

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of earliest event reported): July 21, 2020**

**Progenity, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-39334**  
(Commission  
File Number)

**27-3950390**  
(IRS Employer  
Identification No.)

**Harry Stylli**  
**Chairman and Chief Executive Officer**  
**Progenity, Inc.**  
**4330 La Jolla Village Drive, Suite 200**  
**San Diego, CA 92122**  
(Address of Principal Executive Offices)

**(855) 293-2639**  
(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 210.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<b>Common Stock, par value \$0.001 per share</b>	<b>PROG</b>	<b>The Nasdaq Global Market</b>

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

### Item 1.01. Entry into a Material Definitive Agreement

On July 21, 2020 and July 23, 2020, Progenity, Inc. (the “Company”) entered into agreements with certain governmental agencies to resolve, with respect to such agencies, all of such agencies’ outstanding civil, and where applicable criminal, investigations regarding the Company’s discontinued legacy billing practices for the Company’s non-invasive prenatal tests and microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients. The civil and criminal investigations being settled and the matters investigated were previously disclosed in the Company’s Registration Statement on Form S-1, as amended (File No. 333-238738) (the “Registration Statement”) under “Business—Legal Proceedings—Federal Investigations.”

Specifically, the Company has entered into:

- (i) a civil settlement agreement, effective July 23, 2020, with the U.S. Department of Justice (the “DOJ”) through the U.S. Attorney’s Office for the Southern District of New York, and on behalf of the Office of Inspector General of the Department of Health and Human Services (the “OIG”), and with the relator named therein (the “SDNY Civil Settlement Agreement”);
- (ii) a civil settlement agreement, effective July 23, 2020, with the DOJ through the U.S. Attorney’s Office for the Southern District of California, and on behalf of the Defense Health Agency, the Tricare Program and the Office of Personnel Management, which administers the Federal Employees Health Benefits Program (the “SDCA Civil Settlement Agreement”);
- (iii) a non-prosecution agreement, effective July 21, 2020, with the U.S. Attorney’s Office for the Southern District of California (the “Non-Prosecution Agreement”); and
- (iv) a corporate integrity agreement, effective July 21, 2020, with the OIG (the “Corporate Integrity Agreement” and, together with the SDNY Civil Settlement Agreement, the SDCA Civil Settlement Agreement, and the Non-Prosecution Agreement, the “Agreements”).

The financial terms of the Agreements are substantially the same as the agreement on the monetary terms that the Company disclosed in the Registration Statement. In addition, the Company has negotiated a resolution of claims by various participating states (the “States”) with respect to the investigated matters. The Company expects the States to complete their respective settlement approval processes over the next four to eight weeks, after which the Company expects to separately enter into settlement agreements to resolve the outstanding state claims with the State of New York and each of the other participating states (collectively, the “State Settlement Agreements”). The agreement on the monetary terms with the States includes an aggregate payment of approximately \$13.2 million to the States over a five year period pursuant to the collective settlements, for a total payment by the Company of \$49.0 million (plus interest) payable under the Agreements and the State Settlement Agreements to settle the investigated matters. The State Settlement Agreements are expected to include acceleration provisions similar to the SDNY Civil Settlement Agreement and the SDCA Civil Settlement Agreements described below upon the Company’s receipt of civil settlements, damages awards, and tax refunds, with the amount of acceleration and timing subject to such receipts.

#### *SDNY Civil Settlement Agreement*

The SDNY Civil Settlement Agreement requires the Company to pay a settlement amount of approximately \$19.4 million, which includes approximately \$9.7 million designated as restitution to the U.S. federal government. The settlement amount is payable in six installments as follows:

- approximately \$9.1 million within 14 business days of July 23, 2020;
- approximately \$1.6 million on or before December 31, 2020;
- approximately \$2.0 million on or before December 31, 2021;
- approximately \$2.8 million on or before December 31, 2022;
- approximately \$3.2 million on or before December 31, 2023; and
- approximately \$0.8 million on or before December 31, 2024.

The amounts payable to the government, other than the initial \$9.1 million payment, will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at the option of the Company.

Furthermore, the Company has agreed that, if during calendar years 2020 through 2023, and so long as amounts payable to the government remain unpaid, the Company receives any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed \$5.0 million in a calendar year, it will pay 26% of the amount received in such civil settlement, damages award, or tax refunds as an accelerated payment on the scheduled amounts set forth above, first as a dollar-for-dollar acceleration of the scheduled payment due in December 2025 and then as an accelerated payment of the scheduled payments due in each prior year, up to a maximum total acceleration of \$4.2 million. As previously reported, during the three months ended March 31, 2020, the Company recorded a discrete tax benefit of \$37.7 million related to the net operating loss carryback provisions available under the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”), for taxes paid by the Company in years 2013, 2014, 2015 and 2017 (the “CARES Act Tax Benefit”). In June 2020, the Company received a tax benefit payment of approximately \$22.7 million for a portion of the CARES Act Tax Benefit, and because this tax refund was received prior to the effective date of the SDNY Civil Settlement Agreement, pursuant to the Company’s previously disclosed agreement with the government on monetary terms, the payment to be made within 14 business days of July 23, 2020, includes an added payment of approximately \$5.9 million and the SDNY Civil Settlement Agreement reflects a corresponding reduction in the previously agreed upon payment term and subsequent payment amounts. In addition, if the Company receives the remaining payment in full for the CARES Act Tax Benefit, the Company will pay an accelerated payment to the government under the SDNY Civil Settlement Agreement of approximately \$3.9 million.

