

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
LAKES RADIOLOGY, PLLC**

I. PREAMBLE

Lakes Radiology, PLLC (Lakes Radiology) hereby enters into this Integrity Agreement (IA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this IA, Lakes Radiology is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE IA

A. This IA shall have a term of five years from the Effective Date. The Effective Date shall be the date on which the final signatory signs this IA. 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) Lakes Radiology's final annual report; or (2) any additional materials submitted by Lakes Radiology pursuant to OIG's request, whichever is later.

C. The term "Covered Persons" includes:

1. all owners, members, and employees of Lakes Radiology; and
2. all contractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of Lakes Radiology (the employees of any third party billing company that submits claims to the Federal health care programs on behalf of Lakes Radiology shall not be considered

Covered Persons, provided that Lakes Radiology and the third party billing company provide the certifications required by Section III.J).

III. INTEGRITY OBLIGATIONS

Lakes Radiology shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer

Within 90 days after the Effective Date, Lakes Radiology shall appoint an employee to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the IA. The Compliance Officer shall be a member of senior management of Lakes Radiology, shall report directly to the Chief Executive Officer of Lakes Radiology, 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 Lakes Radiology. 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 IA and with Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters to the Chief Executive Officer of Lakes Radiology, and shall be authorized to report on such matters to the Chief Executive Officer at any time. Written documentation of the Compliance Officer's reports to the Chief Executive Officer shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by Lakes Radiology as well as for any reporting obligations created under this IA.

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

Lakes Radiology shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this IA, within five days after such a change.

B. Policies and Procedures

Within 90 days after the Effective Date, Lakes Radiology shall develop and implement written policies and procedures regarding: (1) the Compliance Program requirements set forth in this IA; and (2) appropriate billing and medical record documentation for compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this IA, Lakes Radiology shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

Within 90 days after the Effective Date, the Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Lakes Radiology shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions or addition of new Policies and Procedures, a description of the revisions shall be communicated to all affected Covered Persons and any revised or new Policies and Procedures shall be made available to all Covered Persons.

C. Posting of Notice

Within 30 days after the Effective Date, Lakes Radiology shall post in a prominent place accessible to all patients and Covered Persons a notice that provides the name and phone number of the Compliance Officer and the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

D. Training and Education

1. *Training Requirements.* All Covered Persons shall receive at least three hours of training during the first Reporting Period, including at least one hour of training to be completed within 60 days after the Effective Date. Training may be completed in-person or online. These training requirements may be satisfied only by the completion of courses provided by the Centers for Medicare & Medicaid Services (CMS)

Medicare Learning Network (MLN), Lakes Radiology's Medicare contractor, or other 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 services furnished by Lakes Radiology;
- b. the Federal health care program medical record documentation requirements relating to the services furnished by Lakes Radiology; and
- c. the personal obligation of each individual involved in the medical record documentation and claims submission processes to ensure that medical records and claims are accurate.

In each of the second through fifth Reporting Periods, all Covered Persons shall receive at least two hours of training that meets the requirements of this Section III.D. New Covered Persons shall receive the training within 30 days after becoming a Covered Person.

2. *Certification.* Lakes Radiology shall maintain written documentation (*e.g.*, written or electronic certificates of completion from the training provider) that all Covered Persons required to receive training have in fact completed such training. The documentation shall specify the type of training received, the individual who completed the training, and the date received.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Lakes Radiology shall engage an individual or entity, such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this

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

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

2. *Claims Review.* The IRO shall review Lakes Radiology's coding, billing, and claims submission to the Medicare and state Medicaid programs and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this IA, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any Claims Review fails to conform to the requirements of this IA; or (b) the IRO's findings or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the IA and/or the findings or Claims Review results are inaccurate (Validation Review). Lakes Radiology shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of a Claims Review submitted as part of Lakes Radiology's final Annual Report shall be initiated no later than one year after Lakes Radiology's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Lakes Radiology in writing of its intent to do so and provide an explanation of the reasons OIG has determined a Validation Review is necessary. Lakes Radiology shall have 30 days following the date of the OIG's written notice to submit a written response to OIG that includes any additional or relevant information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review and/or propose alternatives to the proposed Validation Review. The final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Lakes Radiology a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E; and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this IA.

F. Ineligible Persons

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, or suspended from participation in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of: (a) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (b) a criminal offense relating to neglect or abuse of patients; (c) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health care program); or (d) a felony criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>); and
 - ii. the General Services Administration’s System for Award Management (SAM) (available through the Internet at <http://www.sam.gov>).

