INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ROBERT GAYNOR, DPM
AND
FOOT CARE STORE, INC. d/b/a DIA-FOOT

I. PREAMBLE

Robert Gaynor, DPM (Gaynor) and Foot Care Store, Inc. d/b/a Dia-Foot and (collectively "Dia-Foot") 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, 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, Dia-Foot is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE IA

A. The Effective Date of this IA shall be the date on which the final signatory signs this IA. The term of this IA shall be three years from the Effective Date. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Dia-Foot's final annual report; or (2) any additional materials submitted by Dia-Foot pursuant to OIG's request, whichever is later.

C. The term "Covered Persons" includes: (1) Gaynor, all other owners of Dia-Foot and all employees of Dia-Foot; and (b) all contractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of Dia-Foot, except that the employees of any third party billing company that submits claims to the Federal health care programs on behalf of Dia-Foot shall not be considered Covered Persons, provided that Dia-Foot and the third party billing company provide the certifications required by Section III.J.

III. COMPLIANCE PROGRAM REQUIREMENTS

Dia-Foot shall establish and maintain a compliance program that includes the following elements:

A. Compliance Contact

Within 90 days after the Effective Date, Dia-Foot shall designate a Compliance Contact and shall maintain a Compliance Contact for the term of the IA. The Compliance Contact shall be responsible for: (1) monitoring Dia-Foot's day-to-day compliance activities, (2) meeting any reporting requirements created under this IA, and (3) responding to questions and concerns from OIG regarding Dia-Foot's compliance with the IA. The Compliance Contact shall make periodic (at least quarterly) reports regarding compliance matters to the President of Dia-Foot. Written documentation of the Compliance Contact's reports to the President shall be made available to OIG upon request. The Compliance Contact shall not have any responsibilities that involve acting in any capacity as legal counsel or supervising legal functions for Dia-Foot and any non-compliance job responsibilities shall not involve billing, coding, or claim submission (or oversight for those functions) for Dia-Foot.

Dia-Foot 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 requirements in this IA, within five business days after such a change.

B. Policies and Procedures

Within 90 days after the Effective Date, Dia-Foot shall develop and implement written policies and procedures regarding appropriate billing and medical record documentation for compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall include a requirement that (1) Dia-Foot must maintain documentation necessary to demonstrate that Dia-Foot adhered to the DMEPOS Quality Standards for diabetic shoe inserts set forth at 42 U.S.C. § 1395m(a)(20), and the DME Supplier Standards at 42 CFR § 424.57 (collectively "Quality Standards"); (2) Dia-Foot must maintain documentation to demonstrate that Dia-Foot adhered to the definition of "custom-fabricated" set forth in 42 U.S.C. § 1395m(h) and as determined by the Pricing, Data Analysis and Coding (PDAC) Medicare contractor; (3) for diabetic shoe inserts billed under HCPCS code A5513, Dia-Foot must maintain documentation necessary to demonstrate that Dia-Foot obtained a clear

impression of the specific patient's foot and used that impression to make a make a positive model of the patient's foot from which the final product was crafted; and (4) for diabetic shoe inserts billed under HCPCS code A5514, Dia-Foot must maintain documentation necessary to demonstrate that it obtained a scan of each foot (i.e., right and left) for which an insert was manufactured. Throughout the term of this IA, Dia-Foot shall enforce its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons.

At least annually (and more frequently, if appropriate), Dia-Foot shall assess and update, as necessary, the Policies and Procedures. Any revised or new Policies and Procedures shall be made available to all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. Posting of Notice

Within 90 days after the Effective Date, Dia-Foot 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 Contact 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. *Covered Persons Training*. All Covered Persons shall receive at least three hours of training during the first Reporting Period. Any individuals who become Covered Persons after the Effective Date and during the term of this IA shall receive at least three hours of training within 90 days of becoming a Covered Person.

Training may be completed in-person or online. These training requirements may be satisfied only by the completion of training courses that are submitted to OIG, prior to registration for the training course, for review and approval.

