

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
PROGENITY, INC.**

**I. PREAMBLE**

Progenity, Inc. (Progenity) hereby enters 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, Progenity is entering into a Settlement Agreement with the United States.

Prior to the Effective Date of this CIA, Progenity voluntarily established a Compliance Program which includes, among other things, a Chief Compliance Officer (CCO) and Compliance Committee, internal monitoring by the CCO and Compliance Committee, compliance updates provided to the Board of Directors, regular compliance training and education for employees, written compliance policies and procedures, and a disclosure program. Progenity shall continue these and other aspects of its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below.

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by Progenity 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) Progenity's final annual report; or (2) any additional materials submitted by Progenity 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 Progenity and any actual or potential source of health care business or referrals to Progenity or any actual or potential recipient of health care business or referrals from Progenity; or
  - b. every financial relationship (as defined in 42 C.F.R. § 411.354(a)) that is between Progenity 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 Progenity 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 (1) to whom Progenity refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom Progenity 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. "Focus Arrangements" means every Arrangement that:

- a. is between Progenity and any actual source or recipient of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value; or
- b. is between Progenity 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 Progenity for designated health services (as defined at 42 U.S.C. §1395nn(h)(6)).

Notwithstanding the foregoing provisions of Section II.C.4, 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), or 42 C.F.R. § 357(u) (community-wide health information systems), shall not be considered a Focus Arrangement for purposes of this CIA, provided that Progenity maintains sufficient documentation to demonstrate compliance with the applicable exceptions to 42 U.S.C. § 1395nn (Stark Law). Such documentation shall be made available to OIG upon request.

5. "Covered Persons" includes:

- a. all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), officers, directors, and employees of Progenity; and
- b. all contractors, subcontractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of Progenity excluding vendors whose sole connection with Progenity is selling or otherwise providing medical supplies or equipment to Progenity.

Notwithstanding the above, this term presumptively 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 per year, except that any such natural persons in such categories shall become “Covered Persons” at the point when they work more than 160 hours during a Reporting Period.

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

### **III. CORPORATE INTEGRITY OBLIGATIONS**

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

#### **A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations**

1. *Compliance Officer.* Within 90 days after the Effective Date, Progenity 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 Progenity, shall report directly to the Chief Executive Officer or the President of Progenity, 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 Progenity. 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 in person to the Board of Directors of Progenity (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 Progenity as well as 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.

Progenity shall report to OIG, in writing, any changes in the identity 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 business days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Progenity 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 Progenity'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.

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

3. *Board Compliance Obligations.* The Board of Progenity shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations 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 Progenity's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to the 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 Progenity's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board has made a reasonable inquiry into the operations of Progenity'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, Progenity has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations 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 Progenity.

Progenity 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 obligations 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 Progenity employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Progenity department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer; Chief Financial Officer; Chief Operating Officer; Chief Commercial Officer; Chief Scientific Officer; Chief Medical Officer; and Chief Information Officer. 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, obligations of the Corporate Integrity Agreement, and Progenity policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of Progenity is in compliance with all applicable Federal health care program requirements and the obligations 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, Progenity 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 90 days after the Effective Date, Progenity 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 Progenity's compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address:

- a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and the 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.D (Compliance with the Anti-Kickback Statute and Stark Law).

The Policies and Procedures shall be made available to all Covered Persons. Throughout the term of this CIA, Progenity shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees.

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

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

C. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, Progenity shall develop a written plan (Training Plan) that outlines the steps Progenity will take to ensure that all Covered Persons receive at least annual training regarding Progenity's CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute and the Stark Law; and that all Arrangements Covered Persons receive at least annual training

regarding: (i) 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; (ii) Progenity'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.D of the CIA; (iii) the personal obligation of each individual involved in the development, approval, management, or review of Progenity's Arrangements to know the applicable legal requirements and the Progenity's policies and procedures; (iv) the legal sanctions under the Anti-Kickback Statute and the Stark Law; and (v) examples of violations of the Anti-Kickback Statute and the Stark Law.

