

**INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
GERALD BATIPPS, M.D.**

**I. PREAMBLE**

Gerald Batipps, M.D. (Dr. Batipps) hereby enters into this Integrity Agreement (Agreement) 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, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This commitment to promote compliance applies to any entity that Dr. Batipps owns or in which Dr. Batipps has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Dr. Batipps' and any such entity's Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, Dr. Batipps is entering into a Settlement Agreement with the United States.

**II. TERM OF THE AGREEMENT**

A. The date on which the final signatory of this Agreement executes this Agreement shall be known as the Effective Date. The period of compliance obligations assumed by Dr. Batipps under this Agreement shall be three years from the Effective Date of this Agreement. 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, VIII, IX, X, and XI shall expire no later than 120 days from OIG's receipt of: (1) Dr. Batipps' final Annual Report; or (2) any additional materials submitted by Dr. Batipps pursuant to OIG's request, whichever is later.

C. The scope of this Agreement shall be governed by the following definitions:

1. "Covered Persons" includes:

a. Dr. Batipps and all co-owners, officers, directors, associates, and

employees of Dr. Batipps's medical practice; and

b. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Dr. Batipps.

### **III. INTEGRITY OBLIGATIONS**

Dr. Batipps shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Contact**

Within 30 days after the Effective Date, Dr. Batipps shall designate a person to be responsible for compliance activities (Compliance Contact). Dr. Batipps shall maintain a Compliance Contact for the term of this Agreement. The Compliance Contact shall be responsible for: (1) developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with Federal health care program requirements; (2) monitoring Dr. Batipps' day-to-day compliance activities; and (3) meeting all reporting obligations created under this Agreement.

Dr. Batipps 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 obligations in this Agreement, within 15 days after such change. The name, address, phone number, and a description of any other job responsibilities performed by the Compliance Contact shall be included in the Implementation Report.

#### **B. Posting of Notice**

Within the 90 days after the Effective Date, Dr. Batipps shall post in a prominent place accessible to all patients and Covered Persons a notice detailing his commitment to comply with all Federal health care program requirements in the conduct of his business.

This notice shall include the following information: (i) a means (e.g., telephone number or address) by which billing concerns and other issues may be reported anonymously; (ii) Dr. Batipps' commitment to maintain the confidentiality of the

report; and (iii) notification that reporting concerns and issues will not result in retribution or retaliation by Dr. Batipps.

This notice shall also include 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.

A copy of this notice shall be included in the Implementation Report.

**C. Written Policies and Procedures**

Within 90 days after the Effective Date, Dr. Batipps shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition, Dr. Batipps shall make the promotion of, and adherence to, the written Policies and Procedures an element in evaluating the performance of all employees. The written Policies and Procedures shall, at a minimum, set forth:

1. Dr. Batipps' commitment to full compliance with all Federal health care program requirements, including his commitment to prepare and submit accurate claims consistent with such requirements;
2. the expectation that all of Dr. Batipps' Covered Persons shall be expected to comply with all Federal health care program requirements and with Dr. Batipps' own written Policies and Procedures as implemented pursuant to this Section III.C (including the requirements of this Agreement);
3. the responsibility and requirement that all Covered Persons report suspected violations of any Federal health care program requirements or of Dr. Batipps' own Policies and Procedures to the Compliance Contact, and Dr. Batipps' commitment to maintain confidentiality and anonymity, as appropriate, and not to retaliate with respect to such disclosures;
4. the possible consequences to both Dr. Batipps and Covered Persons of failure to comply with Federal health care program requirements or with Dr. Batipps' written Policies and Procedures and the failure to report such noncompliance;
5. Dr. Batipps' commitment to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda,

newsletters, and any other correspondence from the carrier related to Federal health care program requirements;

6. the proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements;

7. the proper documentation of services and billing information; and

8. the proper use and handling of drug samples in accordance with the Prescription Drug Marketing Act, 21 U.S.C. §§ 331 (t), 333 (c), and 353 (c), and applicable Federal health care program requirements, including the requirement that drug samples not be sold or billed to any payor or any patient.

Within 90 days after the Effective Date, each Covered Person shall certify in writing that he or she has received, read, understood, and shall abide by Dr. Batipps' written Policies and Procedures. New Covered Persons shall receive and review the written Policies and Procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), Dr. Batipps shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

Copies of the written Policies and Procedures shall be included in the Implementation Report. Copies of any written Policies and Procedures that are subsequently revised shall be included in the next Annual Report along with a summary of any change or amendment to each Policy and Procedure required by this Section and the reason for each change.