Additionally, under the SDNY Civil Settlement Agreement, the U.S. federal government and the relator agreed to dismiss all civil claims asserted by the relator under the *qui tam* provisions of the federal False Claims Act.

#### *SDCA Civil Settlement Agreement*

The SDCA Civil Settlement Agreement requires the Company to pay a settlement amount of approximately \$16.4 million, which includes approximately \$10.0 million designated as restitution to the U.S. federal government. The settlement amount is payable in six installments as follows:

- approximately \$7.7 million within ten days of July 21, 2020;
- approximately \$1.3 million on or before December 31, 2020;
- approximately \$1.7 million on or before December 31, 2021;
- approximately \$2.3 million on or before December 31, 2022;
- approximately \$2.7 million on or before December 31, 2023; and
- approximately \$0.7 million on or before December 31, 2024.

The amounts payable to the government, other than the initial \$7.7 million payment, will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at the option of the Company.

On July 21, 2020, the Company issued a promissory note to the U.S. federal government for the full settlement amount in connection with the SDCA Civil Settlement Agreement (the “Promissory Note”). The Promissory Note contains customary events of default and related acceleration of payment provisions. In addition, the Promissory Note provides, among other terms, that, if during calendar years 2020 through 2023, and so long as amounts payable to the government remain unpaid, the Company receives any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed \$5.0 million in a calendar year, it will pay 22% of the amount received in such civil settlement, damages award, or tax refunds as an accelerated payment on the scheduled amounts set forth above, first as a dollar-for-dollar acceleration of the scheduled payment due in December 2024 and then as an accelerated payment of the scheduled payments due in each prior year, up to a maximum total acceleration of approximately \$3.4 million. Because the Company received a tax benefit payment of approximately \$22.7 million for a portion of the CARES Act Tax Benefit in June 2020 and because this tax refund was received prior to the effective date of the Promissory Note, the payment to be made within ten days of July 21, 2020 includes an added payment of \$4.9 million, and the Promissory Note reflects a corresponding reduction in the previously agreed upon payment term and subsequent payment amounts. In addition, if the Company receives the remaining payment in full for the CARES Act Tax Benefit, the Company will pay an accelerated payment to the government under the SDCA Civil Settlement Agreement of approximately \$3.3 million.

### *Non-Prosecution Agreement*

Effective July 21, 2020, the Company entered into the Non-Prosecution Agreement, pursuant to which the Company agreed with the DOJ to (i) pay the restitution provided for under the SDCA Civil Settlement Agreement, (ii) not commit any felonies, (iii) continue to implement a compliance and ethics program designed to prevent and detect violations of applicable fraud and kickback laws throughout its operations and (iv) fulfill certain other disclosure, reporting and cooperation obligations. The DOJ agreed that it will not prosecute the Company for any conduct described in the Non-Prosecution Agreement provided that the Company performs its obligations under the Non-Prosecution Agreement during the period from July 21, 2020 through July 21, 2021. The Non-Prosecution Agreement provides that the DOJ may unilaterally, upon notice to the Company, extend the term of the agreement in 6-month increments, for a maximum total term of 24 months (that is, two 6-month extensions).

### *Corporate Integrity Agreement*

In connection with the resolution of the investigated matters, and in exchange for the OIG's agreement not to exercise its authority to permissively exclude the Company from participating in federal health care programs, effective July 21, 2020, the Company entered into a five-year Corporate Integrity Agreement with the OIG. The Corporate Integrity Agreement requires, among other matters, that the Company maintain a Compliance Officer, a Compliance Committee, board review and oversight of certain federal healthcare compliance matters, compliance programs, and disclosure programs; provide management certifications and compliance training and education; engage an independent review organization to conduct claims and arrangements reviews; and implement a risk assessment and internal review process. The Company's failure to comply with its obligations under the Corporate Integrity Agreement could result in monetary penalties and/or the Company being excluded from participating in federal health care programs.

The SDNY Civil Settlement Agreement, the SDCA Civil Settlement Agreement, the Promissory Note, the Non-Prosecution Agreement and the Corporate Integrity Agreement each contain other terms and conditions and the foregoing descriptions of each of the SDCA Civil Settlement Agreement, the SDNY Civil Settlement Agreement, the Promissory Note, the Non-Prosecution Agreement and the Corporate Integrity Agreement are qualified in their entirety by reference to the full text of each such agreement, which are attached hereto as Exhibits 10.1, 10.2, 10.3, 10.4 and 10.5, respectively, and are incorporated herein by reference.

