

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
DR. MICHAEL ALLEN, D.P.M.
AND
LEXINGTON FOOT AND ANKLE CENTER, P.S.C.**

I. PREAMBLE

Dr. Michael Allen, D.P.M. (Dr. Allen) and Lexington Foot and Ankle Center, P.S.C. (LFAC) hereby enter 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, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This IA applies to Dr. Allen and LFAC, any entity in which Dr. Allen has an ownership or control interest at any time during the term of the IA, as defined in 42 U.S.C. § 1320a-3(a)(3), and any such entity's Covered Persons as defined in Section II.C. Contemporaneously with this IA, Dr. Allen and LFAC are entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE IA

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

C. The term "Covered Persons" includes:
1. Dr. Allen and LFAC and all partners, shareholders, associates, and employees of Dr. Allen and LFAC;

2. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Dr. Allen and LFAC; and

3. all employees of any entity in which Dr. Allen and/or LFAC have an ownership or control interest at any time during the term of this IA (as defined in 42 U.S.C. §1320a-3(a)(3)) and any contractors, agents, or other persons who provide patient care items or services or who perform billing or coding functions on behalf of such entity.

III. INTEGRITY OBLIGATIONS

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

A. Compliance Contact. Within 30 days after the Effective Date, Dr. Allen and LFAC shall designate a Covered Person to be responsible for compliance activities (Compliance Contact). Dr. Allen and LFAC shall maintain a Compliance Contact for the term of this IA. The Compliance Contact shall be responsible for: (1) monitoring Dr. Allen's and LFAC's day-to-day compliance activities; (2) meeting all reporting obligations created under this IA; and (3) responding to questions and concerns from Covered Persons and the OIG regarding compliance with the IA.

Dr. Allen and LFAC shall report to OIG, in writing, any changes in the identity or job responsibilities of the Compliance Contact, or any actions or changes that would affect the Compliance Contact's ability to perform the duties necessary to meet the obligations in this IA within 15 days after such change. The name, phone number, and a description of any other job responsibilities performed by the Compliance Contact shall be included in the Implementation Report.

B. Posting of Notice. Within the 90 days after the Effective Date, Dr. Allen and LFAC shall post in a prominent place accessible to all patients and Covered Persons a notice detailing their commitment to comply with all Federal health care program requirements in the conduct of their businesses.

This notice shall include the following information: (i) a means (e.g., telephone number or address) by which billing concerns and other issues may be reported anonymously; (ii) Dr. Allen's and LFAC's commitment to maintain the confidentiality of the report; and (iii) notification that reporting concerns and issues will not result in retribution or retaliation by Dr. Allen and/or LFAC.

This notice shall also include the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

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

C. Billing and Claims Submission and Medical Record Documentation Procedures. Within 90 days after the Effective Date, Dr. Allen and LFAC shall implement and distribute to all Covered Persons written procedures and requirements for: (i) preparing and submitting claims to Federal health care programs on behalf of Dr. Allen and LFAC and (ii) the proper documentation of medical records and billing information for services furnished on behalf of Dr. Allen and LFAC.

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

At least annually (and more frequently if appropriate), Dr. Allen and LFAC shall assess and update, as necessary, these billing and claims submission and medical record documentation procedures. Within 30 days after the effective date of any revisions, any such revised procedures shall be distributed to all Covered Persons.

Copies of the written billing and claims submission and medical record documentation procedures shall be included in the Implementation Report. Copies of any such procedures that are subsequently revised shall be included in the next Annual Report along with a summary of any change or amendment to the procedures required by this Section and the reason for each change.

D. Training and Certification.

1. *Training.* Within 90 days after the Effective Date and during each subsequent Reporting Period, all Covered Persons (the employees of any third party billing company that submits claims to the Federal health care programs on behalf of Dr. Allen and LFAC shall not be considered Covered Persons for purposes of these training and certification requirements, provided that Dr. Allen and LFAC do not have any ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and the third party billing company provides the certification required by

Section III.I) shall receive at least three hours of training from an individual or entity, other than Dr. Allen or LFAC or another Covered Person. Training may be received from a variety of sources (e.g., CME classes, hospitals, associations, Medicare contractors).