The Training Plan shall include information regarding the following: training topics, identification of Covered Persons and Arrangements Covered Persons required to attend each training session, length of the training sessions(s), schedule for training, and format of the training. Progenity shall furnish training to its Covered Persons and Arrangements 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, 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.* Progenity shall make available to OIG, upon request, training materials and records verifying the training described in Sections III.C.1 and III.C.2 has been provided as required.

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

1. *Focus Arrangements Procedures.* Within 90 days after the Effective Date, Progenity 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 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 and the information specified in Sections III.D.1.b-f below for each existing and new or renewed Focus Arrangement (Focus Arrangements Tracking System);
- b. documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;
- c. tracking all remuneration to and from all parties to Focus Arrangements, to ensure that the parties are complying with the financial terms of the Focus Arrangements and that the Focus Arrangements are commercially reasonable;
- d. documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of the Covered Person(s) who received and/or were otherwise involved with the fair market value determination(s);
- e. 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);

- f. 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);
- g. establishing and implementing a written review and approval process for Focus Arrangements, the purpose of which is to ensure that all existing and new 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 and documenting 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;
- h. ensuring that all existing Focus Arrangements are subject to the review and approval process described in Section III.D.1.g above;
- i. requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and
- j. 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.J and III.K when appropriate.

2. *New or Renewed Focus Arrangements.* No later than 90 days after the Effective Date, and prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements

Procedures set forth above, Progenity shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that all new or renewed written Focus Arrangements are signed by Progenity and the other party(ies) to the Focus Arrangement prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement;
- b. Ensure that all new or renewed Focus Arrangements have been subject to the written review and approval process described in Section III.D.1.g prior to the payment or receipt of any remunerations pursuant to the Focus Arrangement, and that Progenity maintains appropriate documentation of the review and approval of such Focus Arrangement; and
- c. Include in any new or renewed 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.* Progenity 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.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Progenity shall engage an entity (or entities), such as an accounting, auditing or consulting firm, to perform the claims review described in Section III.E.3 and, within 90 days after the Effective Date, Progenity shall engage a law or consulting firm or a lawyer to perform

the arrangements review described in Section III.E.2. The entity (or entities) engaged to perform the claims review and the arrangements review are referred to hereinafter as the “Independent Review Organization” or “IRO.” 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 Progenity shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Progenity) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.E affects Progenity’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.
- d. *Access to Records and Personnel.* Progenity shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E and that all records furnished to the IRO are accurate and complete.

2. *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. *Claims Review.* The IRO shall review claims submitted by Progenity and reimbursed by the Medicare and Medicaid programs, to determine whether the medical necessity of the items and services furnished was 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 C to this CIA, which is incorporated by reference.

4. *Certifications.* The IRO for the Claims Reviews shall include in its report(s) to Progenity a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of all current and prior engagements between Progenity and the IRO. The IRO for the Arrangements Review shall include in its report(s) to Progenity a certification that the IRO (a) does not currently represent or is not currently employed or engaged by Progenity and (b) does not have a current or prior relationship to Progenity or its owners, officers, or directors that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by Section III.E. The IRO's certification shall include a summary of any current and prior relationships between Progenity or its owners, officers, or directors and the IRO.

F. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, Progenity shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Arrangements (as defined in Section II.C.1 above) and Progenity'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 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 Progenity 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. Progenity shall maintain the risk assessment and internal review process for the term of the CIA.

G. Disclosure Program

Within 90 days after the Effective Date, Progenity 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 Progenity’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. Progenity 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 Progenity’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 Progenity. 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, Progenity 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.

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

- a. Progenity shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process or medical staff credentialing process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Progenity shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.
- c. Progenity shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement.* If Progenity has actual notice that a Covered Person has become an Ineligible Person, Progenity shall remove such Covered Person from responsibility for, or involvement with, Progenity'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 Progenity 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 during the term of a physician's or other practitioner's medical staff privileges, Progenity 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.

