

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SNAP DIAGNOSTICS, LLC. AND GIL RAVIV**

I. PREAMBLE

SNAP Diagnostics, LLC. and Gil Raviv (Raviv) (SNAP Diagnostics, LLC and Raviv are collectively referred to as SNAP) 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). Gil Raviv is the President and CEO of SNAP Diagnostics, and an owner of the company. Contemporaneously with this CIA, SNAP is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The Effective Date of this CIA shall be the date on which the final signatory of this CIA executes this CIA. The term of this CIA shall be five years from the Effective Date. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) SNAP’s final Annual Report or (2) any additional materials submitted by SNAP pursuant to OIG’s request, whichever is later.

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

1. “Arrangements” shall mean:

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

or any actual or potential recipient of health care business or referrals from SNAP or

- b. every financial relationship (as defined at 42 C.F.R. § 411.354(a)) that is between SNAP 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 SNAP for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

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

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

4. “Covered Persons” shall include: (a) all owners who are natural persons (other than owners who have an ownership interest of less than 5%), officers, directors, and employees of SNAP; (b) all contractors, subcontractors, agents, and other persons who: (i) furnish patient care items or services, (ii) perform billing or coding functions, or (iii) perform Promotional Functions on behalf of SNAP, but excluding vendors whose sole connection with SNAP is selling or otherwise providing medical supplies or equipment to SNAP; and (c) all physicians and other non-physician practitioners who are members of SNAP's active medical staff.

5. “Government Reimbursed Items and Services” refers to all SNAP items or services that are marketed or furnished by SNAP and reimbursed by Federal health care programs.

6. “Promotional Functions” includes: (a) the marketing, selling, advertising, or promoting of Government Reimbursed Items and Services; and (b) the preparation or external dissemination of promotional materials or information about, or

the provision of promotional services relating to, Government Reimbursed Items and Services, including those functions relating to SNAP's review and approval processes for promotional materials and any applicable review committee(s).

7. "Promotional Covered Persons" includes each Covered Person who perform or is involved with the development, approval, management, or review of SNAP's Promotional Functions (including any sales force members).

III. COMPLIANCE PROGRAM REQUIREMENTS

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

A. Compliance Officer, Compliance Committee, Board of Directors Oversight, and Management Certifications

1. *Compliance Officer.* Within 90 days after the Effective Date, SNAP shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of SNAP, shall report directly to the President and CEO of SNAP, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for SNAP. 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;
- b. making periodic (at least quarterly) reports regarding compliance matters to the Board of Directors of SNAP (Board) and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request; and

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

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

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

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

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

3. *Board of Directors Oversight.* The Board of SNAP shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the requirements of this CIA. The Board must include independent (i.e., non-employee and non-executive) members.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee SNAP's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third-party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of SNAP's compliance with Federal health care program requirements and the requirements of this CIA.
- d. for the first and third Reporting Period of the CIA, the Board shall retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of SNAP's compliance program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to SNAP's compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of SNAP's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by SNAP. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

At minimum, the resolution shall include the following language:

“The Board has made a reasonable inquiry into the operations of SNAP's compliance program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the

Board has concluded that, to the best of its knowledge, SNAP has implemented an effective compliance program to meet Federal health care program requirements and the requirements of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective compliance program at SNAP.

SNAP shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board’s ability to perform the duties necessary to meet the requirements in this CIA, within 15 business days after such a change.

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain SNAP employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable SNAP department is in compliance with applicable Federal health care program requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: President/CEO; CFO; Compliance Officer/Director of Quality and Production; Vice President of Business Development and Marketing; Lab Director; Director of Customer Support; Vice President of Sales; Human Resources Manager; Director of Contracts; IT/Development Manager. For each Reporting Period, each Certifying Employee shall sign a certification that states:

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

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

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

B. Written Standards

Within 120 days after the Effective Date, SNAP shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and SNAP's compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address compliance with 42 U.S.C. §1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and shall include a written review and approval process for Arrangements, the purpose of which is to ensure that all Arrangements do not violate the Anti-Kickback Statute and the Stark Law. In addition, the Policies and Procedures shall address appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Anti-Kickback Statute. Throughout the term of this CIA, SNAP shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons.

