

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
FAMILY DERMATOLOGY, P.C.**

I. PREAMBLE

Dr. Paula Nelson, Yinka Adesokan, Family Dermatology, P.C., Family Dermatology of Pennsylvania, P.C., and Family Dermatology of Delaware, P.A. (Family Dermatology) hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Family Dermatology is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Family Dermatology under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. 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) Family Dermatology’s final annual report; or (2) any additional materials submitted by Family Dermatology pursuant to OIG’s request, whichever is later.

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

1. “Arrangements” shall mean every arrangement or transaction that:
 - a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between

Family Dermatology and any actual or potential source of health care business or referrals to Family Dermatology any actual or potential recipient of health care business or referrals from Family Dermatology. The term “source of health care business or referrals” shall mean any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program and the term “recipient of health care business or referrals” shall mean any individual or entity (1) to whom Family Dermatology refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom Family Dermatology purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or

- b. is between Family Dermatology and a physician (or a physician’s immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Family Dermatology for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

2. “Focus Arrangements” means every Arrangement that:

- a. is between Family Dermatology and any actual source of health care business or referrals to Family Dermatology and involves, directly or indirectly, the offer, payment, or provision of anything of value; or
- b. is between Family Dermatology and any physician (or a physician’s immediate family member) (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Family Dermatology for designated health services (as defined at 42 U.S.C. §1395nn(h)(6)).

Notwithstanding the foregoing provisions of Section II.C.2, any Arrangement that satisfies the requirements of 42 C.F.R. § 411.356 (ownership or investment interests), 42 C.F.R. § 411.357(g) (remuneration unrelated to the provision of designated health services); 42 C.F.R. § 411.357(i) (payments by a physician for items and services); 42 C.F.R. § 411.357(k) (non-monetary compensation); 42 C.F.R. § 411.357(m) (medical staff incidental benefits), 42 C.F.R. § 411.357(o) (compliance training), 42 C.F.R. § 411.357(q) (referral services), 42 C.F.R. § 411.357(s) (professional courtesy), 42 C.F.R. § 357(u) (community-wide health information systems), or any exception to the prohibitions of 42 U.S.C. § 1395nn enacted following the Effective Date that does not require a written agreement shall not be considered a Focus Arrangement for purposes of this CIA.

3. “Covered Persons” includes:
 - a. all owners, officers, directors, and employees of Family Dermatology; and
 - b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Family Dermatology excluding vendors whose sole connection with Family Dermatology is selling or otherwise providing medical supplies or equipment to Family Dermatology and who do not bill the Federal health care programs for such medical supplies or equipment; and

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during a Reporting Period.

4. “Arrangements Covered Persons” includes each Covered Person who is involved with the development, approval, management, or review of Family Dermatology’s Arrangements.

III. CORPORATE INTEGRITY OBLIGATIONS

Family Dermatology shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer

1. Within 90 days after the Effective Date, Family Dermatology shall appoint a Covered Person to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be a member of senior management and shall report directly to the Chief Executive Officer of Family Dermatology, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Chief Executive Officer of Family Dermatology, shall be authorized to report on such matters to the Chief Executive Officer at any time, and shall not be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel to or supervising legal counsel functions for Family Dermatology. Written documentation of the Compliance Officer's reports to the Chief Executive Officer shall be made available to OIG upon request. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements; and
- b. monitoring the day-to-day compliance activities engaged in by Family Dermatology as well as for any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA. Family Dermatology shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

B. Policies and Procedures

Within 90 days after the Effective Date, Family Dermatology shall develop and implement written Policies and Procedures regarding compliance with:

- a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law; and
- b. the requirements set forth in Section III.E (Compliance with the Anti-Kickback Statute and Stark Law).

Throughout the term of this CIA, Family Dermatology shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

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

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

C. Posting of Notice

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

D. Training

All Covered Persons shall receive at least three hours of training during the first Reporting Period, including at least one hour of training to be completed within 60 days after the Effective Date. Training may be completed in-person or online. These training requirements may be satisfied only by training courses that are submitted to OIG, prior to registration for the training course, for review and approval, and may include courses provided by the Centers for Medicare & Medicaid Services (CMS) Medicare Learning Network (MLN), or Family Dermatology's Medicare contractor, if they fulfill the requirements below.