At a minimum, the required training sessions must include the following topics:

a. the Federal health care program billing, coding and claim submission statutes, regulations, and program requirements and directives relating to the items or services furnished by Dia-Foot;

b. the Federal health care program medical record documentation requirements relating to items or services furnished by Dia-Foot;

c. Dia-Foot's Policies and Procedures regarding the documentation necessary (1) to demonstrate that Dia-Foot adhered to the Quality Standards and the definition of "custom-fabricated" set forth in 42 U.S.C. §1395m(h) and as determined by the PDAC Medicare contractor and (2) to support billing for diabetic shoe inserts billed under HCPCS code A5513 and HCPCS code A5514; and

d. the personal obligation of each individual involved in the manufacturing, medical record documentation, and claims submission processes for diabetic shoes and inserts, to ensure that documentation and claims are accurate, and that Dia-Foot's manufacturing process adheres to the Quality Standards and demonstrates that the diabetic shoes and inserts were "custom-fabricated," in compliance with the 42 U.S.C. § 1395m(h) and as determined by the Pricing, Data Analysis and Coding (PDAC) Medicare contractor.

The OIG may, in its discretion, require that Gaynor or all Covered Persons complete additional hours of training regarding the topics identified above, or additional topics, in the second or third years of the IA. The OIG shall provide notice to Dia-Foot of such additional required training at least 180 days prior to the required completion date for such training.

2. *Training Records.* Dia-Foot 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, Dia-Foot 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 Dia-Foot shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Dia-Foot) related to the reviews.

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

2. *Claims Review.* The IRO shall conduct a review of Dia-Foot's claims submitted to and reimbursed by the Medicare and Medicaid programs to determine whether the manufacturing process for the items furnished was appropriately documented and whether the claims were correctly coded, submitted, and reimbursed, for each three-month period during the term of this IA (Quarterly Claims Review) and shall prepare a Quarterly Claims Review Report, as outlined in Appendix B to this IA, which is incorporated by reference. In addition, the IRO's review shall verify whether the items furnished were "custom-fabricated" (as defined in 42 U.S.C. § 1395m(h)) and were manufactured according to the specifications submitted by Dia-Foot to and approved by the PDAC Medicare contractor, including (a) for diabetic shoe inserts billed under HCPCS code A5513, that Dia-Foot maintained documentation to demonstrate that Dia-Foot obtained a clear impression of the specific patient's foot, and used that impression to make a make a positive model of the patient's foot from which the final product was crafted; and (b) for diabetic shoe inserts billed under HCPCS code A5514, that Dia-Foot maintained documentation to demonstrate that it obtained a scan of each foot (i.e., right and left) for which an insert was manufactured. The first three-month period for purposes of the Quarterly Claims Review requirement shall begin 30 days after the Effective Date. Each Quarterly Claims Review Report shall be submitted to OIG within 60 days following the end of the three-month period covered by the Quarterly Claims Review.

3. *Invoice Review.* For items not directly billed by Dia-Foot to Federal health care programs, the IRO shall conduct a review of Dia-Foot's invoices for custom-

fabricated inserts to determine whether Dia-Foot maintained documentation to demonstrate that the items furnished were manufactured in accordance with standards submitted to and approved by the PDAC Medicare contractor for each three-month period during the term of this IA (Quarterly Invoice Review) and shall prepare a Quarterly Invoice Review Report, as outlined in Appendix B to this IA, which is incorporated by reference. The IRO's review shall verify whether the items furnished were "custom-fabricated" (as defined in 42 U.S.C. § 1395m(h)) and were manufactured according to the specifications submitted by Dia-Foot to and approved by the PDAC Medicare contractor, including (a) for diabetic shoe inserts invoiced with HCPCS code A5513, that Dia-Foot maintained documentation to demonstrate that Dia-Foot obtained a clear impression of the specific patient's foot, and used that impression to make a make a positive model of the patient's foot from which the final product was crafted; and (b) for diabetic shoe inserts invoiced with HCPCS code A5514, that Dia-Foot maintained documentation to demonstrate that it obtained a scan of each foot (i.e., right and left) for which an insert was manufactured. The first three-month period for purposes of the Quarterly Invoice Review requirement shall begin 30 days after the Effective Date. Each Quarterly Invoice Review Report shall be submitted to OIG within 60 days following the end of the three-month period covered by the Quarterly Invoice Review.

4. *Independence and Objectivity Certification*. Prior to performing the first Quarterly Claims and Invoice Reviews, and annually thereafter, the IRO shall submit to Dia-Foot 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. The IRO's certification shall include a summary of all current and prior engagements between Dia-Foot and the IRO.

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 from participation in any Federal health care program; 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 List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov).

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

a. Dia-Foot shall screen all prospective Covered Persons against the Exclusion List 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. Dia-Foot shall screen all current Covered Persons against the Exclusion List within 30 days after the Effective Date and on a monthly basis thereafter.

c. Dia-Foot shall require all Covered Persons to immediately disclose immediately if they become an Ineligible Person.