Until the final State Settlement Agreements are approved and signed by the States, there can be no assurance that the amount we have accrued will be sufficient to cover our obligations relating to this matter. Our obligations could also increase, potentially materially, depending on a number of factors including whether or not the agreement on the monetary terms with the States is finalized, whether an individual State or States opt out of the settlement prior to approval in order to pursue a separate action or resolution, the terms of the final approved agreements and the parties to the settlement. For additional information, please see Note 9. Commitments and Contingencies to our audited financial statements for the year ended December 31, 2019 in the Registration Statement, as well as "Risk Factors—Regulatory Risks Related to Our Business—If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and our business operations and financial condition could be adversely affected."

### **Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.**

The information provided in response to Item 1.01 of this report is incorporated by reference into this Item 2.03.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
10.1	<a href="#"><u>Stipulation and Order of Settlement and Dismissal, effective July 23, 2020, among the U.S. Department of Justice through the U.S. Attorney's Office for the Southern District of New York, and on behalf of the Office of Inspector General of the Department of Health and Human Services, and with the relator named therein and Progenity, Inc.</u></a>
10.2	<a href="#"><u>Settlement Agreement, effective July 23, 2020, among the United States of America, acting through the U.S. Department of Justice through the U.S. Attorney's Office for the Southern District of California, and on behalf of the Defense Health Agency, the Tricare Program and the Office of Personnel Management, which administers the Federal Employees Health Benefits Program, and Progenity, Inc.</u></a>
10.3	<a href="#"><u>Promissory Note issued pursuant to the Settlement Agreement, dated July 21, 2020, among the United States of America, acting through the U.S. Department of Justice through the U.S. Attorney's Office for the Southern District of California, and on behalf of the Defense Health Agency, the Tricare Program and the Office of Personnel Management, which administers the Federal Employees Health Benefits Program, and Progenity, Inc.</u></a>
10.4	<a href="#"><u>Non-Prosecution Agreement, effective July 21, 2020, between the U.S. Attorney's Office for the Southern District of California and Progenity, Inc.</u></a>
10.5	<a href="#"><u>Corporate Integrity Agreement, effective July 21, 2020, between the Office of Inspector General of the Department of Health and Human Services and Progenity, Inc.</u></a>

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: July 23, 2020

**Progenity, Inc.**

By: /s/ Harry Stylli  
Harry Stylli  
Chairman and Chief Executive Officer

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* J. DOE, STATE OF NEW YORK  
*ex rel.* J. DOE, STATE OF CALIFORNIA *ex rel.* J. DOE, STATE OF  
TEXAS *ex rel.* J. DOE, STATE OF MICHIGAN *ex rel.* J. DOE,

Plaintiffs,

v.

PROGENITY, INC.,

Defendant.

16 Civ. 9051 (LAP)

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

PROGENITY, INC.,

Defendant.

**STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL**

WHEREAS, this Stipulation and Order of Settlement and Dismissal (“Stipulation”) is entered into by and among Plaintiff the United States of America (the “United States” or “Government”), by its attorney, Audrey Strauss, Acting United States Attorney for the Southern District of New York, and on behalf of the Office of Inspector General of the Department of Health and Human Services (“OIG-HHS”) and the Defense Health Agency (“DHA”), acting on

behalf of the TRICARE Program (“TRICARE”); Relator Demetria Katsanos (the “Relator”), by her authorized representative; and Defendant Progenity, Inc. (“Progenity”) (together with the Government and the Relator, the “Parties”), by its authorized representatives;

WHEREAS, Progenity is a company headquartered in California that provides molecular laboratory testing services to patients, through their healthcare providers, focusing on prenatal testing for genetic and chromosomal abnormalities;

WHEREAS, prior to August 2013, Progenity operated under the name Ascendant MDx, Inc.;

WHEREAS, throughout the period referenced in this Stipulation, Progenity provided services that were reimbursed by Federal healthcare programs, including Medicaid, TRICARE, the Federal Employee Health Benefit Program (“FEHBP”), and the United States Department of Veterans Affairs healthcare program (“VA”);

WHEREAS, on or about November 21, 2016, the Relator filed a complaint in the United States District Court for the Southern District of New York pursuant to the *qui tam* provisions of the False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.* (the “Relator Complaint”), alleging, *inter alia*, that Progenity engaged in illegal kickback schemes to induce physicians to order Progenity tests;

WHEREAS, prior to the filing of the Relator Complaint, the United States Attorney’s Office for the Southern District of California (“USAO SDCA”) and its law enforcement partners were investigating Progenity’s use of Current Procedural Terminology (“CPT”) code 88271 in the submission of claims to TRICARE and the FEHBP seeking reimbursement for certain cell-free DNA sequencing-based non-invasive prenatal tests (“NIPTs”) that can screen for chromosomal aneuploidies and subchromosomal microdeletions to determine the risk that a fetus

will be born with certain genetic disorders or abnormalities through analysis of fetal DNA present in the woman's blood;

