CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MD SPINE SOLUTIONS LLC, D/B/A MD LABS INC., DENIS GRIZELJ, AND MATTHEW RUTLEDGE

I. PREAMBLE

MD Spine Solutions LLC, d/b/a MD Labs Inc., Denis Grizelj (Grizelj), and Matthew Rutledge (Rutledge) (collectively, "MD Labs") hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This CIA applies to MD Spine Solutions LLC, Grizelj, and Rutledge and any entity that provides items or services that are paid for by any Federal health care program in which MD Spine Solutions LLC, Grizelj, and/or Rutledge have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) at any time during the term of the CIA. Contemporaneously with this CIA, MD Spine Solutions LLC, Grizelj, and Rutledge are entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The Effective Date of this CIA shall be the date on which the final signatory of this CIA executes this CIA. The term of this CIA shall be five 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) MD Labs' final Annual Report or (2) any additional materials submitted by MD Labs pursuant to OIG's request, whichever is later.

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

1. "Arrangements" shall mean:

a. every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between MD Labs and any actual or potential source of health care business or referrals to MD Labs or any actual or potential recipient of health care business or referrals from MD Labs or

b. every financial relationship (as defined at 42 C.F.R. § 411.354(a)) that is between MD Labs and a physician (or a physician's immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to MD Labs for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

2. The term "source of health care business or referrals" shall mean any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

3. The term "recipient of health care business or referrals" shall mean any individual or entity (a) to whom MD Labs refers an individual for the furnishing or arranging for the furnishing of any item or service, or (b) from whom MD Labs purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

4. "Covered Persons" shall include: (a) all owners, officers, directors, and employees of MD Labs; (b) all contractors, subcontractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of MD Labs, excluding vendors whose sole connection with MD Labs is selling or otherwise providing medical supplies or equipment to MD Labs; and (c) all physicians

and other non-physician practitioners who are members of MD Labs' active medical staff.

III. COMPLIANCE PROGRAM REQUIREMENTS

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

A. Compliance Officer, Compliance Committee, and Management Certifications

1. *Compliance Officer*. Within 90 days after the Effective Date, MD Labs shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of MD Labs, shall report directly to the Chief Executive Officer of MD Labs, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for MD Labs. The Compliance Officer shall be responsible for, without limitation:

a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements; and

b. monitoring the day-to-day compliance activities engaged in by MD Labs as well as any reporting requirements created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and shall not interfere or conflict with the Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee*. Within 90 days after the Effective Date, MD Labs shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of MD Labs' risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

MD Labs shall report to OIG, in writing, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the requirements in this CIA, within 15 business days after such a change.

3. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain MD Labs employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable MD Labs department is in compliance with applicable Federal health care program requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following:

- Wendy Brown – Director of IT
- Denis Grizelj – Co-Owner
- Chris Holloway – Director of Sales
- Clarissa Martins – Molecular Lab Manager
- Samantha Mills – Billing Office Manager
- Matthew Rutledge – Co-Owner
- Tracy Santiago – Client Services Manager
- Mark Steeves – Director of Operations
- Kyle Whitfield – Operations/HR Manager

For each Reporting Period, each Certifying Employee shall sign a certification that states:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, requirements of the Corporate Integrity Agreement, and MD Labs policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of MD Labs is in compliance with all applicable Federal health care program requirements and the requirements of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 90 days after the Effective Date, MD Labs shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

Within 90 days after the Effective Date, MD Labs shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and MD Labs' compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address compliance with 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and shall include a written review and approval process for Arrangements, the purpose of which is to ensure that all Arrangements do not violate the Anti-Kickback Statute and the Stark Law. Throughout

the term of this CIA, MD Labs shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures 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), MD Labs shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

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

C. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, MD Labs shall develop a written plan (Training Plan) that outlines the steps MD Labs will take to ensure that all Covered Persons receive at least annual training regarding MD Labs' CIA requirements and compliance program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute and the Stark Law. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. MD Labs shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

. 2. *Training Records*. MD Labs shall make available to OIG, upon request, training materials and records verifying that the training described in Section III.C.1 has been provided as required.