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

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

- a. the requirements of Dr. Allen and LFAC's IA;
- b. the accurate coding and submission of claims for services rendered and/or items provided to Federal health care program beneficiaries;
- c. applicable reimbursement statutes, regulations, and program requirements and directives;
- d. the policies, procedures, and other requirements applicable to the documentation of medical records;
- e. the personal obligation of each individual involved in the coding and claims submission process to ensure that such claims are accurate;
- f. the legal sanctions for the submission of improper claims or violations of the Federal health care program requirements;
- g. examples of proper and improper coding and claims submission practices;
- h. Medicare and Medicaid coverage criteria for podiatry items and services;
- i. the importance of complete and accurate documentation to determine the medical necessity of podiatry items and services; and

- j. billing the appropriate level of services based on the level of service provided by an appropriately licensed health care provider.

2. *Certification.* Each individual who is required to receive training shall certify in writing, or in electronic form if the training is computerized, that he or she has received the required training. The certification shall specify the type of training received and the date received. Dr. Allen and LFAC shall retain the certifications along with all training materials. The certifications and the training materials shall be made available to OIG, upon request.

3. *Qualifications of Trainer(s).* Persons providing the training shall be knowledgeable about the subject area.

4. *Update of Training.* The training required by this section shall be updated as necessary to reflect changes in Federal health care program requirements, any issues discovered during the Claims Review, and any other relevant information.

5. *Computer-Based Training.* Dr. Allen and LFAC may provide the training required under this IA through appropriate computer-based training approaches. If Dr. Allen and LFAC choose to provide computer-based training, they shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Dr. Allen and LFAC shall engage an individual or entity, such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Dr. Allen and LFAC in assessing and evaluating their billing and coding practices. The applicable requirements relating to the IRO are outlined in Appendix A to this IA, which is incorporated by reference.

The IRO shall evaluate and analyze Dr. Allen’s and LFAC’s coding, billing, and claims submission to the Federal health care programs and the reimbursement received (Claims Review).

b. *Frequency of Claims Review.* The Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IRO shall perform all components of each annual Claims Review.

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

2. *Claims Review.* The Claims Review shall include Discovery Samples of 50 Paid Claims of: (1) Dr. Allen; (2) LFAC; and (3) Lexington Diabetic Center, P.S.C., and, if the Error Rate for the Discovery Samples is 5% or greater, a Full Sample and Systems Review. The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this IA, which is incorporated by reference.

3. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Reviews performed (Claims Reviews Report). Information to be included in the Claims Reviews Report is described in Appendix B.

4. *Repayment of Identified Overpayments.* Dr. Allen and/or LFAC shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Dr. Allen and/or LFAC shall make available to OIG documentation that reflects the refund of the Overpayment(s) to the payor.

5. *Validation Review.* In the event OIG has reason to believe that: (a) Dr. Allen's, LFAC's, or Lexington Diabetic Center's Claims Reviews fail to conform to the requirements of this IA; or (b) the IRO's findings or results from the Claims Reviews 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). Dr. Allen and LFAC shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after Dr. Allen's and LFAC's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Dr. Allen and LFAC of its intent to do so and provide a written explanation of why OIG believes such a

review is necessary. To resolve any concerns raised by OIG, Dr. Allen and LFAC may request a meeting with OIG to: (a) discuss the results of any Claims Review submissions or findings; (b) present any additional or relevant information to clarify the results of the Claims Review to correct the inaccuracy of the Claims Review; and/or (c) propose alternatives to the proposed Validation Review. Dr. Allen and LFAC agree to provide any additional information requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Claims Review issues with Dr. Allen and LFAC prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

6. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Dr. Allen and LFAC a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Claims Review, and that it has concluded that it is, in fact, independent and objective.

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, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>)

2. *Screening Requirements.* Dr. Allen and LFAC shall not hire, employ or engage as a Covered Person any Ineligible Person. Dr. Allen and LFAC shall ensure that all Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Dr. Allen and LFAC shall screen all Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require Covered Persons to disclose whether they are Ineligible Persons.

b. Dr. Allen and LFAC shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Dr. Allen and LFAC shall require all Covered Persons to immediately disclose any debarment, exclusion, suspension, or other event that makes that Covered Person an Ineligible Person.

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

Nothing in this Section affects the responsibility of (or liability for) Dr. Allen and/or LFAC to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Dr. Allen and LFAC understand that items or services furnished by excluded persons are not payable by Federal health care programs and that Dr. Allen and/or LFAC may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Dr. Allen and LFAC meet the requirements of Section III.F.

