescription drugs recommended by Balotin or any Owned or Controlled Entity, including compounded medications and creams, and all ingredients of these drugs are being used for medically accepted and FDA-approved indications and are medically reasonable and necessary for the medical conditions for which the drugs are prescribed; (c) all verbal orders authorizing prescription drugs, including compounded medications or creams, met all requirements under state law for verbal orders of prescription drugs; (d) all ingredients in each prescription for compounded medications or creams were authorized by the prescriber; (e) all requests to prescribers to authorize changes to prescriptions, including prescriptions for compounded medications and creams, were truthful, accurate, and complete as to the reason for the requested change; (f) all documentation of the prescriptions, including prescriptions for compounded medications and creams, (including any refills) are maintained; (g) all claims are correctly submitted and reimbursed, including compliance with any prior authorization requirements; and (h) all cost-sharing amounts are appropriately collected or appropriately waived.
 - 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 or on behalf of

Balotin or any Owned or Controlled Entity 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 and Medicare program requirements that all prescription drugs recommended by Balotin or any Owned or Controlled Entity, including compounded medications and creams, and all ingredients of these drugs are being used for medically accepted and FDA-approved indications and are medically reasonable and necessary for the medical conditions for which the drugs are prescribed).

- ii. Total number and percentage of instances in which the IRO determined that Balotin or any Owned or Controlled Entity 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 Balotin's or any Owned or Controlled entity's claim submission system or to Balotin's or any Owned or Controlled Entity's controls for ensuring: (1) that all prescription drugs, including compounded medications and creams, billed to the Medicare program are

dispensed and billed in accordance with a valid prescription³ and otherwise meet all Medicare program requirements, including any preauthorization requirements; (2) that all prescription drugs recommended by Balotin or any Owned or Controlled Entity, including all compounded medications and creams, and all ingredients of these drugs are being used for medically accepted and FDA-approved indications and are medically reasonable and necessary for the medical conditions for which the drugs are prescribed; (3) that all verbal orders authorizing prescription drugs, including compounded medications or creams, meet all requirements under state law for verbal orders of prescription drugs; (4) that all ingredients in each prescription for compounded medications or creams were authorized by the prescriber; (5) that all requests to prescribers to authorize changes to prescriptions, including prescriptions for compounded medications or creams, were truthful, accurate, and complete as to the reason for the requested change; (6) that documentation of the prescription, including a prescription for a compounded medication or cream, (including any refills) is maintained, and that the claims are correctly submitted and reimbursed; and (7) that all cost-sharing amounts are appropriately 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.

³ See the definition of “valid prescription” in footnote 1, above.