Dia-Foot shall maintain documentation in order to demonstrate that Dia-Foot: (1) has checked the Exclusion List (i.e., a print screen of the search results) and determined that its Covered Persons are not Ineligible Persons; and (2) has required its Covered Persons to disclose if they are an Ineligible Person.

Nothing in this Section III.F affects Dia-Foot'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. Dia-Foot understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Dia-Foot may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Dia-Foot meets the requirements of Section III.F.

3. *Removal Requirement*. If Dia-Foot has actual notice that a Covered Person has become an Ineligible Person, Dia-Foot shall remove such Covered Person from responsibility for, or involvement with, Dia-Foot's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions*. If Dia-Foot 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, Dia-Foot 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, Dia-Foot shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Dia-Foot conducted or brought by a governmental entity or its agents involving an allegation that Dia-Foot 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. Dia-Foot 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*. An "Overpayment" means any funds that Dia-Foot receives or retains under any Federal health care program to which Dia-Foot, after applicable reconciliation, is not entitled under such Federal health care program.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, Dia-Foot 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, Dia-Foot identifies any Overpayment, Dia-Foot shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and guidance from the Centers for Medicare and Medicaid Services (CMS). Dia-Foot 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 Dia-Foot.

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

2. *Reporting of Reportable Events*. If Dia-Foot determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Dia-Foot 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. and III.I.1.b.* For Reportable Events under Section III.I.1.a and b, the report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of 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, if any;

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

d. a description of the steps taken by Dia-Foot to identify and quantify any Overpayments; and

e. a description of Dia-Foot's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, Dia-Foot shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. §1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.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 List screening that Dia-Foot completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Ineligible Person was identified; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *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 requirements implicated.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Dia-Foot to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Dia-Foot identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Dia-Foot is not required by this Section III.I 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 Dia-Foot contracts with a third-party billing company to submit claims to the Federal health care programs on behalf of Dia-Foot, Dia-Foot 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.

Dia-Foot also shall obtain (as applicable) a certification from any third party billing company that the company: (1) has a policy of not employing any person who is excluded from participation in any Federal health care program to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (2) screens its prospective and current employees against the Exclusion

List ; and (3) provides training in the applicable requirements of the Federal health care programs to those employees involved in the preparation and submission of claims to Federal health care programs.

If applicable, a copy of these certifications shall be included in Dia-Foot's Implementation Report and each Annual Report required by Section V below.

IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS

In the event that, after the Effective Date, Gaynor or Dia-Foot propose to (a) sell any or all of its locations or businesses that are subject to this IA (whether through a sale of assets, sale of stock, or other type of transaction), or (b) purchase or establish a new location or business related to the furnishing of items or services that may be reimbursed by any Federal health care program, the IA shall be binding on the purchaser of any such location or business and any new location or business (and all Covered Persons at each new location or business) shall be subject to the requirements of this IA, unless otherwise determined and agreed to in writing by OIG. Dia-Foot shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or proposed purchase, Dia-Foot wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the IA, Dia-Foot must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the location or business to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION REPORT, IRO REPORTS, AND ANNUAL REPORTS

A. Implementation Report

Within 90 days after the Effective Date, Dia-Foot 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 Contact required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Contact may have;

2. a list 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; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Dia-Foot that includes a summary of all current and prior engagements between Dia-Foot and the IRO;

5. a copy of the search result print screens demonstrating that Dia-Foot has screened all Covered Persons against the Exclusion List as required by Section III.F within 30 days of the Effective Date;

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

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

8. a list of all of Dia-Foot's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and each location's Medicare and state Medicaid program provider number(s), and/or supplier number(s); and

9. a certification by Gaynor, the Compliance Contact, and the President 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, Dia-Foot is in compliance with all of the requirements of this IA; (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; and (d) he or she understands that this certification is being provided to and relied upon by the United States. Gaynor and the President also shall certify that (a) the materials and manufacturing process used to fabricate each custom orthotic sold by Dia-Foot adhered to the specifications previously submitted by Dia-Foot to and approved by the Pricing, Data Analysis and Coding (PDAC) Medicare contractor and (b) Dia-Foot adhered to the Quality Standards (as defined above).

B. IRO Reports

Within 60 days following the end of each three-month period during the term of this IA, Dia-Foot shall provide to OIG a copy of the Quarterly Claims Review Report and Quarterly Invoice Review Report prepared by the IRO for each Quarterly Claims Review and Quarterly Invoice Review performed, along with Dia-Foot's response and corrective action plan related to any recommendations made by the IRO in the Quarterly Claims Review Report and Quarterly Invoice Review Report. Each Quarterly Claims Review Report and Quarterly Invoice Review Report shall include the information specified in Appendix B to this IA.