At least annually (and more frequently, if appropriate), SNAP shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

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

C. Training and Education

1. *Covered Persons Training.* Within 120 days after the Effective Date, SNAP shall develop a written plan (Training Plan) that outlines the steps SNAP will take to ensure that:

- a. all Covered Persons receive at least annual training regarding SNAP's CIA requirements and compliance program and the applicable Federal health care program requirements, including (a) proper billing and coding of sleep tests to the Federal health care programs; (b) the requirements of the Anti-Kickback Statute and the Stark Law; (c) 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; (d) SNAP's policies, procedures, and other requirements relating to Arrangements (e) the personal requirement of each individual involved in the development, approval, management, or review of SNAP's Arrangements to know the applicable legal requirements and the SNAP's policies and procedures; (f) the legal sanctions under the Anti-Kickback Statute and the Stark Law; and (g) examples of violations of the Anti-Kickback Statute and the Stark Law; and
- b. all Promotional Covered Persons receive adequate training regarding: (i) all applicable Federal health care program requirements relating to Promotional Functions; (ii) SNAP's Policies and Procedures and other requirements applicable to Promotional Functions; (iii) the personal obligation of each individual involved in Promotional Functions to comply with all applicable Federal health care program and other applicable legal requirements; (iv) the legal sanctions under the Anti-Kickback Statute; and (v) proper and improper practices related to Promotional Functions.

The Training Plan shall include information regarding the following: training topics, categories of Covered Persons (including the identification of all Promotional Covered Persons) required to attend each training session, length of the training session(s), schedule for training, and format of the training. SNAP shall furnish training to its Covered Persons and Promotional Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Training.* In addition to the training described in Section III.C.1.a, within 90 days after the Effective Date, each member of the Board shall receive training regarding the corporate governance responsibilities of board members and the responsibilities of board members with respect to review and oversight of the compliance program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of the OIG’s guidance on Board member responsibilities.

New members of the Board shall receive the Board training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

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

D. Review Procedures

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, SNAP shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.D. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and SNAP shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and SNAP) related to the reviews.
- c. *Access to Records and Personnel.* SNAP shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.D and that all records furnished to the IRO are accurate and complete.

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

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

E. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, SNAP shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with SNAP's participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries, the Anti-Kickback Statute and Stark Law risks associated with Arrangements (as defined in Section II.C.1 above) and risks associated with Promotional Functions (as defined in Section II.C.6 above). The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted at least annually and shall require SNAP to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. SNAP shall maintain the risk assessment and internal review process for the term of the CIA.

F. Disclosure Program

Within 90 days after the Effective Date, SNAP shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with SNAP's policies, conduct, practices, or procedures with respect to a Federal health

care program believed by the individual to be a potential violation of criminal, civil, or administrative law. SNAP shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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

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

G. Ineligible Persons

1. *Definitions.* For purposes of this CIA:
 - a. an "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded from participation in any Federal health care program; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) but has not yet been excluded.

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

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

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

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

3. *Removal Requirement.* If SNAP has actual notice that a Covered Person has become an Ineligible Person, SNAP shall remove such Covered Person from responsibility for, or involvement with, SNAP’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 SNAP 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, SNAP shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceeding

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

I. Overpayments

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

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

J. Reportable Events

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

- a. a substantial Overpayment;

- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. the employment of or contracting with 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 SNAP.

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

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

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

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of the steps taken by SNAP to identify and quantify any Overpayments; and

- e. a description of SNAP'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, SNAP shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance and provide OIG with a copy of the notification and repayment.

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

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that SNAP 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.J.1.d.* For Reportable Events under Section III.J.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by SNAP to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If SNAP identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then

SNAP is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, SNAP Diagnostics or Raviv proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program; or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. SNAP Diagnostics or Raviv, as applicable, shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, SNAP Diagnostics or Raviv wish to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, SNAP Diagnostics or Raviv, as applicable, must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

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

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

2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. the names of the Board members who are responsible for satisfying the Board compliance requirements described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;
5. a list of the Policies and Procedures required by Section III.B;
6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);
7. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to SNAP that includes a summary of all current and prior engagements between SNAP and the IRO;
8. the following information regarding the individual or entity retained by the Board to be the Compliance Expert: (a) identity, address, and phone number; (b) information to demonstrate the individual's or entity's expertise in compliance with Federal health care program requirements, and (c) a certification from the Compliance Expert that they do not have a current or prior relationship to SNAP that would cause a reasonable person to question the Compliance Expert's objectivity in performing the review.
9. a description of the risk assessment and internal review process required by Section III.E;
10. a description of the Disclosure Program required by Section III.F;
11. a description of the Ineligible Persons screening and removal process required by Section III.G;

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

13. a description of SNAP's corporate structure, including identification of individual owners, any parent and sister companies, subsidiaries, and their respective lines of business;

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

15. the certifications required by Section V.C.