**D. Training and Certification**

Within 90 days after the Effective Date and during each subsequent Reporting Period, Dr. Batipps and Covered Persons shall receive at least three hours of training from an individual or entity, other than Dr. Batipps or another Covered Person. Persons providing the training shall be knowledgeable about the relevant subject areas, including the Prescription Drug Marketing Act, 21 U.S.C. §§

331(t), 333(c), and 353(c), and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

New Covered Persons shall receive the training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. The training for new Covered Persons may either be provided internally by a Covered Person who has completed the required annual training or externally by a qualified individual or entity. A new Covered Person shall work under the direct supervision of a Covered Person who has received such training, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Covered Person completes the training.

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

1. the requirements of Dr. Batipps' Agreement;
2. an overview of Dr. Batipps' compliance program;
3. the accurate coding and submission of claims for services rendered and/or items provided to Federal health care program beneficiaries;
4. applicable reimbursement statutes, regulations, and program requirements and directives;
5. the written Policies and Procedures developed pursuant to Section III.C, above;
6. the policies, procedures, and other requirements applicable to the documentation of medical records;
7. the personal obligation of each individual involved in the coding and claims submission process to ensure that such claims are accurate;
8. the legal sanctions for the submission of improper claims or violations of the Federal health care program requirements;
9. examples of proper and improper coding and claim submission

practices;

10. the Prescriptions Drug Marketing Act, the Anti-Kickback Statute, applicable regulations, and other related documents;
11. applicable legal sanctions and consequences for violations of the Prescription Drug Marketing Act and the Anti-Kickback Statute; and
12. examples of violations of the Prescription Drug Marketing Act and the Anti-Kickback Statute.

Each Covered Person shall annually certify, in writing or in electronic format if the training is computerized, that he or she has received the required training. The certification shall specify the date the training was received. The Compliance Contact shall retain the certifications, along with all training materials. Dr. Batipps shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements and any other relevant information.

Dr. Batipps may provide the training required under this Agreement through appropriate computer-based training approaches. If Dr. Batipps chooses to provide computer-based training, he shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

The training materials shall be provided in the Implementation Report, and to the extent the training is revised, shall also be included in the Annual Reports. The certifications shall be made available to OIG, upon request.

**E. Handling and Reporting of Drug Samples**

This Section III.E pertains to those drugs, which may be separately billed to or reimbursed by any Federal health care program or other third party payor, and specifically to samples of such drugs (hereafter "Drug Samples"). Within 90 days after the Effective Date, Dr. Batipps shall assess his internal procedures relating to the use and financial disposition of Drug Samples. If necessary, Dr. Batipps shall establish and implement, or revise, internal procedures so they are reasonably designed to track the receipt, storage, inventory, use, and financial disposition of Drug Samples, and to prevent the billing of Drug Samples to patients, Federal health care programs, or third party insurers.

As part of each Annual Report, Dr. Batipps shall describe the general procedures used to track the receipt, storage, use, inventory, and financial disposition of Drug Samples. In addition, Dr. Batipps shall report the following information:

1. The aggregate number of Drug Samples for each type of drug that was received during the Reporting Period;
2. The entity or individual who provided each type of Drug Sample;
3. The specific manner in which each Drug Sample was used. For example, if Dr. Batipps used the Drug Samples to treat patients, Dr. Batipps shall list a unique identification number for each patient, the source of the patient's insurance (if any), the number of Drug Sample(s) used to treat each patient, the date(s) of such use, and the manner in which the patient or any insurer was charged (if at all) for the sample. If the Drug Samples were used to replace a damaged or expired product, Dr. Batipps shall provide the number of Drug Sample(s) used in this manner, the date of the replacement, and the number of units of product, if any, returned to the manufacturer. If the Drug Samples were used for training purposes, Dr. Batipps shall identify to whom the training was provided, the date(s) on which the training was provided, and how many Drug Sample(s) were used in providing such training. If Dr. Batipps used the Drug Samples in any other manner, he shall describe, in detail, the manner in which those Drug Samples were used; and
4. A certification by Dr. Batipps that he did not bill any Drug Sample to any patient, Federal health care program, or other third party payor.

In the event the OIG has reason to believe that: (a) Dr. Batipps' use and handling of Drug Samples fails to conform to the requirements of this Agreement; or (b) the Drug Sample information reported in accordance with this Section III.E is inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether Dr. Batipps' use and financial disposition of Drug Samples complies with the requirements of the Agreement and/or the Drug Sample information reported pursuant to Section III.E is inaccurate (Validation Review).