I. Notification of Government Investigation or Legal Proceeding

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

J. Overpayments

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

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

K. 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.H.1.a; or
- d. the filing of a bankruptcy petition by Progenity.

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

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

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

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

names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of the steps taken by Progenity to identify and quantify any Overpayments; and
- e. a description of Progenity'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, Progenity 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 (CMS) guidance and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.K.1.c.* For Reportable Events under Section III.K.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 or medical staff membership;
- c. a description of the Exclusion List screening that Progenity completed before and/or during the Ineligible Person's employment or contract or medical staff membership and any flaw or breakdown in the Ineligible Persons screening process

that led to the hiring or contracting with or credentialing 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 or credentialing an Ineligible Person.

5. *Reportable Events under Section III.K.1.d.* For Reportable Events under Section III.K.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.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of the Stark Law should be submitted by Progenity to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Progenity identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Progenity is not required by this Section III.K to submit the Reportable Event to CMS through the SRDP.

#### **IV. SUCCESSOR LIABILITY**

In the event that, after the Effective Date, Progenity 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. Progenity shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or proposed purchase, Progenity wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Progenity 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, Progenity 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 obligations 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 all 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. a description of (a) the Focus Arrangements Tracking System required by Section III.D.1.a, (b) the internal review and approval process required by Section III.D.1.g; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.D.1;

8. 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 Progenity or that it does not have a prohibited relationship with Progenity as set forth in Section III.E.4, that includes a summary of all current and prior engagements or relationships between Progenity and the IRO, as applicable;

9. a description of the risk assessment and internal review process required by Section III.F;

10. a description of the Disclosure Program required by Section III.G;

11. a description of the Ineligible Persons screening and removal process required by Section III.H;

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

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

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

15. the certifications required by Section V.C.

B. Annual Reports

Progenity shall submit to OIG a 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 obligations, 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;
5. a list of any new or revised Policies and Procedures developed during the Reporting Period;
6. a description of any changes to Progenity's Training Plan developed pursuant to Section III.C, and a summary of any Board training provided during the Reporting Period;
7. a description of (a) any changes to the Focus Arrangements Tracking System required by Section III.D.1.a; (b) any changes to the internal review and approval process required by Section III.D.1.g; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

8. a complete copy of all reports prepared pursuant to Section III.E and Progenity's response to the reports, along with corrective action plan(s) related to any issues raised by the reports, including Progenity'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 Progenity or that the IRO does not have a prohibited relationship with Progenity, as described in Section III.E.4, including a summary of all current and prior engagements or relationships between Progenity and the IRO, as applicable;

10. a description of any changes to the risk assessment and internal review process required by Section III.F, 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 actions plans shall be made available to OIG upon request;

12. a summary of the disclosures in the disclosure log required by Section III.G that: (a) relate to Federal health care programs; or (b) involve allegations of conduct that may involve illegal remuneration or inappropriate referrals in violation of the Anti-Kickback Statute or Stark law (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.H, 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.I. 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.J, including the reasons for such changes;
16. a summary of Reportable Events (as defined in Section III.K) identified during the Reporting Period;
17. a description of all changes to the most recently provided list of Progenity's locations (including addresses) as required by Section V.A.14;
18. a description of any changes to Progenity's corporate structure, including any individual owners, parent and sister companies, subsidiaries, and their respective lines of business; and
19. 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, Progenity shall include the certifications of Certifying Employees as required by Section III.A.4;
2. *Compliance Officer and Chief Executive Officer.* 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, Progenity is in compliance with all of the requirements of this CIA;
  - b. to the best of his or her knowledge, Progenity 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.D of the CIA;

- c. to the best of his or her knowledge, Progenity has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of the CIA;
- d. 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
- e. 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, Progenity has complied with its obligations 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); (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

Progenity 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. Progenity 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