B. Annual Reports

SNAP shall submit to OIG a written report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, a current list of the Board members who are responsible for satisfying the Board compliance requirements, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, and Certifying Employees;

2. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

3. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

4. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution, and a copy of the Compliance Program Review Report;

5. for the first and third Reporting Periods, a copy of the Compliance Program Review Report prepared by the Compliance Expert;
6. a list of any new or revised Policies and Procedures developed during the Reporting Period;
7. a description of any changes to SNAP's Training Plan developed pursuant to Section III.C, and a summary of any Board training provided during the Reporting Period;
8. a complete copy of all reports prepared pursuant to Section III.D and SNAP's response to the reports, along with corrective action plan(s) related to any issues raised by the reports, including SNAP's determination of whether the CMS overpayment rule requires the repayment of an extrapolated Overpayment (as defined in Appendix B);
9. a certification from the IRO regarding its professional independence and objectivity with respect to SNAP, including a summary of all current and prior engagements between SNAP and the IRO;
10. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reasons for such changes;
11. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed, (b) internal audits performed, (c) corrective action plans developed in response to internal audits, and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;
12. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;
13. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;
14. 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;

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

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

17. 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 SNAP's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

18. a description of all changes to the most recently provided list of SNAP's locations as required by Section V.A.13;

19. a description of any changes to SNAP's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business, or individual owners; and

20. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

1. *Certifying Employees.* In each Annual Report, SNAP shall include the certifications of Certifying Employees required by Section III.A.4;

2. *Compliance Officer and President.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

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

- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
- c. he or she understands that the certification is being provided to and relied upon by the United States

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, SNAP has complied with its requirements under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs; and (d) he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

SNAP 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. SNAP 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

SNAP:
Gil Raviv
SNAP Diagnostics LLC
5210 Capitol Drive
Wheeling, IL 60090
gil@snapdiagnostics.com
(847) 777-0000 ext.203

Kim Kopacek
SNAP Diagnostics LLC
5210 Capitol Drive
Wheeling, IL 60090
kkopacek@snapdiagnostics.com
(847) 777-0000 ext.259

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of or copy SNAP's books, records, and other documents and supporting materials, and conduct on-site reviews of any of SNAP's locations, for the purpose of verifying and evaluating: (a) SNAP's compliance with the terms of this CIA and (b) SNAP's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by SNAP 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 SNAP's owners, employees, contractors, and directors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. SNAP shall assist OIG or its duly authorized

representative(s) in contacting and arranging interviews with such individuals upon OIG's request. SNAP's owners, employees, contractors, and directors may elect to be interviewed with or without a representative of SNAP present.

VIII. DOCUMENT AND RECORD RETENTION

SNAP 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 SNAP prior to any release by OIG of information submitted by SNAP pursuant to this CIA and identified upon submission by SNAP as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, SNAP shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties

OIG may assess:

1. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section III.A;
2. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section III.B;
3. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section III.C;
4. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section III.D;
5. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section III.E;

6. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section III.F;
7. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section III.G;
8. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section III.H;
9. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section III.I;
10. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section III.J;
11. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section IV;
12. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section V;
13. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section VII;
14. A Stipulated Penalty of up to \$2,500 for each day SNAP fails to comply with Section VIII; or
15. A Stipulated Penalty of up to \$50,000 for each false certification or false statement made to OIG by or on behalf of SNAP under this CIA.

B. Timely Written Requests for Extensions

SNAP may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. If OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after SNAP 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 SNAP 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 SNAP of: (a) SNAP’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, SNAP shall either: (a) pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG’s determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E.

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

D. Exclusion for Material Breach of this CIA

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

- a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C;
- b. failure to comply with Section III.A.1;
- c. failure to comply with Section III.D;
- d. failure to comply with Section III.J;
- e. failure to comply with Section V;
- f. failure to respond to a Demand Letter in accordance with Section X.C;

- g. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering SNAP to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or
- h. failure to come into compliance with a requirement of this CIA for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by SNAP constitutes an independent basis for SNAP'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 for each material breach. Upon a preliminary determination by OIG that SNAP has materially breached this CIA, OIG shall notify SNAP of: (a) SNAP's material breach; and (b) OIG's intent to exclude SNAP. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice.* SNAP 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 SNAP in writing of its determination to exclude SNAP. (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 SNAP, 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, SNAP may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's issuing a Demand Letter or Exclusion Letter to SNAP, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, SNAP shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 business days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter; and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>

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

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether SNAP was in material breach of this CIA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion

shall take effect 20 days after the DAB decision. SNAP 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 SNAP, SNAP shall be reinstated effective on the date of the exclusion.