C. Annual Reports

Dia-Foot shall submit to OIG a report on its compliance with the IA requirements for each of the three Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

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

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

3. (in the first Annual Report) 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 describes the content of the training program. A copy of all training materials shall be made available to OIG upon request;

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

5. a copy of the search result print screens demonstrating that Dia-Foot screened all prospective and current Covered Persons against the Exclusion List, as required by Section III.F;

6. 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;

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

8. 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;

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

10. a copy of any certifications from Dia-Foot and the third-party billing company required by Section III.J (if applicable);

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

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

13. a certification by Gaynor, the Compliance Contact, and the President 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, Dia-Foot is in compliance with all of the requirements of this IA; (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; and (d) he or she understands that this certification is being provided to and relied upon by the United States. Gaynor and the President also shall certify that (a) the materials and manufacturing process used to fabricate each custom orthotic sold by Dia-Foot adhered to the specifications previously submitted by Dia-Foot to and approved by the Pricing, Data Analysis and Coding (PDAC) Medicare contractor, and (b) Dia-Foot adhered to the Quality Standards (as defined above).

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.

D. Designation of Information

Dia-Foot 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. Dia-Foot 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

Dia-Foot:

Contact Name
Address
Telephone:
Facsimile:
Email Address:

Unless otherwise specified, all notifications and reports required by this IA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Dia-Foot may be required to provide OIG with an additional copy of each notification or report required by this IA in OIG's requested format (electronic or paper).

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of Dia-Foot's books, records, and other documents and supporting materials and conduct on-site reviews of any of Dia-Foot's locations, for the purpose of verifying and evaluating: (a) Dia-Foot's compliance with the terms of this IA and (b) Dia-Foot's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Dia-Foot 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 Dia-Foot's owners, employees, and contractors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Dia-Foot shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Dia-Foot's owners, employees, and contractors may elect to be interviewed with or without a representative of Dia-Foot present.

VIII. DOCUMENT AND RECORD RETENTION

Dia-Foot shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this IA for four years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Dia-Foot prior to any release by OIG of information submitted by Dia-Foot pursuant to its requirements under this IA and identified upon submission by Dia-Foot as trade secrets, or information that is commercial or financial

and privileged or confidential, under the FOIA rules. With respect to such releases, Dia-Foot shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties

OIG may assess:

1. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section III.A;

2. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section III.B;

3. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section III.C;

4. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section III.D;

5. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section III.E;

6. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section III.F;

7. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section III.G;

8. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section III.H;

9. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section III.I;

10. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section III.J (if applicable);

11. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section IV;

12. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section V;

13. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section VII;

14. A Stipulated Penalty of up to $1,000 for each day Dia-Foot fails to comply with Section VIII;

15. A Stipulated Penalty of up to $50,000 for each false certification or false statement made to OIG by or on behalf of Dia-Foot under this IA; or

16. A Stipulated Penalty of up to $100 for each invoice reviewed by the IRO under Section III.E.3 and Appendix B to this IA for which the IRO made a determination that (a) the items furnished were not "custom-fabricated" (as defined in 42 U.S.C. § 1395m(h)) and/or were not manufactured according to the specifications submitted by Dia-Foot to and approved by the PDAC Medicare contractor; (b) for diabetic shoe inserts invoiced with HCPCS code A5513, that Dia-Foot failed to maintain documentation to demonstrate that Dia-Foot obtained a clear impression of the specific patient's foot, and used that impression to make a make a positive model of the patient's foot from which the final product was crafted; or (c) for diabetic shoe inserts invoiced with HCPCS code A5514, that Dia-Foot failed to maintain documentation to demonstrate that it obtained a scan of each foot (i.e., right and left) for which an insert was manufactured.