2. *Screening Requirements.* Lakes Radiology shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Lakes Radiology shall 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. Lakes Radiology shall screen all current Covered Persons against the Exclusion Lists within 30 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.
- c. Lakes Radiology shall require all Covered Persons to immediately disclose any debarment, exclusion, or suspension.

Lakes Radiology shall maintain documentation demonstrating that Lakes Radiology: (1) 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 Lakes Radiology's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. Lakes Radiology understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Lakes Radiology may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Lakes Radiology meets the requirements of Section III.F.

3. *Removal Requirement.* If Lakes Radiology has actual notice that a Covered Person has become an Ineligible Person, Lakes Radiology shall remove such Covered Person from responsibility for, or involvement with, Lakes Radiology's business operations related to the Federal health care programs 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 Federal health care programs or otherwise with Federal

funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Lakes Radiology 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, Lakes Radiology shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceeding

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

H. Overpayments

1. *Definition of Overpayments.* For purposes of this IA, an "Overpayment" shall mean the amount of money Lakes Radiology has received in excess of the amount due and payable under any Federal health care program requirements.

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

3. *Repayment of Overpayments.* If, at any time, Lakes Radiology identifies any Overpayment, Lakes Radiology shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) within 60 days after identification of the Overpayment and take steps to correct the problem and prevent the Overpayment from recurring within 90 days after identification (or such additional time as may be agreed to by the payor). If not yet quantified within 60 days after identification, Lakes Radiology

shall notify the payor at that time of its efforts to quantify the Overpayment amount and provide a schedule of when such work is expected to be completed. Lakes Radiology should follow the payor's policies regarding the form of notification and the repayment process for any Overpayment refunds. Any questions regarding the repayment process should be directed to the payor.

I. Reportable Events

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

- a. a substantial Overpayment;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or
- d. the filing of a bankruptcy petition by Lakes Radiology.

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

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

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to OIG shall be made within 30 days after making the determination that a substantial Overpayment exists, and shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated,

- including an explanation of their roles in the Reportable Event;
- b. the Federal health care programs affected by the Reportable Event;
- c. a description of the steps taken by Lakes Radiology to identify and quantify the Overpayment; and
- d. a description of Lakes Radiology's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, Lakes Radiology shall send to OIG a copy of the notification and repayment (if quantified) to the payor required by Section III.H.2.

4. *Reportable Events under Section III.I.1.b.* For Reportable Events under Section III.I.1.b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil, or administrative laws that are probably violated by the Reportable Event;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of Lakes Radiology's actions taken to correct the Reportable Event and prevent it from recurring; and
- e. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Lakes Radiology to identify and quantify the Overpayment.

5. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.1.c, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion Lists screening that Lakes Radiology completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Reportable Event was discovered; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

6. *Reportable Events under Section III.I.1.d.* If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

7. *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 Lakes Radiology to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.H.2 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of solely the Stark Law that is disclosed to CMS pursuant to the SRDP. If Lakes Radiology identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Lakes Radiology is not required by this Section III.H to submit the Reportable Event to CMS through the SRDP.

J. Third Party Billing

If, prior to the Effective Date or at any time during the term of this IA Lakes Radiology contracts with a third party billing company to submit claims to the Federal health care programs on behalf of Lakes Radiology, Lakes Radiology must certify to OIG that it does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company.

Lakes Radiology also shall obtain (as applicable) a certification from any third party billing company that the company: (i) 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; (ii) screens its prospective and current employees against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's System for Award Management; and (iii) 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 Lakes Radiology's Implementation Report and each Annual Report required by Section V below.

IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS

A. Change or Closure of Location

In the event that, after the Effective Date, Lakes Radiology changes locations or closes a location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Lakes Radiology shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Location or Business

In the event that, after the Effective Date, Lakes Radiology purchases or establishes a new location or business related to the furnishing of items or services that may be reimbursed by Federal health care programs, Lakes Radiology shall notify OIG at least 30 days prior to such purchase or the operation of the new location or business. This notification shall include the address of the new location or business, phone number, fax number, Medicare and state Medicaid program provider number and/or supplier number, and the name and address of each Medicare and state Medicaid program

contractor to which Lakes Radiology currently submits claims. Each new location or business and all Covered Persons at each new location or business shall be subject to the applicable requirements of this IA, unless otherwise determined and agreed to in writing by OIG.