D. Review Procedures

1. *General Description*

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, MD Labs shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.D.

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

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

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

2. *Claims Review.* The IRO shall review claims submitted by MD Labs and reimbursed by the Medicare and Medicaid programs, to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claims were correctly coded, submitted and reimbursed (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to MD Labs a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of all current and prior engagements between MD Labs and the IRO.

E. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, MD Labs shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with MD Labs' participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries and the Anti-

Kickback Statute and Stark Law risks associated with Arrangements (as defined in Section II.C.1 above). The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted at least annually and shall require MD Labs to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. MD Labs shall maintain the risk assessment and internal review process for the term of the CIA.

F. Disclosure Program

Within 90 days after the Effective Date, MD Labs shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with MD Labs' policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. MD Labs shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of MD Labs' Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by MD Labs. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, MD Labs shall

conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record all disclosures, whether or not related to a potential violation of criminal, civil, or administrative law related to the Federal health care programs, in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the individual or department responsible for reviewing the disclosure, the status of the review, and any corrective action taken in response to the review.

G. Ineligible Persons

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

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 criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) but has not yet been excluded from participation in any Federal health care program.

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

a. MD Labs shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process or medical

staff credentialing process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. MD Labs shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.

c. MD Labs shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement*. If MD Labs has actual notice that a Covered Person has become an Ineligible Person, MD Labs shall remove such Covered Person from responsibility for, or involvement with, MD Labs' 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 MD Labs 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, or during the term of a physician's or other practitioner's medical staff privileges, MD Labs 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.

H. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, MD Labs shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to MD Labs conducted or brought by a governmental entity or its agents involving an allegation that MD Labs 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. MD Labs also shall provide written notice to OIG within 30 days after the resolution of the matter and a description of the findings and/or results of the investigation or proceeding, if any.

I. Overpayments

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

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

J. Reportable Events

1. *Definition of Reportable Event*. For purposes of this CIA, 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 or having as a member of the active medical staff a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by MD Labs.

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

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

3. *Reportable Events under Section III.J.1.a. and III.J.1.b.* For Reportable Events under Section III.J.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 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, if any;

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

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

e. a description of MD Labs' 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, MD Labs 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.J.1.c.* For Reportable Events under Section III.J.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 or medical staff membership;

c. a description of the Exclusion List screening that MD Labs completed before and/or during the Ineligible Person's employment or contract or medical staff membership and any flaw or breakdown in the screening process that led to the hiring or contracting with or credentialing of 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 or credentialing of an Ineligible Person.

5. *Reportable Events under Section III.J.1.d*. For Reportable Events under Section III.J.1.d, the report to 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 MD Labs to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If MD Labs identifies a probable violation of

the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then MD Labs is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, MD Labs proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program; or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. MD Labs 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 a proposed purchase, MD Labs wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, MD Labs 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 business, business unit, or location 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 AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, MD Labs shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A;

3. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

4. a list of the Policies and Procedures required by Section III.B;

5. the Training Plan required by Section III.C.1 (including a summary of the topics covered, the length of the training, and when the training was provided);

6. the following information regarding the IRO(s): (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 CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to MD Labs that includes a summary of all current and prior engagements between MD Labs and the IRO;

7. a description of the risk assessment and internal review process required by Section III.E;

8. a description of the Disclosure Program required by Section III.F;

9. a description of the Ineligible Persons screening and removal process required by Section III.G;

10. a copy of MD Labs' policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I;

11. a description of MD Labs' corporate structure, including identification of any individual owners, parent and sister companies, subsidiaries, and their respective lines of business;

12. a list of all of MD Labs' locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and the

location's Medicare and state Medicaid program provider number and/or supplier number(s); and

13. the certifications required by Section V.C.