B. Timely Written Requests for Extensions

Dia-Foot may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this IA. If OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Dia-Foot fails to meet the revised deadline set by OIG. If OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Dia-Foot receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received

by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter*. If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify Dia-Foot of: (a) Dia-Foot's failure to comply; and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter*. Within 15 business days after the date of the Demand Letter, Dia-Foot shall either: (a) pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

D. Exclusion for Material Breach of this IA

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

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

b. failure to comply with Section III.A;

c. failure to comply with Section III.E;

d. failure to comply with Section III.I;

e. failure to comply with Section V;

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

g. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Dia-Foot to pay the Stipulated Penalties or within 20 days after the HHS Departmental

Appeals Board (DAB) issues a decision upholding the determination of OIG; or

h. failure to come into compliance with a requirement for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this IA by Dia-Foot constitutes an independent basis for Gaynor's and/or Dia-Foot's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than three years for each material breach. Upon a preliminary determination by OIG that Dia-Foot has materially breached this IA, OIG shall notify Dia-Foot of: (a) Dia-Foot's material breach; and (b) OIG's intent to exclude Gaynor and/or Dia-Foot. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice*. Dia-Foot and/or Gaynor shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter*. If OIG determines that exclusion is warranted, OIG shall notify Dia-Foot and/or Gaynor in writing of its determination to exclude Dia-Foot. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by Dia-Foot, including administrative and management services, except as stated in regulations found at 42 C.F.R. 1001.1901(c). Reinstatement to program participation is not automatic. At the end of the period of exclusion, Dia-Foot and/or Gaynor (as applicable) may apply for reinstatement, by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights*. Upon OIG's issuing a Demand Letter or Exclusion Letter, and as an agreed-upon remedy for the resolution of disputes arising under this IA, Dia-Foot shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by

an HHS ALJ and, in the event of an appeal, the DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this IA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter; and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this IA shall be: (a) whether Dia-Foot was in full and timely compliance with the requirements of this IA for which OIG demands payment; and (b) the period of noncompliance. Dia-Foot shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Dia-Foot has breached this IA and orders Dia-Foot to pay Stipulated Penalties, Dia-Foot must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless Dia-Foot properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, Dia-Foot must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the DAB issues its decision.

3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this IA shall be whether Dia-Foot was in material breach of this IA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Dia-Foot shall waive its right to any notice by OIG of the exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Dia-Foot, Dia-Foot shall be reinstated effective on the date of the exclusion.

4. *Finality of Decision*. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. The parties to this IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA and Dia-Foot

agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XI. EFFECTIVE AND BINDING AGREEMENT

Dia-Foot 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 Dia-Foot's requirements under this IA based on a certification by Dia-Foot 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 Dia-Foot is relieved of its IA requirements, Dia-Foot shall be required to notify OIG in writing at least 30 days in advance if Dia-Foot 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) Dia-Foot'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 Dia-Foot 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. Electronically transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this IA.

ON BEHALF OF ROBERT GAYNOR, DPM AND FOOT CARE STORE, INC.
d/b/a DIA-FOOT

_____/Robert Gaynor/_____ ___12/23/21_____
ROBERT GAYNOR, DPM DATE

_____/Robert Gaynor/_____ ___12/23/21_____
ROBERT GAYNOR, DPM DATE
President, Foot Care Store, Inc. d/b/a Dia-Foot

___/Kelly Custer/_____ ____12/23/21_____
KELLY T. CUSTER DATE
Counsel for Dia-Foot
Brown & Fortunato

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

_____/Lisa M. Re/_____ ___12/29/21_____
LISA M. RE DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

____/Tonya Keusseyan/_____ __12-30-21_____
TONYA KEUSSEYAN DATE
Senior Counsel
Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Dia-Foot shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.4 of the IA or any additional information submitted by Dia-Foot in response to a request by OIG, whichever is later, OIG will notify Dia-Foot if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Dia-Foot may continue to engage the IRO.

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

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Quarterly Claims Review who have expertise in the billing, coding, claims submission and other applicable Medicare (including Medicare Part C) and state Medicaid program requirements;

2. assign individuals to conduct the Quarterly Invoice Review who have expertise in the DMEPOS Quality Standards for diabetic shoe inserts set forth at 42 U.S.C. § 1395m(a)(20), and the DME Supplier Standards applicable to diabetic shoe inserts, including those found at 42 CFR § 424.57;

3. assign individuals to design and select the Quarterly Claims Review and Quarterly Invoice Review sample who are knowledgeable about the appropriate statistical sampling

techniques;

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

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

C. IRO Responsibilities

The IRO shall:

1. perform each Quarterly Claims Review and Quarterly Invoice 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 Quarterly Claims Review and Quarterly Invoice Review;

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

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

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

D. Dia-Foot Responsibilities

Dia-Foot shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in Section III.E of this IA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform the Quarterly Claims Review and the Quarterly Invoice Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