WHEREAS, contemporaneously herewith, the USAO SDCA has entered into a non-prosecution agreement as well as a separate civil settlement agreement with Progenity to resolve claims relating to the submission of false claims to TRICARE and the FEHBP seeking reimbursement for NIPTs, under which Progenity has agreed to pay a sum of \$16,400,000;

WHEREAS, in addition to investigating the allegations in the Relator Complaint, the United States Attorney's Office for the Southern District of New York also initiated an investigation into Progenity's use of CPT code 88271 in the submission of claims to Medicaid and the VA seeking reimbursement for NIPTs;

WHEREAS, the Government alleges that from March 2014 through April 2016, in violation of the FCA, Progenity knowingly and willfully submitted false claims to Medicaid and the VA by fraudulently using CPT code 88271 to seek reimbursement for NIPTs when this code misrepresented the services Progenity actually provided, and, as a result, Progenity received payments for non-reimbursable tests, or received substantially higher payments than it was entitled to receive for the genetic testing services provided ("Miscoding Covered Conduct");

WHEREAS, the Government further alleges that, in violation of the Anti-Kickback Statute (the "AKS"), 42 U.S.C. §§ 13320a-7b(b), Progenity knowingly and willfully induced physicians to order Progenity tests for Federal healthcare program beneficiaries by: (1) from January 2012 through March 2016, offering and providing remuneration in the form of above fair market value payments, or "draw fees," to physicians or physician offices for blood specimens collected for Progenity tests; (2) from January 2012 through December 2018, offering and providing remuneration in the form of meals and happy hours for physicians and their

employees; and (3) from January 2012 through April 2018, routinely offering to reduce or waive, and routinely reducing or waiving, coinsurance and deductible payments that Federal healthcare program beneficiaries were required to pay without making individualized determinations of financial need or reasonable collection efforts. As a result of the foregoing, Progenity submitted false claims for payment to Federal healthcare programs. The conduct described in this paragraph is referred to as the “Kickback Covered Conduct”;

WHEREAS, contemporaneous with the filing of this Stipulation, the Government, through the Office of the United States Attorney for the Southern District of New York, is filing a Notice of Election to Partially Intervene and a Complaint-In-Intervention in the above-referenced *qui tam* action (“Government Complaint”), in which it is asserting claims under the FCA against Progenity for the Miscoding Covered Conduct and the Kickback Covered Conduct;

WHEREAS, Progenity intends on entering into separate settlement agreements (“State Settlements”) with various states that participate in Medicaid (“States”) to resolve claims related to the Miscoding Covered Conduct and the Kickback Covered Conduct and has agreed to pay a total of \$13,150,684 to the States pursuant to the State Settlements;

WHEREAS, in connection with settlement discussions and in order to allow the Government to assess Progenity’s ability to make payments to resolve this matter, Progenity has submitted information concerning its financial condition to the Government, including but not limited to information relating to its assets, liabilities, expenses, revenues, profits, and financial projections (the “Progenity Financial Information”);

WHEREAS, the Parties have, through this Stipulation, reached a mutually agreeable resolution addressing the claims asserted against Progenity in the Government Complaint and the Relator Complaint;

WHEREAS, the Relator's claim to a share of the proceeds from the settlement of claims arising from the Relator Complaint will be the subject of a separate agreement between the Relator and the United States, and the Relator acknowledges that this claim is limited to a share of the proceeds for the settlement of claims related to the Kickback Covered Conduct;

NOW, THEREFORE, upon the Parties' agreement, IT IS HEREBY ORDERED that:

**TERMS AND CONDITIONS**

1. The Parties agree that this Court has subject matter jurisdiction over this action and consent to this Court's exercise of personal jurisdiction over each of them.

2. Progenity admits, acknowledges, and accepts responsibility for the following conduct:

**Miscoding:**

- a. CPT codes are part of a numerical coding system that physicians and laboratories must use on claim forms to bill payors for healthcare services and to receive payments. The CPT code affects the rate that the payor will reimburse the provider. When there is no existing CPT code that accurately describes a specific service or test, an unlisted or miscellaneous CPT code should be used for a provider to seek reimbursement.
- b. From March 2014 through April 2016, Progenity knowingly submitted false claims for payment to Medicaid and the VA by using CPT code 88271 to obtain reimbursement for NIPTs.
- c. Progenity improperly used CPT code 88271, which applies to fluorescence in situ hybridization ("FISH") procedures, knowing that its genetic tests were cell-free DNA sequencing-based NIPTs that are not FISH procedures and that CPT code 88271 did not accurately represent the tests performed.
- d. Until January 2015, there was no CPT code specific to NIPTs. In the absence of a designated code prior to January 2015, Progenity used CPT code 88271 when

seeking reimbursement for certain NIPTs, instead of the miscellaneous CPT code 81479. The Medicaid reimbursement rate for CPT code 88271 during the relevant period was substantially more than the reimbursement rate for the miscellaneous CPT code 81479.