B. Annual Reports

MD Labs shall submit to OIG a written report on its compliance with the CIA requirements for each of the five 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 Officer; a current list of the Compliance Committee members, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee and Certifying Employees;

2. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.3;

3. a list of any new or revised Policies and Procedures developed during the Reporting Period;

4. a description of any changes to MD Labs' Training Plan developed pursuant to Section III.C;

5. a complete copy of all reports prepared pursuant to Section III.D and MD Labs' response to the reports, along with corrective action plan(s) related to any issues raised by the reports, including MD Labs' determination of whether the CMS overpayment rule requires the repayment of an extrapolated Overpayment (as defined in Appendix B);

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

7. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reasons for such changes;

8. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed, (b) internal audits performed, (c) corrective action plans developed in response to internal audits, and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

9. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

10. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

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

12. a description of any changes to the Overpayment policies and procedures required by Section III.I, including the reasons for such changes;

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

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

15. a description of all changes to the most recently provided list of MD Labs' locations as required by Section V.A.12;

16. a description of any changes to MD Labs' corporate structure, including any individual owners, parent and sister companies, subsidiaries, and their respective lines of business; and

17. the certifications required by Section V.C.

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. Certifications

1. *Certifying Employees.* In each Annual Report, MD Labs shall include the certifications of Certifying Employees required by Section III.A.3;

2. *Compliance Officer, Individual Owners, and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer, MD Labs' Individual Owners, and Chief Executive Officer that:

a. to the best of his or her knowledge, except as otherwise described in the report, MD Labs has implemented and is in compliance with all of the requirements of this CIA;

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and

c. he or she understands that the certification is being provided to and relied upon by the United States

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, MD Labs has complied with its requirements under the Settlement Agreement: (a) not to

resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs; and (d) he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

MD Labs 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. MD Labs 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 CIA 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, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

MD Labs:

Alexander Trankovsky
Compliance Officer
10715 Double R Boulevard
Suite 102, Reno, Nevada 89521
Telephone: 775.391.5221
Facsimile: 775.737.9133
Email Address: ATrankovsky@MDLabs.com

Unless otherwise specified, all notifications and reports required by this CIA 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, MD Labs may be required to provide OIG with an additional copy of each notification or report required by this CIA 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 or copy MD Labs' books, records, and other documents and supporting materials, and conduct on-site reviews of any of MD Labs' locations, for the purpose of verifying and evaluating: (a) MD Labs' compliance with the terms of this CIA and (b) MD Labs' compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by MD Labs 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 MD Labs' owners, employees, contractors, and directors 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. MD Labs shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. MD Labs' owners, employees, contractors, and directors may elect to be interviewed with or without a representative of MD Labs present.

VIII. DOCUMENT AND RECORD RETENTION

MD Labs shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six 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 MD Labs prior to any release by OIG of information submitted by MD Labs pursuant to this CIA and identified upon submission by MD Labs as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, MD Labs 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 $2,500 for each day MD Labs fails to comply with Section III.A;

2. A Stipulated Penalty of up to $2,500 for each day MD Labs fails to comply with Section III.B;

3. A Stipulated Penalty of up to $2,500 for each day MD Labs fails to comply with Section III.C;

4. A Stipulated Penalty of up to $2,500 for each day MD Labs fails to comply with Section III.D;

5. A Stipulated Penalty of up to $2,500 for each day MD Labs fails to comply with Section III.E;

6. A Stipulated Penalty of up to $2,500 for each day MD Labs fails to comply with Section III.F;

7. A Stipulated Penalty of up to $2,500 for each day MD Labs fails to comply with Section III.G;

8. A Stipulated Penalty of up to $2,500 for each day MD Labs fails to comply with Section III.H;

9. A Stipulated Penalty of up to $2,500 for each day MD Labs fails to comply with Section III.I;

10. A Stipulated Penalty of up to $2,500 for each day MD Labs fails to comply with Section III.J;

11. A Stipulated Penalty of up to $2,500 for each day MD Labs fails to comply with Section IV;

12. A Stipulated Penalty of up to $2,500 for each day MD Labs fails to comply with Section V;

13. A Stipulated Penalty of up to $2,500 for each day MD Labs fails to comply with Section VII;

14. A Stipulated Penalty of up to $2,500 for each day MD Labs 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 MD Labs under this CIA.