1. *Dia-Foot and IRO*. If Dia-Foot terminates its IRO or if the IRO withdraws from the engagement during the term of the IA, Dia-Foot 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. Dia-Foot must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO*. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Dia-Foot in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Dia-Foot 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 Dia-Foot regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Dia-Foot in writing that Dia-Foot shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Dia-Foot 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 Dia-Foot to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

QUARTERLY CLAIMS AND INVOICE REVIEWS

A. Quarterly Claims and Invoice Reviews. The IRO shall conduct a review of Dia-Foot's claims submitted to and reimbursed by the Medicare and Medicaid programs, to determine whether the manufacturing process for the items furnished was appropriately documented, and whether the claims were correctly coded, billed, and reimbursed, for each three-month period during the term of this IA (Quarterly Claims Review) and prepare a report for each Quarterly Claims Review performed.

For custom-fabricated items sold to Dia-Foot customers and not directly billed by Dia-Foot to Federal health care programs, the IRO shall conduct a review of Dia-Foot's invoices sent to customers for custom-fabricated products (Customer Invoices) to determine whether the items furnished were custom-manufactured and were manufactured according to the specifications submitted by Dia-Foot to and approved by the PDAC Medicare contractor for each three-month period during the term of this IA (Quarterly Invoice Review) and shall prepare a Quarterly Invoice Review Report.

The first three-month period shall begin 30 days following the Effective Date of this IA.

1. *Definitions*. For the purposes of this Appendix B, the following definitions shall be used:

   a. Overpayment: The amount of money Dia-Foot 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 Quarterly Claims Review performed under this Appendix.

   b. Paid Claim: A claim submitted by Dia-Foot and for which Dia-Foot has received reimbursement from the Medicare program, a Medicare Part C plan, or a state Medicaid program.

   c. Population: The Population for the Quarterly Claims Review shall be defined as all Paid Claims during the three-month period covered by the Quarterly Claims Review and the Population for the Quarterly Invoice Review shall be all Customer Invoices during the three-month period covered by the Quarterly Invoice Review.

2. *Quarterly Claims Sample.*

   a. Within 15 days following the end of each three-month period during the term of the IA, the IRO shall randomly select a sample of 30 Paid Claims submitted by or on behalf of Dia-Foot during the preceding three-month

period (Quarterly Claims Sample). The sample must be selected through the use of OIG's Office of Audit Services' Statistical Sampling Software, also known as RAT-STATS, which is currently available at https://oig.hhs.gov/compliance/rat-stats/index.asp.

b. Dia-Foot shall provide the IRO with a list of all Dia-Foot's Paid Claims for the three-month period covered by the Quarterly Claims Sample. The IRO should number each Paid Claim in the Population sequentially prior to generating the random numbers used to select the Quarterly Claims Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the 30 Paid Claims in the Population that will be subject to review by the IRO.

c. The randomly selected 30 Paid Claims shall be reviewed by the IRO based on the supporting documentation available at Dia-Foot's office or under Dia-Foot's control and applicable Medicare and state Medicaid program requirements to determine whether the manufacturing process for the items furnished was appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed. In addition, the IRO's review shall verify whether the items furnished were "custom-fabricated" (as defined in 42 U.S.C. § 1395m(h)) and were manufactured according to the specifications submitted by Dia-Foot to and approved by the PDAC Medicare contractor, including (1) for diabetic shoe inserts billed under HCPCS code A5513, that Dia-Foot maintained documentation to demonstrate that Dia-Foot obtained a clear impression of the specific patient's foot, and used that impression to make a make a positive model of the patient's foot from which the final product was crafted; and (2) for diabetic shoe inserts billed under HCPCS code A5514, that Dia-Foot maintained documentation to demonstrate that it obtained a scan of each foot (i.e., right and left) for which an insert was manufactured.

d. The IRO shall prepare a written report of its findings from the Quarterly Claims Sample, as described in Section B below (Quarterly Claims Review Report). The Quarterly Claims Review Report shall be submitted to the OIG within 60 days following the end of the three-month period covered by each Quarterly Claims Review.