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

- a. Arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law, as well as the regulations and other guidance documents related to these statutes;
- b. Family Dermatology's policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Tracking System, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.E of the CIA;
- c. The personal obligation of each individual involved in the development, approval, management, or review of Family Dermatology's Arrangements to know the applicable legal requirements and the Family Dermatology's policies and procedures;
- d. The legal sanctions under the Anti-Kickback Statute and the Stark Law; and
- e. Examples of violations of the Anti-Kickback Statute and the Stark Law.

New Covered Persons shall receive at least three hours of training within 45 days after becoming a Covered Person. 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.

The OIG may, in its discretion, require that Covered Persons complete additional hours of training regarding the topics identified above, or additional topics, in the second, third, fourth, and fifth years of the CIA. The OIG shall provide notice to Family Dermatology of such additional required training at least 180 days prior to the required completion date for such training.

Certification. Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials.

E. Compliance with the Anti-Kickback Statute and Stark Law

1. *Focus Arrangements Procedures.* Within 90 days after the Effective Date, Family Dermatology shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Focus Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements (Focus Arrangements Tracking System);
- b. tracking remuneration to and from all parties to Focus Arrangements;
- c. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);
- d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

- e. establishing and implementing a written review and approval process for all Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and Stark Law, (ii) a process for specifying the business need or business rationale for all Focus Arrangements, and (iii) a process for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement;
- f. requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures; and
- g. implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Sections III.I and III.J when appropriate.

2. *New or Renewed Arrangements.* Prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, Family Dermatology shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that each Focus Arrangement is set forth in writing and signed by Family Dermatology and the other parties to the Focus Arrangement;
- b. Include in the written agreement a requirement that each party to a Focus Arrangement who meets the definition of a Covered Person shall complete at least one hour of training regarding the Anti-Kickback Statute and the Stark Law and examples of arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law. Additionally, Family Dermatology shall provide each party to the Focus

Arrangement with a copy of its Code of Conduct and Stark Law and Anti-Kickback Statute Policies and Procedures;

- c. Include in the written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.

3. *Records Retention and Access.* Family Dermatology shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System and all supporting documentation of the Focus Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

F. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Family Dermatology shall engage an individual or entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.F. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and Family Dermatology shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Family Dermatology) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.F affects Family Dermatology’s responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

2. *Arrangements Review.* The IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined in Appendix B to this CIA, which is incorporated by reference.

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

Prior to initiating a Validation Review, OIG shall notify Family Dermatology 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, Family Dermatology may request a meeting with OIG to: (a) discuss the results of any Arrangements Review submissions or findings; (b) present any additional information to clarify the results of the Arrangements Review or to correct the inaccuracy of the Arrangements Review; and/or (c) propose alternatives to the proposed Validation Review. Family Dermatology agrees to provide any additional information as may be requested by OIG under this Section III.F.3 in an expedited manner. OIG will attempt in good faith to resolve any Arrangements Review issues with Family Dermatology 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.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Family Dermatology a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.F and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

G. Ineligible Persons

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, 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 (LEIE) (available through the Internet at <http://www.oig.hhs.gov>); and
 - ii. the General Services Administration’s System for Award Management (SAM) (available through the Internet at <http://www.sam.gov>).

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

- a. Family Dermatology shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Family Dermatology shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.

- c. Family Dermatology shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

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

4. *Pending Charges and Proposed Exclusions.* If Family Dermatology has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term or Family Dermatology 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 any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, Family Dermatology shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Family Dermatology conducted or brought by a governmental entity or its agents involving an allegation that Family Dermatology 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. Family Dermatology 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 proceedings, if any.

I. Repayment of Overpayments

1. *Definition of Overpayments.* For purposes of this CIA, an “Overpayment” shall mean the amount of money Family Dermatology has received in excess of the amount due and payable under any Federal health care program requirements.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, Family Dermatology 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.*

- a. If, at any time, Family Dermatology identifies any Overpayment, Family Dermatology shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) within 60 days after identification of the Overpayment and take remedial steps within 90 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 60 days after identification, Family Dermatology shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies.
- 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.

J. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

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

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

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

3. *Reportable Events under Section III.J.1.a.* For Reportable Events under Section III.J.1.a, the report to OIG shall be made within 30 days of the identification of the Overpayment and shall include:

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

- b. the Federal health care programs affected by the Reportable Event;
- c. a description of the steps taken by Family Dermatology to identify and quantify the Overpayment; and
- d. a description of Family Dermatology's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, Family Dermatology shall provide OIG with a copy of the notification and repayment (if quantified) to the payor required in Section III.I.3.