- e. On January 2, 2015, a new CPT code, 81420 (Genomic Sequencing Procedures and Other Molecular Multianalyte Assays), became active. Upon its implementation, CPT code 81420 became the correct code that Progenity should have used to bill for its NIPTs. However, Progenity knew that it would receive significantly higher reimbursement amounts by using CPT code 88271, and continued to knowingly submit false claims to Medicaid and the VA using the incorrect CPT code 88271.
- f. In addition, Progenity knew that the Medicaid programs for some states, such as Texas, Kansas, and New York, explicitly excluded reimbursement for certain NIPTs, such as those that tested for microdeletions, and allowed reimbursement for other NIPTs only if the patient had one or more high-risk factors, such as being over the age of 35 or having an ultrasound result showing an increased risk of aneuploidy. Progenity submitted claims seeking reimbursement for tests provided to Medicaid beneficiaries in these states even though it was aware that the tests were not eligible for coverage.
- g. As a result of fraudulently using CPT code 88721 and misrepresenting the type of test performed when submitting claims for payment to Medicaid and the VA for NIPTs, Progenity received payments for non-reimbursable tests, or received substantially higher payments than it was entitled to receive for the genetic testing services provided.

**Draw Fee Payments:**

- h. From January 2012 through March 2016, Progenity knowingly made “draw fee” payments to physicians or physicians’ offices for the collection of blood specimens for Progenity tests performed on Federal healthcare program beneficiaries. In total, Progenity paid over \$1.7 million in draw fees during this period.
- i. Progenity entered into agreements with physicians that specified the amount it would receive for each specimen collected for Progenity tests, and then paid the physician or physician’s office for those draws at the agreed-upon amount.
- j. The draw fees paid by Progenity exceeded the fair market value of the services performed when collecting blood specimens. Progenity frequently paid physicians \$20 or more for each blood draw. Progenity paid dozens of physicians and physician offices thousands of dollars in above fair market draw fee payments during the relevant time period.

**Meals and Happy Hours:**

- k. From 2012 through 2018, Progenity knowingly provided meals and happy hours to physicians who ordered Progenity tests for Federal healthcare program beneficiaries, as well to individuals who worked in physicians' offices. The value of these meals and happy hours exceeded Stark Law limits. In total, Progenity expended millions of dollars on food and drinks for physicians and their staff during this period.
- l. Progenity's sales management directed sales representatives to make frequent contact with physicians' practices, and sales representatives were permitted to provide meals and happy hours in order to facilitate these contacts. Sales staff purchased food and drinks for physicians and their staff at gatherings that often involved little or no educational or informational content. These gatherings included happy hours at bars and other establishments.
- m. During the vast majority of the relevant period, Progenity did not have effective systems in place to ensure that the company's expenses for meals and happy hours for physicians and their employees complied with the Stark Law and the AKS. For example, Progenity did not (i) reliably track the amount it spent on meals and happy hours for physicians or their staff; (ii) maintain accurate sign-in sheets reflecting attendance at Progenity-sponsored gatherings; (iii) keep records of materials or topics that were discussed during Progenity-sponsored gatherings; and (iv) implement and enforce limits on the total nonmonetary compensation that could be provided to physicians.

**Waiver of Patient Coinsurance and Deductible Payments:**

- n. From January 2012 through April 2018, Progenity knowingly routinely reduced or waived Federal healthcare program beneficiaries' coinsurance and deductible payments without making the required individualized determinations of financial need or reasonable collection efforts. Progenity offered to reduce or waive coinsurance and deductible payments as part of its sales efforts.
- o. Some of the Progenity tests were costly and required significant patient payments. To market its costly tests, sales representatives informed physicians and their staff, as well as patients, that Progenity would waive coinsurance and deductibles, or limit the patient's payment to a certain maximum out-of-pocket amount regardless of the actual coinsurance or deductible amount. Progenity often referred to this practice as the "Peace of Mind" program. Progenity used the Peace of Mind program to induce physicians to prescribe, and patients to consent to, Progenity tests.

3. Progenity shall pay to the United States the sum of \$19,449,316 plus applicable interest (the "Settlement Amount") to be paid in six installments according to the schedule set

forth below. Progenity shall make the below-referenced payments in accordance with instructions to be provided by the Financial Litigation Unit of the United States Attorney's Office for the Southern District of New York. Of the Settlement Amount, \$9,724,658 plus applicable interest constitutes restitution to the United States. The sum of \$9,664,998 plus applicable interest is being paid to resolve claims for the Miscoding Covered Conduct, and the sum of \$9,784,318 plus applicable interest is being paid to resolve claims for the Kickback Covered Conduct. The Government will allocate each installment payment proportionally between the amount being paid to resolve claims for the Miscoding Covered Conduct and the amount being paid to resolve claims for the Kickback Covered Conduct.