3. *Quarterly Invoice Sample.*

a. Within 15 days following the end of each three-month period during the term of the IA, the IRO shall randomly select a sample of 30 Customer Invoices issued by Dia-Foot during the preceding three-month period (Quarterly Invoice Sample). The sample must be selected through the use of OIG's Office of Audit Services' Statistical Sampling Software, also

known as RAT-STATS, which is currently available at https://oig.hhs.gov/compliance/rat-stats/index.asp.

b. Dia-Foot shall provide the IRO with a list of all Dia-Foot's Customer Invoices for the three-month period covered by the Quarterly Invoice Sample. The IRO should number each Customer Invoice in the Population sequentially prior to generating the random numbers used to select the Quarterly Invoices Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the 30 Customer Invoices in the Population that will be subject to review by the IRO.

c. The randomly selected 30 Customer Invoices shall be reviewed by the IRO based on the supporting documentation available at Dia-Foot's office or under Dia-Foot's control and to determine whether the items furnished were "custom-fabricated" (as defined in 42 U.S.C. § 1395m(h)) and were manufactured according to the specifications submitted by Dia-Foot to and approved by the PDAC Medicare contractor, including (1) for diabetic shoe inserts billed under HCPCS code A5513, that Dia-Foot maintained documentation to demonstrate that Dia-Foot obtained a clear impression of the specific patient's foot, and used that impression to make a make a positive model of the patient's foot from which the final product was crafted; and (2) for diabetic shoe inserts billed under HCPCS code A5514, that Dia-Foot maintained documentation to demonstrate that it obtained a scan of each foot (i.e., right and left) for which an insert was manufactured.

d. The IRO shall prepare a written report of its findings from the Quarterly Invoice Sample, as described in Section C below (Quarterly Invoice Review Report). The Quarterly Invoice Review Report shall be submitted to the OIG within 60 days following the end of the three-month period covered by each Quarterly Invoice Review.

B. Claims Review Report. The IRO shall prepare a Claims Review Report for each Quarterly Claims Review performed (Quarterly Claims Review Report). The following information shall be included in each Quarterly Claims Review Report.

1. *Claims Review Methodology*.

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

b. Source of Data. A description of (1) the process used to identify Paid Claims in the Population, and (2) the specific documentation relied upon

by the IRO when performing the Quarterly 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 contractor manual or bulletins (including issue and date), other policies, regulations, or directives).

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

d. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in each Quarterly Claims Sample and Dia-Foot shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Quarterly Claims Sample. If the IRO accepts any supplemental documentation or materials from Dia-Foot after the IRO has completed its initial review of the Quarterly Claims Sample (Supplemental Materials), the IRO shall identify in the Quarterly 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 Quarterly Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Statistical Sampling Documentation*. A copy of the printout of the random numbers generated by the "Random Numbers" function of RAT-STATS used by the IRO to select the Quarterly Claims Sample.

3. *Claims Review Findings*.

a. Narrative Results.

i. For the first Quarterly Claims Review Report only, a description of (a) Dia-Foot's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing, and (b) a description of controls in place to ensure that (i) the manufacturing processes for all items billed to Medicare or a state Medicaid program by Dia-Foot are appropriately documented, (ii) Dia-Foot adhered to the Quality Standards (as defined in Section III.B. of the CIA), and (iii) that the materials and manufacturing process used to fabricate each custom orthotic adhered to the specifications previously submitted by Dia-Foot to and approved by the PDAC Medicare contractor. Subsequent Quarterly Claims Review Reports should describe any significant changes to items (a) and (b) or, if no significant changes were made, state that the systems and controls remain the same as described in the prior Quarterly Claims Review Report.

ii. A narrative explanation of the results of the Quarterly Claims Sample, including reasons for errors, patterns noted, etc.

b. Quantitative Results.

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

ii. Total number and percentage of instances in which the IRO determined that a Paid Claim included items that were not "custom-fabricated" or were not manufactured according to the specifications submitted by Dia-Foot to and approved by the PDAC Medicare contractor, including (a) for diabetic shoe inserts billed under HCPCS code A5513, that Dia-Foot failed to maintain documentation to demonstrate that Dia-Foot obtained a clear impression of the specific patient's foot, and used that impression to make a make a positive model of the patient's foot from which the final product was crafted; and (b) for diabetic shoe inserts billed under HCPCS code A5514, that Dia-Foot failed to maintain documentation to demonstrate that it obtained a scan of each foot (i.e., right and left) for which an insert was manufactured, and in

which such errors resulted in an Overpayment to Dia-Foot.

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

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

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

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

viii. A spreadsheet of the Quarterly Claims Sample results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, HCPCS code submitted, HCPCS code reimbursed, allowed amount reimbursed by payor, correct HCPCS code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

c. Recommendations. The IRO's report shall include any recommendations for improvements to: (i) Dia-Foot's billing and coding system, (ii) Dia-Foot's controls for ensuring that: the manufacturing processes for all items billed to Medicare or a state Medicaid program are appropriately documented, Dia-Foot adhered to the Quality Standards (as defined in Section III.B. of the CIA), and that the materials and manufacturing process used to fabricate each custom orthotic adhered to the specifications previously submitted by Dia-Foot to and approved by the PDAC Medicare contractor, based on the findings of the Quarterly Claims Review.

d. Credentials. The names and credentials of the individuals who: (1) designed the review methodology utilized for the Quarterly Claims Review and (2) performed the Quarterly Claims Review.