C. Sale of Location or Business

In the event that, after the Effective Date, Lakes Radiology proposes to sell any or all of its locations or businesses that are subject to this IA, Lakes Radiology shall notify OIG at least 30 days prior to the proposed sale. This notification shall include a description of the location or business to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This IA shall be binding on the purchaser of such location or business, unless otherwise determined and agreed to in writing by OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 90 days after the Effective Date, Lakes Radiology shall submit a written report to OIG summarizing the status of its implementation of the requirements of this IA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. a copy of the Policies and Procedures required by Section III.B.;
3. a copy of the notice required by Section III.C, a description of where the notice is posted, and the date the notice was posted;
4. the following information regarding the IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this IA; (d) a summary and description of any and all current and prior engagements and agreements between Lakes Radiology and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Lakes Radiology;

5. a copy of the documentation demonstrating that Lakes Radiology has screened all Covered Persons against the Exclusion Lists, as required by Section III.F within 30 days of the Effective Date;

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

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

8. a list of all of Lakes Radiology's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s), and the name and address of each Medicare and state Medicaid program contractor to which Lakes Radiology currently submits claims; and

9. certifications by the Compliance Officer and Chief Executive Officer that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Implementation Report, Lakes Radiology is in compliance with all of the requirements of this IA; and (c) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. Annual Reports

Lakes Radiology shall submit to OIG annually a report with respect to the status of, and findings regarding, Lakes Radiology's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall, at a minimum, include:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer described in Section III.A;

2. a description of any changes to the Policies and Procedures required by Section III.B;

3. a description of any changes to the notice required by Section III.C, and the reason for such changes, along with a copy of the revised notice;

4. the following information regarding the training required by Section III.D: a copy of the training program registration for each Covered Person who completed the training; the name of the training course; the name of the entity that provided the training; the location, date, and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program. A copy of all training materials shall be made available to OIG upon request;

5. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter and Lakes Radiology's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

6. a summary and description of any and all current and prior engagements and agreements between Lakes Radiology and the IRO (if different from what was submitted as part of the Implementation Report) and a certification from the IRO regarding its professional independence and objectivity with respect to Lakes Radiology;

7. a copy of the documentation demonstrating that Lakes Radiology screened all prospective and current Covered Persons against the Exclusion Lists, as required by Section III.F;

8. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

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

10. 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;

11. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;

12. a copy of any certifications from Lakes Radiology and the third party billing company required by Section III.J (if applicable);

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

14. certifications signed by Lakes Radiology's Compliance Officer and Chief Executive Officer stating that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Annual Report, Lakes Radiology is in compliance with all of the requirements of this IA; and (c) he or she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

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

Lakes Radiology 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. Lakes Radiology shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this IA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW

Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Lakes Radiology, PLLC:

Iddo Netanyahu, M.D.
5 The Circle
Hornell, NY 14843
Telephone: (607) 324-8255
Facsimile: (607) 324-8774

Unless otherwise specified, all notifications and reports required by this IA shall be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Lakes Radiology may be required to provide OIG with an electronic copy of each notification or report required by this IA in searchable portable document format (pdf), in addition to a paper copy.

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

VIII. DOCUMENT AND RECORD RETENTION

Lakes Radiology shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this IA 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 Lakes Radiology prior to any release by OIG of information submitted by Lakes Radiology pursuant to its obligations under this IA and identified upon submission by Lakes Radiology as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Lakes Radiology shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Lakes Radiology is expected to fully and timely comply with all of its IA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Lakes Radiology and OIG hereby agree that failure to comply with certain obligations set forth in this IA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Lakes Radiology fails to:
 - a. appoint a Compliance Officer as required by Section III.A;
 - b. establish and implement the Policies and Procedures required by Section III.B;
 - c. post a notice in accordance with the requirements of Section III.C;

- d. complete the training required for Covered Persons and maintain training certifications, in accordance with the requirements of Section III.D;
- e. screen Covered Persons in accordance with the requirements of Section III.F or require Covered Persons to disclose if they are debarred, excluded, or suspended in accordance with the requirements of Section III.F; and maintain documentation of screening and disclosure requirements in accordance with the requirements of Section III.F;
- f. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.G;
- g. establish policies and procedures regarding the repayment of Overpayments;
- h. repay any Overpayments as required by Section III.H and Appendix B;
- i. report a Reportable Event in accordance with Section III.I;
- j. disclose any changes to locations or business under Section IV; or
- k. provide to OIG the certifications required by Section III.K relating to any third party biller engaged by Lakes Radiology during the term of the IA.

2. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lakes Radiology fails to engage and use an IRO, as required by Section III.E, Appendix A, or Appendix B.

3. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lakes Radiology fails to submit the Implementation Report, IRO Report, or any Annual Report to OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of \$1,000 for each day Lakes Radiology fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Lakes Radiology fails to grant access.)

4. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Lakes Radiology as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or as otherwise required by this IA.

5. A Stipulated Penalty of \$1,000 for each day Lakes Radiology fails to comply fully and adequately with any obligation of this IA. OIG shall provide notice to Lakes Radiology stating the specific grounds for its determination that Lakes Radiology has failed to comply fully and adequately with the IA obligation(s) at issue and steps Lakes Radiology shall take to comply with the IA. (This Stipulated Penalty shall begin to accrue 10 days after the date Lakes Radiology receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section.

B. Timely Written Requests for Extensions

Lakes Radiology 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. Notwithstanding any other provision in this Section, 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 Lakes Radiology fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, 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 days after Lakes Radiology 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 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.* Upon a finding that Lakes Radiology has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Lakes Radiology of: (a) Lakes

Radiology's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Lakes Radiology shall either: (a) cure the breach to OIG's satisfaction and 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. In the event Lakes Radiology elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Lakes Radiology cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this IA and shall be grounds for exclusion under Section X.D.

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.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Lakes Radiology has materially breached this IA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this IA

1. *Definition of Material Breach.* A material breach of this IA means:
 - a. a failure by Lakes Radiology to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.I;
 - b. repeated violations or a flagrant violation of any of the obligations under this IA, including, but not limited to, the obligations addressed in Section X.A;
 - c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

- d. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, or Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this IA by Lakes Radiology constitutes an independent basis for Lakes Radiology'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 five years per material breach. Upon a determination by OIG that Lakes Radiology has materially breached this IA and that exclusion is the appropriate remedy, OIG shall notify Lakes Radiology of: (a) Lakes Radiology's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* Lakes Radiology shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) Lakes Radiology has begun to take action to cure the material breach; (ii) Lakes Radiology is pursuing such action with due diligence; and (iii) Lakes Radiology has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Lakes Radiology fails to satisfy the requirements of Section X.D.3, OIG may exclude Lakes Radiology from participation in the Federal health care programs. OIG shall notify Lakes Radiology in writing of its determination to exclude Lakes Radiology. (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 Lakes Radiology's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Lakes Radiology 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 delivery to Lakes Radiology of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this IA, Lakes Radiology 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 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this IA. 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 HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. 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 Lakes Radiology was in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. Lakes Radiology shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this IA and orders Lakes Radiology to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Lakes Radiology requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 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 Lakes Radiology was in material breach of this IA and, if so, whether:

- a. Lakes Radiology cured such breach within 30 days of its receipt of the Notice of Material Breach; or

- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Lakes Radiology's receipt of the Notice of Material Breach: (i) Lakes Radiology had begun to take action to cure the material breach; (ii) Lakes Radiology pursued such action with due diligence; and (iii) Lakes Radiology provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Lakes Radiology, only after a DAB decision in favor of OIG. Lakes Radiology's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Lakes Radiology upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Lakes Radiology may request review of the ALJ decision by the DAB. 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. Lakes Radiology shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Lakes Radiology, Lakes Radiology shall be reinstated effective on the date of the original 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. Consequently, 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.

XI. EFFECTIVE AND BINDING AGREEMENT

Lakes Radiology and OIG agree as follows:

- A. This IA shall become final and binding on the date the final signature is obtained on the IA.
- B. This IA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this IA.
- C. OIG may agree to a suspension of Lakes Radiology's obligations under this IA based on a certification by Lakes Radiology 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 Lakes Radiology is relieved of its IA obligations, Lakes Radiology shall be required to notify OIG in writing at least 30 days in advance if Lakes Radiology plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the IA will be reactivated or modified.

D. All requirements and remedies set forth in this IA are in addition to and do not affect (1) Lakes Radiology's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

E. The undersigned Lakes Radiology signatories represent and warrant that they are authorized to execute this IA. The undersigned OIG signatories represent that they are signing this IA in their official capacity and that they are authorized to execute this IA.