- a. Within fourteen (14) business days of the Effective Date (defined below in Paragraph 34), Progenity shall pay the United States the sum of \$9,073,361.77.
- b. On or before December 31, 2020, Progenity shall pay the United States the sum of \$1,587,699.27, plus interest which shall be compounded annually at a rate of 1.25% accruing from the Effective Date.
- c. On or before December 31, 2021, Progenity shall pay the United States the sum of \$1,984,624.08, plus interest which shall be compounded annually at a rate of 1.25% accruing from the Effective Date.
- d. On or before December 31, 2022, Progenity shall pay the United States the sum of \$2,778,473.71, plus interest which shall be compounded annually at a rate of 1.25% accruing from the Effective Date.
- e. On or before December 31, 2023, Progenity shall pay the United States the sum of \$3,175,398.53, plus interest which shall be compounded annually at a rate of 1.25% accruing from the Effective Date.

f. On or before December 31, 2024, Progenity shall pay the United States the sum of \$849,758.64, plus interest which shall be compounded annually at a rate of 1.25% accruing from the Effective Date.

4. In the event that, during any calendar year from 2020 through 2023, Progenity receives any civil settlements, damages awards, or tax refunds which exceed the aggregate value of \$5,000,000 in a calendar year (referred to herein as a "Windfall Event"), Progenity shall pay to the United States 26% of the value of the Windfall Event. This payment shall be made within 15 days of the occurrence of the Windfall Event, and Progenity shall promptly notify the United States of the Windfall Event and its value prior to making the payment. Each payment made pursuant to this provision will proportionately reduce the amount due in the last remaining installment payment set forth in Paragraph 3 above. (For example, if Progenity were to receive \$10,000,000 from a future Windfall Event that occurred in calendar year 2020, Progenity would be required to pay \$2,600,000 to the United States within 15 days of the occurrence of the Windfall Event, and this payment would proportionately reduce future installment payments so that Progenity would no longer need to make the payment required in Paragraph 3(f) above, and the payment required in Paragraph 3(e) would be reduced to \$1,425,157.17.) The aggregate amount of accelerated payments made pursuant to this Paragraph for the life of this Stipulation shall not exceed \$4,200,000. This provision shall no longer be operative after the Settlement Amount due under Paragraph 3 has been fully paid (\$19,449,316 plus applicable interest).

5. Harry G. Stylli, the Chief Executive Officer of Progenity, has executed a guaranty agreement with the United States personally guarantying up to \$2,000,000 of the Settlement Amount owed to the United States by Progenity, a copy of which is attached hereto as Exhibit A.

6. Progenity shall execute and agree to the entry of a consent judgment in favor of the Government and against Progenity in the amount of \$19,449,316, a copy of which is attached hereto as Exhibit B (the "Progenity Consent Judgment"). The Government may use the Progenity Consent Judgment to obtain a security interest in any asset or property of Progenity, but shall not engage in other collection activity with respect to the Progenity Consent Judgment so long as Progenity fully complies with the terms of this Stipulation. Should Progenity comply fully with the payment schedule set forth above as well as the other terms of this Stipulation, the Progenity Consent Judgment shall be deemed to be satisfied in full. Within thirty (30) calendar days after Progenity makes the final payment under the payment schedule, and upon Progenity's request, the Government shall file with the Clerk of the Court and deliver to Progenity a Full Satisfaction of Judgment. In the event that Progenity fully pays the Settlement Amount faster than as provided in the payment schedule set forth above, and fully complies with all other terms of the Stipulation, the Progenity Consent Judgment shall be deemed to be satisfied in full and, upon Progenity's request, the Government shall file with the Clerk of the Court and deliver to Progenity a Full Satisfaction of Judgment. Should Progenity fail to comply fully with the payment schedule set forth above or any other term of this Stipulation, Progenity shall be in default of this Stipulation, in which case the Government may take any of the actions set forth in Paragraph 16 below.

7. Progenity agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Stipulation. Upon reasonable notice, Progenity shall encourage, and agrees not to impair, the cooperation of Progenity's directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent

with the rights and privileges of such individuals. Progenity further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Miscoding Covered Conduct and Kickback Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

8. Subject to the exceptions in Paragraphs 14 and 21 below (concerning excluded claims and bankruptcy proceedings), and conditioned upon Progenity's full compliance with the terms of this Stipulation, including full payment of the Settlement Amount to the United States pursuant to Paragraphs 3 and 4 above, the United States releases Progenity, including Progenity's subsidiaries and corporate predecessors, successors, and assigns, including Molecular Diagnostic Health Sciences, LLC, Progenity Holding Company, Inc., SPX3, Inc., Avero Laboratory Holdings LLC, Progenity UK Limited, and Progenity Pty Ltd, from any civil or administrative monetary claim that the United States has for the Miscoding Covered Conduct and the Kickback Covered Conduct under the FCA, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-3812, the civil monetary provisions of the Stark Law, 42 U.S.C. §§ 1395nn(g)(3) and (4), and the common law theories of fraud, payment by mistake, and unjust enrichment. For avoidance of doubt, this Stipulation does not release any current or former officer, director, employee, or agent of Progenity from liability of any kind.