3. *Removal Requirement.* If Dr. Allen and/or LFAC have actual notice that a Covered Person has become an Ineligible Person, Dr. Allen and/or LFAC shall remove

such Covered Person from responsibility for, or involvement with, Dr. Allen's and/or LFAC'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 rendered, 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 Dr. Allen and/or LFAC have 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, Dr. Allen and/or LFAC 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, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings. Within 30 days after discovery, Dr. Allen and/or LFAC shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Dr. Allen and/or LFAC conducted or brought by a governmental entity or its agents involving an allegation that Dr. Allen and/or LFAC have committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Dr. Allen and/or LFAC shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Repayment of Overpayments.

1. *Definition of Overpayments.* For purposes of this IA, an "Overpayment" shall mean the amount of money Dr. Allen and/or LFAC have received in excess of the amount due and payable under any Federal health care program requirements.

2. *Reporting of Overpayments.*

a. If, at any time, Dr. Allen or LFAC identifies or learns of any Overpayment, Dr. Allen and/or LFAC shall repay the Overpayment to the appropriate payor (e.g., Medicare fiscal intermediary or

carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified within 30 days after identification, Dr. Allen and/or LFAC 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. Notification and repayment to the payor shall be done in accordance with the payor's policies, and for Medicare contractors shall include the information contained on the Overpayment Refund Form, provided as Appendix C to this IA.

b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

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; or
- c. the filing of a bankruptcy petition by Dr. Allen and/or LFAC.

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

2. *Reporting of Reportable Events.* If Dr. Allen or LFAC determine (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Dr. Allen and/or LFAC 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 at the same time as the repayment to the payor required in Section III.H., and shall include:

- a. a copy of the notification and repayment to the payor required in Section III.H.2;
- b. a description of the steps taken by Dr. Allen and/or LFAC to identify and quantify the Overpayment;
- c. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- d. a description of Dr. Allen's and/or LFAC's actions taken to correct the Reportable Event; and
- e. any further steps Dr. Allen and/or LFAC plan to take to address the Reportable Event and prevent it from recurring.

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

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- b. a description of Dr. Allen's and/or LFAC's actions taken to correct the Reportable Event; and
- c. any further steps Dr. Allen and/or LFAC plan to take to address the Reportable Event and prevent it from recurring; and
- d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Dr. Allen and/or LFAC to identify and quantify the Overpayment.

5. *Reportable Events under Section III.I.1.c.* 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.

J. Third Party Billing. If, prior to the Effective Date or at any time during the term of this IA Dr. Allen and/or LFAC contract with a third party billing company to submit claims to the Federal health care programs on behalf of Dr. Allen and/or LFAC, Dr. Allen and/or LFAC must certify to OIG that they does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company. Such certification must be included in the Implementation Report and each Annual Report (as applicable) submitted to OIG.

Dr. Allen and LFAC also shall obtain and provide to OIG in the Implementation Report and each Annual Report (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 List of Parties Excluded from Federal Programs; 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.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS; NEW EMPLOYMENT OR CONTRACTUAL ARRANGEMENT

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Dr. Allen and/or LFAC change locations or closes a business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Allen and/or LFAC 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 Unit or Location. In the event that, after the Effective Date, Dr. Allen and/or LFAC purchase or establish a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Allen and/or LFAC shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number,

Medicare and state Medicaid program provider identification number and/or supplier number, and the name and address of the contractor that issued each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this IA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Dr. Allen and/or LFAC propose to sell any or all of their business units or locations that are subject to this IA, Dr. Allen and/or LFAC shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. This notification shall include a description of the business unit or location 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 business unit or location, unless otherwise determined and agreed to in writing by OIG.