Progenity:

Hutan Hashemi  
Chief Compliance Officer  
Progenity, Inc.  
4330 La Jolla Village Drive, Suite 200  
San Diego, CA 92122  
Telephone: 858.732.3911  
Email: [Hutan.Hashemi@Progenity.com](mailto:Hutan.Hashemi@Progenity.com)

Unless otherwise specified, all notifications and reports required by this CIA may be made by 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, Progenity 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 Progenity's books, records, and other documents and supporting materials, and conduct on-site reviews of any of Progenity's locations for the purpose of verifying and evaluating: (a) Progenity's compliance with the terms of this CIA; and (b) Progenity's compliance with the requirements of the Federal health care programs. The

documentation described above shall be made available by Progenity 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 Progenity'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. Progenity shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Progenity's owners, employees, contractors, and directors may elect to be interviewed with or without a representative of Progenity present.

## **VIII. DOCUMENT AND RECORD RETENTION**

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

## **X. BREACH AND DEFAULT PROVISIONS**

Progenity 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, Progenity 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 \$2,500 (which shall begin to accrue on the day after the date the obligation became due) per obligation for each day Progenity fails to establish, implement or comply with any of the following obligations as described in Sections III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board compliance obligations as required by Section III.A.3.;
- d. the management certification obligations and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4;
- e. written Policies and Procedures;
- f. the development of a written training plan and the training and education of Covered Persons, Arrangements Covered Persons, and Board members;
- g. the Focus Arrangements Procedures and/or Focus Arrangements Requirements;
- h. a risk assessment and internal review process;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. notification of Government investigations or legal proceedings;
- l. policies and procedures regarding the repayment of Overpayments; and

m. reporting of Reportable Events.

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

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Progenity fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Progenity fails to submit any Arrangements Review Report in accordance with the requirements of Section III.E and Appendix B.

5. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Progenity fails to submit any Claims Review Report in accordance with the requirements of Section III.E and Appendix C or fails to repay any Overpayment identified by the IRO as required by Appendix C.

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

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

8. A Stipulated Penalty of \$2,500 for each day Progenity fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.E., and for each day Progenity fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix A.

9. A Stipulated Penalty of \$1,000 for each day Progenity fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Progenity stating the specific grounds for its determination that Progenity has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Progenity shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 business days after the date Progenity 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 1-8 of this Section.

B. Timely Written Requests for Extensions

Progenity 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 Progenity 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 business days after Progenity 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 Progenity 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 Progenity of: (a) Progenity'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 business days after the receipt of the Demand Letter, Progenity 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

Progenity elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Progenity 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 Progenity 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 Progenity to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.K;
- 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, Appendix B, or Appendix C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Progenity constitutes an independent basis for

Progenity'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 Progenity has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Progenity of: (a) Progenity'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.* Progenity 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) Progenity has begun to take action to cure the material breach; (ii) Progenity is pursuing such action with due diligence; and (iii) Progenity has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Progenity fails to satisfy the requirements of Section X.D.3, OIG may exclude Progenity from participation in the Federal health care programs. OIG shall notify Progenity in writing of its determination to exclude Progenity. (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 Progenity's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Progenity 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 Progenity 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, Progenity 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 Progenity was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Progenity 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 Progenity to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Progenity 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 Progenity was in material breach of this CIA and, if so, whether:

- a. Progenity 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 Progenity's receipt of the Notice of Material Breach: (i) Progenity had begun to take action to cure the

material breach; (ii) Progenity pursued such action with due diligence; and (iii) Progenity 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 Progenity, only after a DAB decision in favor of OIG. Progenity's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Progenity 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 Progenity 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. Progenity 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 Progenity, Progenity 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**

Progenity 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 Progenity's obligations under this CIA based on a certification by Progenity 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 Progenity is relieved of its CIA obligations,

Progenity shall be required to notify OIG in writing at least 30 days in advance if Progenity 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) Progenity'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 Progenity 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 or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF PROGENITY**