Prior to initiating such a Validation Review, the OIG shall notify Dr. Batipps of its intent to do so and provide a written explanation of why the OIG believes such a Validation Review is necessary. The OIG will attempt in good faith to resolve any issues relating to the Validation Review with Dr. Batipps prior to

conducting the Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG. Dr. Batipps agrees to pay for the reasonable cost of any such Validation Review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final Annual Report is received by the OIG.

**F. Ineligible Persons**

1. Definitions. For purposes of this Agreement:

- a. An "Ineligible Person" shall include an individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. "Exclusion Lists" include: (i) the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and (ii) the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>)
- c. "Screened Persons" include prospective and current co-owners, officers, directors, employees, contractors, and agents of Dr. Batipps and/or his medical practice.

2. Screening Requirements. Dr. Batipps shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Dr. Batipps shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.
- b. Dr. Batipps shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Dr. Batipps shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Dr. Batipps shall maintain documentation demonstrating that: (1) he has checked the Exclusion Lists (e.g., print screens from search results) and determined that such individuals or entities are not Ineligible Persons; and (2) has required individuals and entities to disclose if they are an Ineligible Person (e.g., employment applications).

Nothing in this Section affects the responsibility or liability of Dr. Batipps to refrain from billing Federal health care programs for services of the Ineligible Person.

3. Removal Requirement. If Dr. Batipps has notice that any individual or entity in one of the positions identified in Section III.F.1.c has become an Ineligible Person, Dr. Batipps shall remove such individual or entity from responsibility for, or involvement with, Dr. Batipps' business operations related to the Federal health care programs and shall remove such individual or entity from any position for which the individual's or entity's compensation or the items or services rendered, ordered, or prescribed by the individual or entity are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the individual or entity is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If Dr. Batipps has notice that an individual identified in Section III.F.1.c is charged with a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), or an individual or entity identified in Section III.F.1.c is proposed for exclusion during his, her or its employment, involvement or contract term, Dr. Batipps shall take all appropriate actions to ensure that the responsibilities of that individual or entity have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

**G. Notification of Government Investigation or Legal Proceedings**

Within 30 days after discovery, Dr. Batipps shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Dr. Batipps conducted or

brought by a governmental entity or its agents involving an allegation that Dr. Batipps 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. Dr. Batipps 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 proceedings, if any.

## H. Reporting

### 1. Overpayments

a. *Definition of Overpayments.* For purposes of this Agreement, an "Overpayment" shall mean the amount of money Dr. Batipps has received in excess of the amount due and payable under any Federal health care program requirements.

b. *Reporting of Overpayments.* If, at any time, Dr. Batipps identifies or learns of any Overpayment, Dr. Batipps shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Dr. Batipps shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified within 30 days after identification, Dr. Batipps shall notify the payor at that time of his efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and for Medicare contractors shall include the information contained on the Overpayment Refund Form, provided as Appendix A to this Agreement. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

### 2. Reportable Events

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

- i. a substantial Overpayment; or
- ii. 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.

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

b. *Reporting of Reportable Event.* If Dr. Batipps determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Dr. Batipps shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

iii. a description of Dr. Batipps' actions taken to correct the Reportable Event; and

iv. any further steps Dr. Batipps plans to take to address the

Reportable Event and prevent it from recurring.

**I. Third Party Billing**

If, at any time during the term of this Agreement, Dr. Batipps contracts with a third party billing company to submit claims to the Federal health care programs, at least 30 days prior to executing the contract, Dr. Batipps shall submit a certification to OIG indicating whether he has an ownership or control interest (as defined in 42 U.S.C. § 1320a – 3(a)(3)) in the third party billing company and whether he is employed by or acts as a consultant to the third party billing company.

Within 30 days after Dr. Batipps contracts with the third party billing company, Dr. Batipps shall obtain a certification from the third party billing company that the company: (i) is presently in compliance with all Federal health care program requirements as they relate to the submission of claims to Federal health care programs; (ii) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; and (iii) provides the required training in accordance with Section III.D of the Agreement for those employees involved in the preparation and submission of claims to Federal health care programs.

If Dr. Batipps contracts with a new third party billing company during the term of this Agreement, Dr. Batipps shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this Section III.I.2.

**IV. NEW BUSINESS UNITS OR LOCATIONS**

In the event that, after the Effective Date, Dr. Batipps changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Batipps shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number, and/or supplier number, and the corresponding contractor's name and address that issued each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements in this Agreement.