D. New Employment or Contractual Arrangement. Prior to Dr. Allen and/or LFAC becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Allen and/or LFAC shall notify that party of this IA. This notification shall include a copy of the IA, a statement indicating the remaining term of the IA, and a summary of Dr. Allen's and LFAC's obligations under the IA. In addition, Dr. Allen and LFAC shall notify OIG of such relationship in their next Annual Report.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Dr. Allen and LFAC 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, phone number, and a description of any other job responsibilities performed by the Compliance Contact, and the date the Compliance Contact was appointed;
2. a copy of the notice Dr. Allen and LFAC posted in their offices as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;
3. a copy of the procedures required by Section III.C;

4. a description of the training provided in accordance with the requirements of Section III.D, including a summary of the topics covered, the length of each session, and a schedule of when the training session(s) were held;

5. the following information regarding the IRO: (a) identity, address and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any current and prior engagements between Dr. Allen and/or LFAC and the IRO;

6. a certification from the IRO regarding its professional independence and objectivity with respect to Dr. Allen and LFAC;

7. a certification by Dr. Allen and LFAC that all prospective and current Covered Persons are being screened against the Exclusion Lists, as required by section III.F;

8. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F, the actions taken in response to the screening and removal obligations set forth in Section III.F, and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered, or prescribed by such Ineligible Person;

9. a copy of any certifications from Dr. Allen and LFAC and the third party billing company required by Section III.J (if applicable);

10. a list of all of Dr. Allen's and LFAC'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 identification number(s), and/or supplier number(s), and the name and address of each Medicare and state Medicaid program contractor to which Dr. Allen and/or LFAC currently submits claims;

11. if Dr. Allen and/or LFAC became an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Allen and/or LFAC shall inform OIG of the name, location, relationship, and his/its responsibilities with respect to Dr. Allen's and/or LFAC's employment or contract; and

12. a certification by Dr. Allen and LFAC and the Compliance Contact that: (a) he or she has reviewed the IA in its entirety, understands the requirements

described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Implementation Report, Dr. Allen and LFAC are 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. Dr. Allen and LFAC shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Dr. Allen's and LFAC'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 name, phone number, or job responsibilities of the Compliance Contact;
2. any changes to the posted notice and the reason for such changes;
3. a copy of any new or revised procedures required by Section III.C and the reason(s) for any revisions (e.g., change in contractor policies, etc.);
4. a description of the training provided in accordance with the requirements of Section III.D, including a summary of the topics covered; the length of each session; and a schedule of when the training session(s) was held;
5. a complete copy of all reports prepared pursuant to Section III.E;
6. Dr. Allen's and LFAC's response to the reports prepared pursuant to Section III.E, including corrective action plan(s) related to any issues raised by the reports;
7. a summary and description of any current and prior engagements and agreements between Dr. Allen and/or LFAC and the IRO, if different from what was submitted as part of the Implementation Report;
8. a certification from the IRO regarding its professional independence and objectivity with respect to Dr. Allen and LFAC;
9. a certification by Dr. Allen and LFAC that all prospective and current Covered Persons are being screened against the Exclusion Lists, as required by section III.F;

10. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F, the actions taken in response to the screening and removal obligations set forth in Section III.F, and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered, or prescribed by such Ineligible Person;

11. 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;

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

13. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

14. a copy of any certifications from Dr. Allen and LFAC and the third party billing company required by Section III.J (if applicable);

15. a description of all changes to the most recently provided list of Dr. Allen's and LFAC's locations (including addresses) as required by Section V.A.10; 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 identification number(s), and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Dr. Allen and LFAC currently submit claims;

16. if Dr. Allen and/or LFAC become an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Allen and/or LFAC shall inform OIG of the name, location, relationship, and his/its responsibilities with respect to Dr. Allen's and/or LFAC's employment or contract; and

17. a certification signed by Dr. Allen and LFAC and the Compliance Contact certifying 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, Dr. Allen and LFAC are 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. Dr. Allen and LFAC shall clearly identify any portions of its submissions that he/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. Dr. Allen and LFAC 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

Dr. Allen's and LFAC's Compliance Contact:
Amy Allen
Lexington Foot and Ankle Center, P.S.C.
5613 Mount Horeb Pike
Lexington, Kentucky 40511
Telephone: (859) 494-5334
Facsimile: (859) 977-9955

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, Dr. Allen and/or LFAC 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), either instead of or 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 or request copies of Dr. Allen's and/or LFAC's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Dr. Allen's and/or LFAC's locations for the purpose of verifying and evaluating: (a) Dr. Allen's and LFAC's compliance with the terms of this IA; and (b) Dr. Allen's and/or LFAC's compliance with the requirements of the Federal health care programs in which he/it participates. The documentation described above shall be made available by Dr. Allen and/or LFAC to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Dr. Allen's and/or LFAC's employees, contractors, or agents 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. Dr. Allen and LFAC shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Dr. Allen's and LFAC's employees may elect to be interviewed with or without a representative of Dr. Allen or LFAC present.