\_\_\_\_\_/Clarke Neumann/  
Clarke Neumann  
General Counsel, Progenity

\_\_\_\_\_/July 21, 2020/  
DATE

\_\_\_\_\_/Jonathan Phillips/  
Jonathan M. Phillips  
M. Kendall Day  
Gibson, Dunn & Crutcher LLP  
Counsel for Progenity

\_\_\_\_\_/7/21/20/  
DATE

**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

07/20/2020  
DATE

/Tamar Terzian/  
TAMAR TERZIAN  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

July 21, 2020  
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. Progenity shall engage an IRO to perform the Claims Review that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the Claims Review in a professionally independent and objective fashion, as set forth in Paragraph E.

2. Progenity shall engage an IRO to perform the Arrangements Review that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall not have a prohibited relationship to Progenity as set forth in Paragraph F.

3. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by Progenity in response to a request by OIG, whichever is later, OIG will notify Progenity if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Progenity may continue to engage the IRO.

4. If Progenity 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, Progenity shall submit the information identified in Section V.A.8 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 Progenity at the request of OIG, whichever is later, OIG will notify Progenity if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Progenity 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;

2. possess expertise in fair market valuation issues or have the ability to associate a valuation firm to assist in conducting the transactions review component of the Arrangements Review;

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

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

5. 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);

6. 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

7. 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 and 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 inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B and Appendix C (as applicable) to the CIA.

D. Progenity Responsibilities

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

E. IRO Independence and Objectivity

The IRO engaged to perform the Claims Review 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 Relationship to Progenity

The IRO engaged to perform the Arrangements Review shall not (1) currently represent or currently be employed or engaged by Progenity or (2) have a current or prior relationship to Progenity or its owners, officers, or directors that would cause a reasonable person to question the IRO's objectivity in performing the Arrangements Review.

G. Assertions of Privilege

Progenity shall not assert claims of attorney-client privilege in order to avoid disclosing to OIG information related to or resulting from the IRO's engagement to perform the Arrangements Review. Progenity's engagement letter with the IRO shall include a provision stating that the IRO agrees not to assert claims of work product privilege in order to avoid disclosing to OIG information related to or resulting from its engagement.

H. IRO Removal/Termination

1. *Progenity and IRO.* If Progenity terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Progenity 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. Progenity 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 E or has a prohibited relationship as set forth in paragraph F (as applicable), or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Progenity in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Progenity shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence, relationship to Progenity or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Progenity regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Progenity in writing that Progenity shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Progenity 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 Progenity 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 Progenity's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If Progenity 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 Progenity's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. Progenity'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. Progenity's systems, policies, processes, and procedures for documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;
3. Progenity's systems, policies, processes, and procedures for tracking all remuneration to and from all parties to Focus Arrangements to ensure that the parties are complying with the financial terms of the Focus Arrangements and that the Focus Arrangements are commercially reasonable;
4. Progenity's systems, policies, processes and procedures for documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value

amount or range, and the names and positions of the Arrangements Covered Person(s) involved with the fair market value determination(s);

5. Progenity'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);

6. Progenity'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);

7. Progenity'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;

8. Progenity's systems, policies, processes, and procedures for the internal review and approval of existing, new and renewed Focus Arrangements, including those policies that identify the individuals required to approve each type or category of Focus Arrangement entered into by Progenity, the internal controls designed to ensure that all required approvals are obtained, the processes for determining and documenting the business need or business rationale for all Focus Arrangements, the processes for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement, 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;

9. the Compliance Officer's annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, Progenity's internal review and approval process, and other Focus Arrangements systems, process, policies, and procedures;

10. Progenity'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

11. Progenity'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 Progenity's systems, policies, processes, and procedures relating to the items identified in Section A.1-11 above;
3. findings and supporting rationale regarding weaknesses in Progenity's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-11 above, if any; and
4. recommendations to improve Progenity's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-11 above.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 25 randomly selected Focus Arrangements that were entered into or renewed by Progenity during the Reporting Period. The IRO shall assess whether Progenity 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.