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

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

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

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

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

7. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Family Dermatology to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.I.3 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP. If Family Dermatology identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Family Dermatology is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Sale of Business, Business Unit or Location.

In the event that, after the Effective Date, Family Dermatology proposes to sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, Family Dermatology shall notify OIG of the proposed sale at least 30 days prior to the sale of its business, business unit or location. This notification shall include a description of the business, 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 CIA shall be binding on the purchaser of the business, business unit or location, unless otherwise determined and agreed to in writing by the OIG.

B. Change or Closure of Business, Business Unit or Location

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

C. Purchase or Establishment of New Business, Business Unit or Location

In the event that, after the Effective Date, Family Dermatology purchases or establishes a new business, business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Family Dermatology shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit or location. This notification shall include the address of the new business, business unit or location, phone number, fax number, the location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Family Dermatology currently submits claims. Each new business, business unit or location and all Covered Persons at each new business, business unit or location shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

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

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. a copy of the policies and procedures required by Section III.B.;
3. a copy of the notice Family Dermatology posted in its office as 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 training required by Section III.D: a copy of the training certifications for each Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program.

A copy of all training materials shall be made available to OIG upon request.

5. 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 CIA; (d) a summary and description of any and all current and prior engagements and agreements between Family Dermatology and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Family Dermatology;

6. a copy of the documentation demonstrating that Family Dermatology has screened all Covered Persons against the Exclusion Lists, as required by Section III.G within 30 days of the Effective Date;

7. a copy of Family Dermatology's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I;

8. a list of all of Family Dermatology'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 Family Dermatology currently submits claims; and

9. certifications by each owner, the Compliance Officer, Chief Executive Officer, and Chief Operating Officer that: (a) he or she has reviewed the CIA 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, Family Dermatology is in compliance with all of the requirements of this CIA; (c) to the best of his or her knowledge, Family Dermatology has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Focus Arrangements Procedures required in Section III.E of the CIA; (d) to the best of his or her knowledge, Family Dermatology has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.E.2 of the CIA; and (e) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding the content and believes that the information is accurate and truthful.

B. Annual Reports

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

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer described in Section III.A;
2. a description of any changes to the policies and procedures required by Section III.B.;

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

4. (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 describe the content of the training program;

A copy of all training materials shall be made available to OIG upon request.

5. a description of (a) any changes to the Focus Arrangements Tracking System required by Section III.E.1.a; (b) any changes to the internal review and approval process required by Section III.E.1.e; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.E.1;

6. a complete copy of all reports prepared pursuant to Section III.F, along with a copy of the IRO's engagement letter;

7. Family Dermatology's response to the reports prepared pursuant to Section III.E, along with corrective action plan(s) related to any issues raised by the reports;

8. a summary and description of any and all current and prior engagements and agreements between Family Dermatology and the IRO (if different from what was submitted as part of the Implementation Report);

9. a certification from the IRO regarding its professional independence and objectivity with respect to Family Dermatology;

10. a copy of the documentation demonstrating that Family Dermatology screened all prospective and current Covered Persons against the Exclusion Lists, as required by Section III.G;

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

description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

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

13. a 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;

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

15. a description of all changes to the most recently provided list of Family Dermatology's locations (including addresses) as required by Section V.A.9; and

16. a certification signed by Family Dermatology's owners, Compliance Officer, Chief Executive Officer, and Chief Financial Officer that (a) he or she has reviewed the CIA 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, Family Dermatology is in compliance with all of the requirements of this CIA; (c) to the best of his or her knowledge, Family Dermatology has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Focus Arrangements Procedures required in Section III.E of the CIA; (d) to the best of his or her knowledge, Family Dermatology has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.E.2 of the CIA; and (e) 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

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

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG: Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Family Dermatology: Yinka Adesokan
629 Beaver Ruin Road
Suite B
Lilburn, Georgia 30037
(770) 231-5284

Unless otherwise specified, all notifications and reports required by this CIA may 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, Family Dermatology may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

Family Dermatology shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Family Dermatology prior to any release by OIG of information submitted by Family Dermatology pursuant to its obligations under this CIA and identified upon submission by Family Dermatology as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Family Dermatology shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Family Dermatology is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