VIII. DOCUMENT AND RECORD RETENTION

Dr. Allen and LFAC 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 Dr. Allen and LFAC prior to any release by OIG of information submitted by Dr. Allen and LFAC pursuant to its obligations under this IA

and identified upon submission by Dr. Allen and LFAC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Dr. Allen and LFAC shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Dr. Allen and LFAC are expected to fully and timely comply with all of their IA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Dr. Allen and LFAC and OIG hereby agree that failure to comply with certain obligations set forth in this IA (unless a timely written request for an extension has been submitted and approved in accordance with Section B below) 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 \$750 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Allen and LFAC fail to:
 - a. designate a Compliance Contact in accordance with the requirements of Section III.A;
 - b. establish and/or post a notice in accordance with the requirements of Section III.B;
 - c. implement, distribute, or update the procedures required by Section III.C;
 - d. establish and implement a training program in accordance with the requirements of Section III.D;
 - e. engage an IRO in accordance with the requirements of Section III.E and Appendix A;
 - f. submit the IRO’s annual Claims Review Report in accordance with the requirements of Section III.E and Appendix B;

g. obtain and/or maintain the following documentation: written procedures certifications in accordance with the requirements of Section III.C, training certification(s) in accordance with the requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Section III.F;

h. screen Covered Persons in accordance with the requirements of Section III.F; or require Covered Persons to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.F;

i. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.G;

j. provide to OIG the certifications required by Section III.J relating to any third party biller engaged by Dr. Allen and LFAC during the term of the IA; or

k. report a Reportable Event.

2. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Allen and LFAC fail to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of \$750 for each day Dr. Allen and LFAC fail to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Dr. Allen and LFAC fail to grant access.)

4. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day Dr. Allen and/or LFAC employ or contract with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Dr. Allen's and/or LFAC's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Dr.

Allen and/or LFAC can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

5. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Dr. Allen and LFAC as part of its Implementation Report, Annual Reports, additional documentation to a report (as requested by OIG), or as otherwise required by this IA.

6. A Stipulated Penalty of \$750 for each day Dr. Allen and LFAC fail to comply fully and adequately with any obligation of this IA. OIG shall provide notice to Dr. Allen and LFAC stating the specific grounds for its determination that Dr. Allen and LFAC have failed to comply fully and adequately with the IA obligation(s) at issue and steps Dr. Allen and LFAC shall take to comply with the IA. (This Stipulated Penalty shall begin to accrue 10 days after the date Dr. Allen and LFAC receive 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 1-5 of this Section.

B. Timely Written Requests for Extensions. Dr. Allen and LFAC 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 Dr. Allen and LFAC fail 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 business days after Dr. Allen and LFAC receive 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.* Upon a finding that Dr. Allen and/or LFAC have failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Dr. Allen and/or LFAC of: (a) Dr. Allen's and/or LFAC's failure to comply; and (b) OIG's intent to exercise its contractual

right to demand payment of the Stipulated Penalties (this notification is referred to as the “Demand Letter”).

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Dr. Allen and/or LFAC shall either: (a) cure the breach to OIG’s satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to OIG a request for 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 Dr. Allen and/or LFAC elect to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. Allen and/or LFAC cure, 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 Dr. Allen and/or LFAC have 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 Dr. Allen and/or LFAC to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.H;
- b. a repeated or flagrant violation 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.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this IA by Dr. Allen and/or LFAC constitutes an independent basis for Dr. Allen's and/or LFAC's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Dr. Allen and/or LFAC have materially breached this IA and that exclusion is the appropriate remedy, OIG shall notify Dr. Allen and/or LFAC of: (a) Dr. Allen's and/or LFAC's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Dr. Allen and/or LFAC shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. Dr. Allen and/or LFAC are in compliance with the obligations of the IA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Dr. Allen and/or LFAC have begun to take action to cure the material breach; (ii) Dr. Allen and/or LFAC are pursuing such action with due diligence; and (iii) Dr. Allen and/or LFAC have provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Dr. Allen and/or LFAC fail to satisfy the requirements of Section X.D.3, OIG may exclude Dr. Allen and/or LFAC from participation in the Federal health care programs. OIG shall notify Dr. Allen and/or LFAC in writing of its determination to exclude Dr. Allen and/or LFAC (this letter shall be referred to hereinafter 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 Dr. Allen's and/or LFAC's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Dr. Allen and/or LFAC 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 Dr. Allen and/or LFAC 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, Dr. Allen and/or LFAC 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 the 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.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this IA shall be: (a) whether Dr. Allen and/or LFAC were in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. Dr. Allen and/or LFAC 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 Dr. Allen and/or LFAC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dr. Allen and/or LFAC request 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 Chapter 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:

- a. whether Dr. Allen and/or LFAC were in material breach of this IA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30 day period, but that: (i) Dr. Allen and/or LFAC had begun to take action to cure the material breach within that period; (ii) Dr. Allen and/or LFAC have pursued and are pursuing such action with due diligence; and (iii) Dr. Allen and/or LFAC provided to OIG within that period a reasonable timetable for curing the material breach and Dr. Allen and/or LFAC have followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Dr. Allen and/or LFAC, only after a DAB decision in favor of OIG. Dr. Allen's and/or LFAC's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Dr. Allen and/or LFAC 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 Dr. Allen and/or LFAC 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. Dr. Allen and/or LFAC shall waive their 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 Dr. Allen and/or LFAC, Dr. Allen and/or LFAC shall be reinstated effective 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

Dr. Allen and LFAC 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 prior written consent of the parties to this IA.

C. This IA shall be binding on the successors, assigns, and transferees of Dr. Allen and LFAC.

D. OIG may agree to a suspension of Dr. Allen's and/or LFAC's obligations under this IA based on a certification by Dr. Allen and/or LFAC that they are no longer providing health care items or services that will be billed to any Federal health care programs and they 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 Dr. Allen and/or LFAC are relieved of their IA obligations, Dr. Allen and/or LFAC shall be required to notify OIG in writing at least 30 days in advance if Dr. Allen and/or LFAC 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, the OIG shall evaluate whether the IA will be reactivated or modified.

E. All requirements and remedies set forth in this IA are in addition to, and do not effect (1) Dr. Allen's and/or LFAC'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 program requirements.

F. The undersigned Dr. Allen and LFAC signatories represent and warrant that they are authorized to execute this IA. The undersigned OIG signatory represents that he is signing this IA in his official capacity and that he is authorized to execute this IA.

G. 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 DR. MICHAEL C. ALLEN, D.P.M. AND
LEXINGTON FOOT AND ANKLE CENTER, P.S.C.

/Dr. Michael C. Allen, D.P.M./

Dr. Michael C. Allen, D.P.M.

1/24/10
Date

/Dr. Michael C. Allen/

Dr. Michael C. Allen
President
Lexington Foot and Ankle Center, P.S.C.

1/24/10
Date

/Richard E. Plymale, Esq./

Richard E. Plymale, Esq.
Frost, Brown, Todd, LLC
250 West Main Street, Suite 2800
Lexington, Kentucky 40507
Counsel for Dr. Allen and LFAC

1/20/10
Date

/Denise H. McClelland, Esq./

Denise H. McClelland, Esq.
Frost, Brown, Todd, LLC
250 West Main Street, Suite 2800
Lexington, Kentucky 40507
Counsel for Dr. Allen and LFAC

1/20/10
Date

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

/Gregory E. Demske/

2/2/10

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

Date

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement. Dr. Allen and LFAC 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 written notice of the identity of the selected IRO, OIG will notify Dr. Allen and LFAC if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Dr. Allen and LFAC may continue to engage the IRO.

If Dr. Allen and LFAC engage a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Dr. Allen and LFAC shall submit the information identified in Section V.A.5 and Section V.A.6 of the IA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Dr. Allen and LFAC if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Dr. Allen and LFAC 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, reporting, and other requirements of the Federal health care programs for podiatric health care and diabetic care and in the general requirements of the Federal health care program(s) from which Dr. Allen and LFAC seek reimbursement;

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, Medicaid, and Federal Employees Health Benefits Programs (FEHBP) rules and reimbursement guidelines in making assessments in the Claims Review;
3. if in doubt of the application of a particular Medicare, Medicaid, or FEHBP policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);
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 IA.