B. Timely Written Requests for Extensions

MD Labs 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 CIA. 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 MD Labs 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 MD Labs 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 MD Labs of: (a) MD Labs' 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, MD Labs 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 CIA

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

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

b. failure to comply with Section III.A.1;

c. failure to comply with Section III.D;

d. failure to comply with Section III.J;

e. failure to comply with Section V;

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

g. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering MD Labs 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 of this CIA 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 CIA by MD Labs constitutes an independent basis for MD Labs' 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 five years for each material breach. Upon a preliminary determination by OIG that MD Labs has materially breached this CIA, OIG shall notify MD Labs of: (a) MD Labs' material breach; and (b) OIG's intent to exclude MD Labs. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice*. MD Labs 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 MD Labs in writing of its determination to exclude MD Labs. (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 MD Labs, 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, MD Labs 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 to MD Labs, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, MD Labs 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 CIA 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 business 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 CIA shall be: (a) whether MD Labs was in full and timely compliance with the requirements of this CIA for which OIG demands payment; and (b) the period of noncompliance. MD Labs shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that MD Labs has breached this CIA and orders MD Labs to pay Stipulated Penalties, MD Labs must (a) come into compliance with the requirement(s) of this CIA that resulted in the OIG imposing Stipulated Penalties, and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless MD Labs 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, MD Labs 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 CIA shall be whether MD Labs was in material breach of this CIA. 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. MD Labs 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 MD Labs, MD Labs 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 CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and MD Labs 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

MD Labs and OIG agree as follows:

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

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

C. OIG may agree to a suspension of the requirements of this CIA with respect to MD Spine Solutions LLC based on a certification by MD Spine Solutions LLC 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 MD Spine Solutions LLC is relieved of its CIA requirements, MD Spine Solutions LLC shall

be required to notify OIG in writing at least 30 days in advance if it 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 CIA will be reactivated or modified. In addition, OIG may agree to a suspension of the requirements of this CIA with respect to Grizelj or Rutledge, as applicable, if (1) Grizelj or Rutledge no longer have an ownership or control interest in or are no longer employed by or affiliated with MD Spine Solutions LLC or (2) do 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 OIG relieves Grizelj or Rutledge of their CIA requirements, they shall be required to notify OIG in writing at least 30 days in advance if they plan to resume providing any items or services that are paid for by 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 CIA will be reactivated or modified with respect to Grizelj or Rutledge, as applicable.

D. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) MD Labs' 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 MD Labs signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

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

ON BEHALF OF MD SPINE SOLUTIONS LLC, D/B/A MD LABS INC.

__/Denis Grizelj/_____ ___9/30/2021_____
DENIS GRIZELJ DATE
Co-Founder of MD Spine Solutions LLC,
d/b/a MD Labs Inc.

___/Matthew Rutledge/_____ ____9-30-2021_____
MATTHEW RUTLEDGE DATE
Co-Founder of MD Spine Solutions LLC,
d/b/a MD Labs Inc.

___/Barak Cohen/_____ _____9-30-2021_____
BARAK COHEN DATE
Perkins Coie LLP
Counsel for MD Spine Solutions LLC,
d/b/a MD Labs Inc.

ON BEHALF OF DENIS GRIZELJ

___/Denis Grizelj/_____ ____9/30/2021_____
DENIS GRIZELJ DATE
Co-Founder of MD Spine Solutions LLC,
d/b/a MD Labs Inc.

___/Barak Cohen/_____ ____9-30-2021_____
BARAK COHEN DATE
Perkins Coie LLP

ON BEHALF OF MATTHEW RUTLEDGE

___/Matthew Rutledge/_____ ____9-30-2021_____
MATTHEW RUTLEDGE DATE
Co-Founder of MD Spine Solutions LLC,
d/b/a MD Labs Inc.