C. Invoice Review Report. The IRO shall prepare an Invoice Review Report for each Quarterly Invoice Review performed (Quarterly Invoice Review Report). The following information shall be included in each Quarterly Invoice Review Report.

1. *Invoice Review Methodology*.

a. Invoice Review Population. A description of the Population subject to the Quarterly Invoice Review.

b. Source of Data. A description of (1) the process used to identify Customer Invoices in the Population, and (2) the specific documentation relied upon by the IRO when performing the Quarterly Invoice Review

c. Review Protocol. A narrative description of how the Quarterly Invoice Review was conducted and what was evaluated.

d. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Invoices in each Quarterly Invoice Sample and Dia-Foot shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Quarterly Invoice Sample. If the IRO accepts any supplemental documentation or materials from Dia-Foot after the IRO has completed its initial review of the Quarterly Invoice Sample (Supplemental Invoice Materials), the IRO shall identify in the Quarterly Invoice 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 Quarterly Invoice Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Statistical Sampling Documentation*. A copy of the printout of the random numbers generated by the "Random Numbers" function of RAT-STATS used by the IRO to select the Quarterly Invoice Sample.

3. *Invoice Review Findings*.

a. Narrative Results.

i. For the first Quarterly Invoice Review Report only, a description of (a) Dia-Foot's manufacturing and fabrication process(es) and system(s), including the identification, by position description, of the personnel involved in manufacturing and fabrication; and (b) a description of controls in place to ensure that (i) Dia-Foot adhered to the Quality Standards (as defined in Section III.B., (ii) the materials and manufacturing process used to fabricate each custom orthotic adhered to the specifications previously submitted by Dia-Foot to and approved by the PDAC Medicare contractor. Subsequent Quarterly Invoice Review Reports should describe any significant changes to items (a) and (b) or, if no significant changes were made, state that the systems and controls remain the same as described in the prior Quarterly Invoice Review Report.

ii. A narrative explanation of the results of the Quarterly Invoice Sample, including reasons for errors, patterns noted, etc.

b. Quantitative Results.

i. The total number and percentage of instances in which the IRO determined that the items reflected in a Customer Invoice were not "custom-fabricated" (as defined in 42 U.S.C. § 1395m(h)) and/or were not manufactured according to the specifications submitted by Dia-Foot to and approved by the PDAC Medicare contractor.

ii. The total number and percentage of instances in which the IRO determined that, for diabetic shoe inserts invoiced under HCPCS code A5513, that Dia-Foot failed to maintain documentation to demonstrate that Dia-Foot obtained a clear impression of the specific patient's foot, and used that impression to make a make a positive model of the patient's foot for which the final product was crafted.

iii. The total number and percentage of instances in which the IRO determined that, for diabetic shoe inserts invoiced under HCPCS code A5514, Dia-Foot failed to maintain documentation to demonstrate that it obtained a scan of each foot (i.e., right and left) for which an insert was manufactured.

c. Recommendations. The IRO's report shall include any recommendations for improvements to Dia-Foot's controls for ensuring that: the manufacturing processes for all items furnished to Dia-Foot customers are appropriately documented, Dia-Foot adheres to the Quality Standards (as defined in Section III.B. of the CIA), and the materials and manufacturing process used to fabricate each custom orthotic sold to a Dia-Foot customer adheres to the specifications previously submitted by Dia-Foot to and approved by the PDAC Medicare contractor, based on the findings of the Quarterly Invoice Review.

d. Credentials. The names and credentials of the individuals who: (1) designed the review methodology utilized for the Quarterly Invoice Review and (2) performed the Quarterly Invoice Review.

D. Other Requirements. The following requirements apply to any Quarterly Claims or Quarterly Invoice Review performed pursuant to this Appendix B.

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

2. *Customer Invoices without Supporting Documentation.* Any Customer Invoice for which Dia-Foot cannot produce documentation shall be considered an error. Replacement sampling for Customer Invoices with missing documentation is not permitted.

2. *Use of First Samples Drawn*. For the purposes of all samples discussed in this Appendix, the Paid Claims or Customer Invoices 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 sample).