9. In consideration of Progenity's obligations in this Settlement Stipulation and the Corporate Integrity Agreement ("CIA") entered into between OIG-HHS and Progenity, and conditioned upon Progenity's full payment of the Settlement Amount, and except as expressly reserved in this Paragraph and in Paragraph 14 (concerning excluded claims), the OIG-HHS

agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal healthcare programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Progenity under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Miscoding Covered Conduct and the Kickback Covered Conduct. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Progenity from Medicare, Medicaid, and other Federal healthcare programs under

42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Miscoding Covered Conduct and the Kickback Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 14 below.

10. In consideration of the obligations of Progenity set forth in this Settlement Stipulation, and conditioned upon Progenity's full payment of the Settlement Amount, and except as expressly reserved in this Paragraph and in Paragraph 14 (concerning excluded claims), DHA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from TRICARE against Progenity under 32 C.F.R. § 199.9 for the Kickback Covered Conduct. DHA expressly reserves authority to exclude Progenity from TRICARE under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion), based upon the Kickback Covered Conduct. Nothing in this Paragraph precludes DHA or TRICARE from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 14 below.

11. Progenity fully and finally releases the United States and its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses

of every kind and however denominated) that Progenity has asserted, could have asserted, or may assert in the future against the United States and its agencies, officers, employees, servants, or agents related to the Miscoding Covered Conduct and Kickback Covered Conduct and the United States' investigation, prosecution and settlement thereof.

12. Conditioned on Progenity's timely payment of the full Settlement Amount pursuant to Paragraphs 3 and 4 above, the Relator, for herself and her heirs, successors, attorneys, agents, and assigns, releases Progenity, including its subsidiaries and corporate predecessors, successors and assigns, as well as all of their current and former officers, directors, employees, attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that the Relator has against Progenity; provided, however, that nothing in this Stipulation shall preclude the Relator from seeking to recover her reasonable expenses and attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d). Defendant's payment to the Relator for expenses, attorney's fees, and costs pursuant to 31 U.S.C. § 3730(d) shall be addressed by separate agreement.

13. In consideration of the execution of this Stipulation by the Relator and the Relator's release as set forth in Paragraph 12 above, Progenity, including Progenity's subsidiaries, predecessors, and corporate successors and assigns, as well as all of their current and former officers, directors, employees, attorneys, and other agents release the Relator and her successors, heirs, assigns, attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that Progenity has against the Relator related to or arising from the Relator Complaint.

14. Notwithstanding the release given in Paragraph 8, or any other term of this Stipulation, the following claims of the Government are specifically reserved and are not released by this Stipulation:

- a. any liability arising under Title 26, United States Code (Internal Revenue Code);
- b. any criminal liability;
- c. except as explicitly stated in this Stipulation, any administrative liability, including mandatory exclusion from Federal healthcare programs;
- d. any liability to the United States (or its agencies) for any conduct other than the Miscoding Covered Conduct and the Kickback Covered Conduct;
- e. any liability based upon obligations created by this Stipulation; and
- f. any liability of individuals.

15. Progenity has provided the Progenity Financial Information to the United States, and the United States has relied on the accuracy and completeness of that information in reaching this Stipulation. Progenity warrants that the Progenity Financial Information is complete, truthful, and accurate. If the United States learns of any misrepresentation or inaccuracy in the Progenity Financial Information, or of assets in which Progenity had an interest at the time of this Stipulation that were not disclosed in the Progenity Financial Information, and if such nondisclosure or misrepresentation changes either the estimated net worth, annual net income, or assets set forth in the Progenity Financial Information by 5% or more, the United States may at its option: (i) rescind this Stipulation and reinstate the claims asserted against Progenity in the Government Complaint, or (ii) let the Stipulation stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth, net income or

assets that were previously not disclosed. Progenity agrees not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorneys' fees and expenses.

16. Progenity shall be in default of this Stipulation if it fails to make the required payments set forth in Paragraphs 3 and 4 above on or before the due date for such payments, or if it fails to comply materially with any other term of this Stipulation ("Default"). The Government shall provide written notice to Progenity of any Default in the manner set forth in Paragraph 33 below. Progenity shall then have an opportunity to cure the Default within ten (10) calendar days from the date of delivery of the notice of Default. In the event that a Default is not fully cured within ten (10) calendar days of the delivery of the notice of Default ("Uncured Default"), interest shall accrue at the rate of 12% per annum compounded daily on the remaining unpaid principal balance of the settlement amount set forth in Paragraph 3 above, beginning ten (10) calendar days after mailing of the notice of Default. The United States may also, at its option, (a) rescind this Stipulation and reinstate the claims asserted against Progenity in the Government Complaint; (b) seek specific performance of this Stipulation; (c) offset the remaining unpaid balance of the Settlement Amount set forth in Paragraph 3 above from any amounts due and owing Progenity by any department, agency, or agent of the United States; or (d) exercise any other rights granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. Progenity shall not contest any offset imposed or any collection undertaken by the Government pursuant to this Paragraph, either administratively or in any Federal or State court. In addition, Progenity shall pay the Government all reasonable costs of collection and enforcement under this Paragraph, including attorneys' fees and expenses. In the event that the United States opts to rescind this Stipulation pursuant to this Paragraph, Progenity shall not

plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that relate to the Miscoding Covered Conduct or Kickback Covered Conduct.