D. IRO Independence and Objectivity. The IRO must perform the Claims Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Dr. Allen and LFAC.

E. IRO Removal/Termination.

1. *Practitioner.* If Dr. Allen and LFAC terminate its IRO during the course of the engagement, Dr. Allen and LFAC must submit a notice explaining its reasons to OIG no later than 30 days after termination. Dr. Allen and LFAC must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that 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 may, at its sole discretion, require Dr. Allen and LFAC to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Dr. Allen and LFAC to engage a new IRO, OIG shall notify Dr. Allen and LFAC of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Dr. Allen and LFAC may request a meeting with OIG to discuss any aspect of the IRO's qualifications,

independence or performance of its responsibilities and to present additional information regarding these matters. Dr. Allen and LFAC shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Dr. Allen and LFAC prior to requiring Dr. Allen and LFAC to terminate the IRO. However, the final determination as to whether or not to require Dr. Allen and LFAC to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B
CLAIMS REVIEW

A. Claims Review.

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

- a. Overpayment: The amount of money Dr. Allen and/or LFAC have received in excess of the amount due and payable under any Federal health care program requirements.
- b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).
- c. Paid Claim: A code or line item submitted by Dr. Allen and/or LFAC and for which Dr. Allen and/or LFAC have received reimbursement from Medicare, Medicaid, and Federal Employees Health Benefits Programs (FEHBP).
- d. Population: For the first Reporting Period, the Population shall be defined as all Items for which a code or line item has been submitted by or on behalf of Dr. Allen and/or LFAC and for which Dr. Allen and/or LFAC have received reimbursement from Medicare, Medicaid, or FEHBP (i.e., Paid Claim) during the 12-month period covered by the first Claims Review.

For the remaining Reporting Periods, the Population shall be defined as all Items for which Dr. Allen and/or LFAC have received reimbursement from Medicare, Medicaid, or FEHBP (i.e., Paid Claim) during the 12-month period covered by the Claims Review.

To be included in the Population, an Item must have resulted in at least one Paid Claim.

- e. 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 Items in the sample.

2. *Discovery Sample.* The IRO shall randomly select and review samples of 50 Paid Claims submitted by or on behalf of: (1) Dr. Allen; (2) LFAC; and (3) Lexington Diabetic Center, P.S.C. (Discovery Samples). The Paid Claims shall be reviewed based on the supporting documentation available at Dr. Allen's and LFAC's offices or under Dr. Allen's and LFAC's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

If the Error Rates (as defined above) for the Discovery Samples are 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, Dr. Allen and/or LFAC should, as appropriate, further analyze any errors identified in the Discovery Samples. Dr. Allen and LFAC recognize that OIG or other 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 Samples or any other segment of the universe.)

3. *Full Sample.* If the Discovery Samples indicate that the Error Rates are 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Full Sample shall be designed to: (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at Dr. Allen's and/or LFAC's office or under Dr. Allen's and/or LFAC's control and applicable billing and coding regulations and guidance to determine whether the claim submitted 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, Dr. Allen and/or LFAC may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample, if: (1) statistically appropriate and (2) Dr. Allen and/or LFAC select the Full Sample Items using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Dr. Allen and/or LFAC to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

4. *Systems Review.* If Dr. Allen’s, LFAC’s, and/or Lexington Diabetic Center’s Discovery Samples identify Error Rates of 5% or greater, Dr. Allen’s and/or LFAC’s IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Samples and Full Samples that resulted in an Overpayment, the IRO shall perform a “walk through” of the system(s) and process(es) that generated the claim to 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. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Reviews, any Paid Claim for which Dr. Allen and/or LFAC cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Dr. Allen and/or LFAC for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Replacement Sampling. Replacement sampling is not permitted for Items with missing documentation.

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 associated with the Items selected in each first sample (or first sample for each strata, if applicable) 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).

B. Claims Review Report. The following information shall be included in the Claims Review Reports for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology.*

a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review.

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

c. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

d. Sampling Frame. A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. 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).

f. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation.*

a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.

b. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.

c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.

d. 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 Dr. Allen's and LFAC'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 Dr. Allen and/or LFAC (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 Dr. Allen and/or LFAC.
- iii. Total dollar amount of all Overpayments in the sample.
- iv. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.
- v. Error Rate in the sample.
- vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure 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.

4. *Systems Review.* Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

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.