1. The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:
  - a. verifying that the Focus Arrangement is maintained in Progenity's centralized tracking system in a manner that permits the IRO to identify: (i) the parties to the Focus Arrangement, (ii) the name(s) and position(s) of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of the Focus Arrangement; (iii) the relevant terms of the Focus Arrangement (i.e., the items, services, equipment, or space to be provided, the amount of compensation, the effective date, the expiration date, etc.); and (iv) the parties' performance under the Focus Arrangement (i.e., items or

services actually provided, equipment or space actually provided or leased, amount of payments, dates of payment, etc.);

b. 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;

c. verifying that the remuneration related to the Focus Arrangement has been determined in accordance with Progenity's policies and procedures for determining and documenting the fair market value of the remuneration, that the remuneration is properly tracked, and that the parties to the Focus Arrangement are complying with the financial terms of the Focus Arrangement;

d. verifying that the business need or business rationale for the Focus Arrangement is specified and is consistent with Progenity's policies and procedures;

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

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

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

2. For any Focus Arrangement for which the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above, the IRO shall identify and review the system(s) and process(es) that resulted in the identified non-compliance and recommend improvements to such system(s) and process(es). The IRO may need to review additional documentation and/or interview personnel to identify the system(s) and process(es) that resulted in the identified non-compliance.

3. If the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above with respect to at least 90% of the Focus Arrangements subject to the Arrangements Transactions Review, then, at its discretion, within 60 days of receipt of the Arrangements Transactions Review Report, the OIG may require the IRO to select an additional sample of Focus Arrangements, not to exceed the number of Focus Arrangements initially reviewed by the IRO, that will be subject to the Arrangements Transactions Review (Additional Transactions Review) and complete and

submit to Progenity and OIG an Additional Transactions Review Report that includes the information specified in Section D below, within 60 days of the date the OIG notifies Progenity and its IRO that an Additional Transactions Review will be required.

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

1. *Review Methodology*.

- a. Review Protocol. A description of the process used by the IRO to identify the Focus Arrangements subject to review in the Arrangements Transactions Review.
- b. Sources of Data. A full description of the documentation and other information relied upon by the IRO in performing the Arrangements Transactions 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 Transactions Review and Progenity 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 Progenity after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transactions 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 Transactions 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 Progenity 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, including findings for each item listed in Sections C.1.a-g above.

In addition, as applicable, the Arrangements Transactions Review Report shall include the IRO's recommendations as required by Section C.2 above.

3. *Names and Credentials.* The names and credentials of the individuals who conducted the Arrangements Systems Review and the Arrangements Transactions Review.

**APPENDIX C**  
**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 Progenity has received in excess of the amount due and payable under Medicare, any state Medicaid program requirements, or TriCare, as determined by the IRO in connection with the Claims Review performed under this Appendix C.
- b. Paid Claim: A claim submitted by Progenity and for which Progenity has received reimbursement from the Medicare program, a state Medicaid program, or TriCare.
- 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 Progenity's office or under Progenity's control and applicable Medicare and state Medicaid program requirements to determine whether the medical necessity of the items and services furnished was 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 Progenity 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 Progenity 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 Progenity cannot produce documentation shall be considered an error and the total reimbursement received by Progenity 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.* Progenity 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 or Centers for Medicare and Medicaid Services (CMS) guidance (the "CMS overpayment rule"). If Progenity determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Progenity shall repay that amount at the mean point estimate as calculated by the IRO. Progenity 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 Progenity 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 Progenity’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 Progenity 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 Progenity differed from what should have been the correct coding and in which such difference resulted in an Overpayment to Progenity.
- 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 Progenity.
- iii. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items or services that did not have appropriate documentation of medical necessity and resulted in an Overpayment to Progenity.
- 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 Progenity's billing and coding system or to Progenity'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.