___/Barak Cohen/_____ ___9-30-2021_____
BARAK COHEN DATE
Perkins Coie LLP

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

___/Lisa M. Re/_____ _____10/19/2021_____
LISA M. RE DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

___/John W. O'Brien/_____ ___10/15/2021_____
JOHN W. O'BRIEN DATE
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. MD Labs 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.6 of the CIA or any additional information submitted by MD Labs in response to a request by OIG, whichever is later, OIG will notify MD Labs if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, MD Labs may continue to engage the IRO.

2. If MD Labs engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, MD Labs shall submit the information identified in Section V.A.6 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by MD Labs at the request of OIG, whichever is later, OIG will notify MD Labs if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, MD Labs 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 Medicare and state Medicaid program 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 professionals acting within their scope of practice and specialized expertise) to make the medical necessity determinations required by the Claims Review; and

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

C. IRO Responsibilities

The IRO shall:

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

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

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

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

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

D. MD Labs Responsibilities

MD Labs shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.D of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform the 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. MD Labs *and IRO*. If MD Labs terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, MD Labs 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. MD Labs 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 MD Labs in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. MD Labs 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 MD Labs regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify MD Labs in writing that MD Labs shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. MD Labs 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 MD Labs to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review.

1. *Definitions*. For the purposes of the Claims Review, the following definitions shall be used:

a. Overpayment: The amount of money MD Labs 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 submitted by MD Labs and for which MD Labs 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 12-month period covered by the Claims Review.

2. *Claims Review Sample.* The IRO shall randomly select and review a sample of 100 Paid Claims (Claims Review Sample). The Paid Claims shall be reviewed based on the supporting documentation available at MD Labs's office or under MD Labs's control and applicable Medicare and state Medicaid program requirements to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed. For each Paid Claim in the Claims Review Sample that results in an Overpayment, the IRO shall review the system(s) and process(es) that generated the Paid Claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the Paid Claim.

3. *Other Requirements.*

a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in the Claims Review Sample and MD Labs shall furnish such documentation and materials to the IRO prior to the IRO initiating

its review of the Claims Review Sample. If the IRO accepts any supplemental documentation or materials from MD Labs after the IRO has completed its initial review of the Claims Review Sample (Supplemental Materials), the IRO shall identify in the 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 Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

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

c. Use of First Samples Drawn. For the purposes of the Claims Review Sample discussed in this Appendix, the first set of Paid Claims selected 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 Claims Review Sample).

4. *Repayment of Identified Overpayments.* MD Labs shall repay within 60 days the Overpayment(s) identified by the IRO in the Claims Review 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 MD Labs determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, MD Labs shall repay that amount at the mean point estimate as calculated by the IRO. MD Labs 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 Claims Review Sample (and any related work papers) received from MD Labs to the appropriate Medicare or state Medicaid program contractor for appropriate follow up by the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report.

1. *Claims Review Methodology.*

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

b. Claims Review Objective. A clear statement of the objective intended to be achieved by 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 relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual 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 MD Labs's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A description of controls in place at MD Labs to ensure that all items and services billed to Medicare or a state Medicaid program are medically necessary and appropriately documented.

iii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Claims Review Sample.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the coding of the Paid Claims submitted by MD Labs differed from what should have been the correct coding and in which such difference resulted in an Overpayment to MD Labs.

ii. Total number and percentage of instances in which the IRO determined that a Paid Claim was not appropriately documented and in which such documentation errors resulted in an Overpayment to MD Labs.

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 MD Labs.

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

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

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

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

viii. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct

allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

c. Recommendations. The IRO's report shall include any recommendations for improvements to MD Labs's billing and coding system or to MD Labs'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 Claims Review.

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.