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

ON BEHALF OF LAKES RADIOLOGY, PLLC

/Iddo Netanyahu/

IDDO NETANYAHU, M.D.
Member
Lakes Radiology, PLLC

July 22, 2015
DATE

/Bruce Smith/

BRUCE SMITH, ESQ.
Wood & Smith PC
Counsel to Lakes Radiology, PLLC

July 22, 2015
DATE

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

/Robert K. DeConti/

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

7/29/15

DATE

/Kaitlyn L. Dunn/

KAITLYN L. DUNN
Associate Counsel
Office of Inspector General
U.S. Department of Health and Human Services

7/23/15

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Lakes Radiology 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 D. Within 30 days after OIG receives the information identified in Section V.A.4 of the IA or any additional information submitted by Lakes Radiology in response to a request by OIG, whichever is later, OIG will notify Lakes Radiology if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Lakes Radiology may continue to engage the IRO.

2. If Lakes Radiology 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, Lakes Radiology shall submit the information identified in Section V.A.4 of the IA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Lakes Radiology at the request of OIG, whichever is later, OIG will notify Lakes Radiology if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Lakes Radiology 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 billing, coding, claims submission, and other applicable Medicare and state Medicaid program requirements;

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); and

4. 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 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 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. 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.

E. IRO Removal/Termination

1. *Lakes Radiology and IRO.* If Lakes Radiology terminates its IRO or if the IRO withdraws from the engagement during the term of the IA, Lakes Radiology 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. Lakes Radiology 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 D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Lakes Radiology in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Lakes

Radiology 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 Lakes Radiology regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Lakes Radiology in writing that Lakes Radiology shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Lakes Radiology 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 Lakes Radiology 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 Lakes Radiology 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 reviews performed under this Appendix B, including any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.
- b. Paid Claim: A claim submitted by Lakes Radiology and for which Lakes Radiology 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.
- d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Paid Claims in the sample.

2. *Discovery Sample*. The IRO shall randomly select and review a sample of 100 Paid Claims (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at Lakes Radiology's office or under Lakes

Radiology's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Lakes Radiology should, as appropriate, further analyze any errors identified in the Discovery Sample. Lakes Radiology recognizes that OIG or another HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample.* If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at Lakes Radiology's office or under Lakes Radiology's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Lakes Radiology to the appropriate Federal health care program payor (e.g., Medicare contractor), for appropriate follow-up by that payor.

4. *Systems Review.* If Lakes Radiology's Discovery Sample identifies an Error Rate of 5% or greater, Lakes Radiology's IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

- a. a review of Lakes Radiology's billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system; the process by which claims are coded; safeguards to ensure proper coding, claims submission, and billing; and procedures to identify and correct inaccurate coding and billing); and

- b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the 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 claim.

5. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and Lakes Radiology shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from Lakes Radiology after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (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 Lakes Radiology cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Lakes Radiology 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 all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims selected in each first sample shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

6. *Repayment of Identified Overpayments.* Lakes Radiology shall repay within 30 days any Overpayment(s) identified in the Discovery Sample, regardless of the Error Rate, and (if applicable) the Full Sample, including the IRO's estimate of the actual Overpayment in the Population as determined in accordance with Section A.3 above, in accordance with payor refund policies. Lakes Radiology shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix B for each Claims Review performed. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

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 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 Section A.5.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 copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.
 - c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.
3. *Claims Review Findings.*
- a. Narrative Results.
 - i. A description of Lakes Radiology's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
 - ii. 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 Discovery Sample, and the results of the Full Sample (if any).
 - b. Quantitative Results.
 - i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Lakes Radiology (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.
 - ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Lakes Radiology.
 - iii. Total dollar amount of all Overpayments in the Discovery Sample and the Full Sample (if applicable).
 - iv. Total dollar amount of Paid Claims included in the Discovery Sample and the Full Sample and the net Overpayment associated with the Discovery Sample and the Full Sample.
 - v. Error Rate in the Discovery Sample and the Full Sample.

- vi. 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.
 - vii. If a Full Sample is performed, the methodology used by the IRO to estimate the actual Overpayment in the Population and the amount of such Overpayment.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to Lakes Radiology's billing and coding system based on the findings of the Claims Review.
4. *Systems Review Findings.* The IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the IRO's observations, findings, and recommendations regarding:
- a. the strengths and weaknesses in Lakes Radiology's billing systems and processes;
 - b. the strengths and weaknesses in Lakes Radiology's coding systems and processes; and
 - c. possible improvements to Lakes Radiology's billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.
5. *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.