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

1. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Family Dermatology fails to:
 - a. appoint a Compliance Officer as required by Section III.A;
 - b. implement the policies and procedures required by Section III.B;
 - c. establish and/or post a notice in accordance with the requirements of Section III.C;
 - d. complete the training required for Covered Persons and maintain training certifications, in accordance with the requirements of Section III.D;
 - e. complete the Focus Arrangements Procedures and/or Focus Arrangements Requirements described in Sections III.E.1 and III.E.2;
 - f. screen Covered Persons in accordance with the requirements of Section III.G 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.G; and maintain documentation of screening and disclosure requirements in accordance with the requirements of Section III.G;
 - g. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.H;
 - h. establish policies and procedures regarding the repayment of Overpayments;

- i. repay any Overpayments in accordance with Section III.I;
- j. report a Reportable Event in accordance with Section III.J; or
- k. disclose any changes to location or business under Section IV.

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 Family Dermatology fails to engage and use an IRO, as required in Section III.F, Appendix A, and Appendix B.

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

4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Family Dermatology fails to submit any Arrangements Review Report in accordance with the requirements of Section III.F and Appendix B.

5. A Stipulated Penalty of \$1,500 for each day Family Dermatology fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Family Dermatology fails to grant access.)

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Family Dermatology as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Family Dermatology fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Family Dermatology stating the specific grounds for its determination that Family Dermatology has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Family Dermatology shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Family Dermatology receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this

Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions

Family Dermatology may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. 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 Family Dermatology fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after Family Dermatology receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Family Dermatology has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Family Dermatology of: (a) Family Dermatology's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Family Dermatology shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Family Dermatology elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Family Dermatology cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA 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 Family Dermatology has materially breached this CIA, 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 CIA

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

- a. a failure by Family Dermatology to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.J;
- b. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, and Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Family Dermatology constitutes an independent basis for Family Dermatology's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Family Dermatology has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Family Dermatology of: (a) Family Dermatology's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

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

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Family Dermatology fails to satisfy the requirements of Section X.D.3, OIG may exclude Family Dermatology from participation in the Federal health care programs. OIG shall notify Family Dermatology in writing of its determination to exclude Family Dermatology. (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 Family Dermatology’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Family Dermatology 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 Family Dermatology of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Family Dermatology 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 CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The

procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Family Dermatology was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Family Dermatology 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 CIA and orders Family Dermatology to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Family Dermatology requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Family Dermatology was in material breach of this CIA and, if so, whether:

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

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Family Dermatology, only after a DAB decision in favor of OIG. Family Dermatology's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Family Dermatology

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 Family Dermatology 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. Family Dermatology shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Family Dermatology, Family Dermatology shall be reinstated effective on the date of the original exclusion.

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

XI. EFFECTIVE AND BINDING AGREEMENT

Family Dermatology and OIG agree as follows:

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

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

C. OIG may agree to a suspension of Family Dermatology's obligations under this CIA based on a certification by Family Dermatology that it is no longer providing health care items or services that will be billed to any Federal health care program and that 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 Family Dermatology is relieved of its CIA obligations, Family Dermatology will be required to notify OIG in writing at least 30 days in advance if Family Dermatology plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. The undersigned Family Dermatology signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent

that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

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

ON BEHALF OF FAMILY DERMATOLOGY

/Yinka Adesokan/

4.21.15

Yinka Adesokan

DATE

On behalf of himself and Family Dermatology, P.C.,
Family Dermatology of Pennsylvania, P.C., and
Family Dermatology of Delaware, P.A.

/Dr. Paula Nelson/

4.21.15

Dr. Paula Nelson

DATE

On behalf of himself and Family Dermatology, P.C.,
Family Dermatology of Pennsylvania, P.C., and
Family Dermatology of Delaware, P.A.

/Gail Kinney, Esq./

4.21.15

Gail Kinney, Esq.

DATE

Counsel for Family Dermatology, P.C.,
Family Dermatology of Pennsylvania, P.C., and
Family Dermatology of Delaware, P.A.

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

/Gregory E. Demske for RKD/

4/20/15

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

DATE

/Karen S. Glassman/

4/16/15

Karen S. Glassman
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

DATE

/Lauren Marziani/

4/16/15

Lauren Marziani
Senior Counsel
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 CIA.