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

SNAP 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 SNAP's requirements under this CIA based on a certification by SNAP 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 SNAP is relieved of its CIA requirements, SNAP shall be required to notify OIG in writing at least 30 days in advance if SNAP 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. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) SNAP'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 SNAP signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are

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

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

ON BEHALF OF SNAP DIAGNOSTICS, LLC AND GIL RAVIV

/Gil Raviv/

Gil Raviv
On behalf of himself individually and as
President and CEO of SNAP Diagnostics, LLC

5/29/2022
DATE

/Bradley James Bolerjack/

Steven A. Miller
Bradley J. Bolerjack
Andrew C. Bernasconi
REED SMITH LLP

05/29/2022
DATE

As Counsel to SNAP Diagnostics, LLC and Gil Raviv

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

/Lisa M. Re/

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

06/01/2022

DATE

/Geeta Taylor/

GEETA TAYLOR
Senior Counsel
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

06/01/2022

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. SNAP 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.7 of the CIA or any additional information submitted by SNAP in response to a request by OIG, whichever is later, OIG will notify SNAP if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SNAP may continue to engage the IRO.

2. If SNAP engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, SNAP shall submit the information identified in Section V.A.7 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 SNAP at the request of OIG, whichever is later, OIG will notify SNAP if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SNAP may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the Medicare and state Medicaid program requirements applicable to the claims being reviewed;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained

this certification (e.g., completed applicable continuing education requirements);

4. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professionals acting within their scope of practice and specialized expertise) to make the medical necessity determinations required by the Claims Review; and

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

C. IRO Responsibilities

The IRO shall:

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

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

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

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

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

D. SNAP Responsibilities

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

E. IRO Independence and Objectivity

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

F. IRO Removal/Termination

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

APPENDIX B

CLAIMS REVIEW

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

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

- a. Overpayment: The amount of money SNAP has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix B.
- b. Paid Claim: A claim submitted by SNAP and for which SNAP has received reimbursement from the Medicare program or a state Medicaid program.
- c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.

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

3. *Other Requirements*.

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in the

Claims Review Sample and SNAP shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Claims Review Sample. If the IRO accepts any supplemental documentation or materials from SNAP after the IRO has completed its initial review of the Claims Review Sample (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

- b. Paid Claims without Supporting Documentation. Any Paid Claim for which SNAP cannot produce documentation shall be considered an error and the total reimbursement received by SNAP for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. Use of First Samples Drawn. For the purposes of the Claims Review Sample discussed in this Appendix, the first set of Paid Claims selected shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Claims Review Sample).

4. *Repayment of Identified Overpayments.* SNAP shall repay within 60 days the Overpayment(s) identified by the IRO in the Claims Review Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance (the "CMS overpayment rule"). If SNAP determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, SNAP shall repay that amount at the mean point estimate as calculated by the IRO. SNAP shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Claims Review Sample (and any related work papers) received from SNAP to the appropriate Medicare or state Medicaid program contractor for appropriate follow up by the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as

described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report.

1. *Claims Review Methodology.*
 - a. Claims Review Population. A description of the Population subject to the Claims Review.
 - b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
 - c. Source of Data. A description of (1) the process used to identify Paid Claims in the Population and (2) the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
 - d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
 - e. Supplemental Materials. A description of any Supplemental Materials as required by A.3.a., above.
2. *Statistical Sampling Documentation.*
 - a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
 - b. A description or identification of the statistical sampling software package used by the IRO.
3. *Claims Review Findings.*
 - a. Narrative Results.

- i. A description of SNAP's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
 - ii. A description of controls in place at SNAP to ensure that all items and services billed to Medicare or a state Medicaid program are medically necessary and appropriately documented.
 - iii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Claims Review Sample.
- b. Quantitative Results.
- i. Total number and percentage of instances in which the IRO determined that the coding of the Paid Claims submitted by SNAP differed from what should have been the correct coding and in which such difference resulted in an Overpayment to SNAP.
 - ii. Total number and percentage of instances in which the IRO determined that a Paid Claim was not appropriately documented and in which such documentation errors resulted in an Overpayment to SNAP.
 - iii. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items or services that were not medically necessary and resulted in an Overpayment to SNAP.
 - iv. Total dollar amount of all Overpayments in the Claims Review Sample.
 - v. Total dollar amount of Paid Claims included in the Claims Review Sample.
 - vi. Error Rate in the Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in the

Claims Review Sample by the total dollar amount associated with the Paid Claims in the Claims Review Sample.

- vii. An estimate of the actual Overpayment in the Population at the mean point estimate.
 - viii. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to SNAP's billing and coding system or to SNAP's controls for ensuring that all items and services billed to Medicare or a state Medicaid program are medically necessary and appropriately documented, based on the findings of the Claims Review.

4. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.