A. IRO Engagement

1. Family Dermatology shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by Family Dermatology in response to a request by OIG, whichever is later, OIG will notify Family Dermatology if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Family Dermatology may continue to engage the IRO.

2. If Family Dermatology engages 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, Family Dermatology shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Family Dermatology at the request of OIG, whichever is later, OIG will notify Family Dermatology if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Family Dermatology may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law and the regulations and other guidance documents related to these statutes; and

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

C. IRO Responsibilities

The IRO shall:

1. perform each Arrangements Review in accordance with the specific requirements of the CIA;
2. respond to all OIG inquiries in a prompt, objective, and factual manner; and
3. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Arrangements Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *Provider and IRO.* If Family Dermatology terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Family Dermatology must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Family Dermatology 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 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 Family Dermatology to engage a new IRO in accordance with Paragraph A of this Appendix. Family Dermatology must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Family Dermatology to engage a new IRO, OIG shall notify Family Dermatology 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, Family Dermatology may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Family Dermatology prior to requiring Family Dermatology to terminate the IRO. However, the final determination as to whether or not to require Family Dermatology to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The IRO shall perform all components of each Arrangements Review. If there are no material changes to Family Dermatology's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If Family Dermatology materially changes the Arrangements systems, processes, policies and procedures, the IRO shall perform an Arrangements Systems Review for the Reporting Period in which such changes were made in addition to conducting the systems review for the first and fourth Reporting Periods. The Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

A. Arrangements Systems Review. The Arrangements Systems Review shall be a review of Family Dermatology's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. Family Dermatology's systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing and new and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System;
2. Family Dermatology's systems, policies, processes, and procedures for tracking remuneration to and from all parties to Focus Arrangements;
3. Family Dermatology's systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);
4. Family Dermatology's systems, policies, processes, and procedures for monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);
5. Family Dermatology's systems, policies, processes, and procedures for initiating Arrangements, including those policies that identify the

individuals with authority to initiate an Arrangement and that specify the business need or business rationale required to initiate an Arrangement;

6. Family Dermatology's systems, policies, processes, and procedures for the internal review and approval of all Arrangements, including those policies that identify the individuals required to approve each type or category of Arrangement entered into by Family Dermatology, the internal controls designed to ensure that all required approvals are obtained, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law;

7. the Compliance Officer's annual review of the Focus Arrangements Tracking System, Family Dermatology's internal review and approval process, and other Arrangements systems, process, policies, and procedures;

8. Family Dermatology's systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate; and

9. Family Dermatology's systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.D.2 of the CIA.

B. Arrangements Systems Review Report. The IRO shall prepare a report based upon each Arrangements Systems Review performed. The Arrangements Systems Review Report shall include the following information:

1. a description of the documentation (including policies) reviewed and personnel interviewed;

2. a detailed description of Family Dermatology's systems, policies, processes, and procedures relating to the items identified in Section A.1-9 above;

3. findings and supporting rationale regarding weaknesses in Family Dermatology's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-9 above; and

4. recommendations to improve Family Dermatology's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-9 above.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of all of the Focus Arrangements that were entered into or renewed by Family Dermatology during the Reporting Period. The IRO shall assess whether Family Dermatology has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.D.1 and III.D.2 of the CIA, with respect to the selected Focus Arrangements.

The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

1. verifying that the Focus Arrangement is maintained in Family Dermatology's centralized tracking system in a manner that permits the IRO to identify the parties to the Focus Arrangement and the relevant terms of the Focus Arrangement (*i.e.*, the items/services/equipment/space to be provided, the amount of compensation, the effective date, the expiration date, etc.)

2. verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented;

3. verifying that the remuneration related to the Focus Arrangement is properly tracked;

4. verifying that the service and activity logs are properly completed and reviewed (if applicable);

5. verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); and

6. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.D.2 of the CIA.

D. Arrangements Transaction Review Report. The IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transaction Review Report shall include the following information:

1. *Review Methodology*

- a. Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for the sample reviewed.
- b. Sources of Data: A full description of the documentation and other information, if applicable, relied upon by the IRO in performing the Arrangements Transaction Review.
- c. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transaction Review and Family Dermatology shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental documentation or materials from Family Dermatology after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transaction 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 Arrangements Transaction Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings*. The IRO's findings with respect to whether Family Dermatology has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO. In addition, the Arrangements Transactions Review Report shall include observations, findings and recommendations on possible improvements to Family Dermatology's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.