17. The Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Stipulation; the Relator agrees and confirms that the terms of this Stipulation are fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

18. Progenity waives and shall not assert any defenses it may have to any criminal prosecution or administrative action relating to the Miscoding Covered Conduct or the Kickback Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Stipulation bars a remedy sought in such criminal prosecution or administrative action.

19. Progenity, having truthfully admitted to the conduct set forth in Paragraph 2 above (the "Admitted Conduct"), agrees that it shall not, through its attorneys, agents, officers, or employees, make any public statement, including but not limited to any statement in a press release, social media forum, or website, that contradicts or is inconsistent with the Admitted Conduct or suggests that the Admitted Conduct is not wrongful (a "Contradictory Statement"). Any Contradictory Statement by Progenity or its attorneys, agents, officers, or employees shall constitute a violation of this Stipulation, thereby authorizing the Government to pursue any of the remedies set forth in Paragraph 16 above, or seek other appropriate relief from the Court. Before pursuing any remedy, the Government shall notify Progenity that it has determined that Progenity has made a Contradictory Statement. Upon receiving such notice from the

Government, Progenity may cure the violation by repudiating the Contradictory Statement in a press release or other public statement within four business days. If Progenity learns of a potential Contradictory Statement by its attorneys, agents, officers, or employees, Progenity must notify the Government of the statement within 24 hours. The decision as to whether any statement constitutes a Contradictory Statement or will be imputed to Progenity for the purpose of this Stipulation, or whether Progenity adequately repudiated a Contradictory Statement to cure a violation of this Stipulation, shall be within the sole discretion of the Government. Consistent with this provision, Progenity may raise defenses and/or assert affirmative claims or defenses in any proceedings brought by private and/or public parties, so long as doing so would not contradict the Admitted Conduct.

20. Progenity represents and warrants that it has reviewed its financial situation, that it is currently not insolvent as such term is defined in 11 U.S.C. § 101(32), and that it reasonably believes it shall remain solvent following payment to the Government of the Settlement Amount referenced in Paragraph 3 above. Further, the Parties warrant that, in evaluating whether to execute this Stipulation, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Progenity, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Progenity was or became indebted to on or after the date of this Stipulation, within the meaning of 11 U.S.C. § 548(a)(1).

21. If within 91 days of the Effective Date of this Stipulation or any payment made under this Stipulation, Progenity commences any case, action, or other proceeding under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, or a third party commences any case, action, or other proceeding under any law related to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking an order for relief of Progenity's debts, or seeking to adjudicate Progenity as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Progenity or for all or part of Progenity's assets, Progenity agrees as follows:

- a. Progenity's obligations under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and Progenity shall not argue or otherwise take the position in any such case, action, or proceeding that (i) Progenity's obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) Progenity is insolvent at the time this Stipulation was entered into; or (iii) the mutual promises, covenants, and obligations set forth in this Stipulation do not constitute a contemporaneous exchange for new value given to Progenity.
- b. If any of Progenity's obligations under this Stipulation are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the Government, at its option, may rescind the release in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against Progenity for the claims that would otherwise be covered by the release in Paragraph 8 above. Progenity agrees that (i) any such claim, action, or proceeding brought by the Government would not be subject to an "automatic stay" pursuant to

11 U.S.C. § 362(a) as a result of the case, action, or proceeding described in the first sentence of this Paragraph, and Progenity shall not argue or otherwise contend that the Government's claim, action, or proceeding is subject to an automatic stay; (ii) Progenity shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any claim, action, or proceeding that is brought by the Government within 60 calendar days of written notification to Progenity that the release has been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the date the Relator Complaint was filed; and (iii) the Government has an undisputed, noncontingent, and liquidated allowed claim against Progenity in the amount of the Settlement Amount set forth in Paragraph 3 above and the Government may pursue its claim in the case, action, or proceeding described in the first sentence of this Paragraph, as well as in any other case, action, or proceeding, and shall be allowed to offset the remaining unpaid balance of its claim from any amounts due and owing Progenity by any department, agency, or agent of the United States without seeking further authorization from any court under 11 U.S.C. § 362(a)(7).

- c. Progenity acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Stipulation.

22. Progenity agrees to the following:

- a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social

Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Progenity, including Progenity's present or former officers, directors, employees, and agents in connection with:

- (1) the matters covered by this Stipulation;
  - (2) the United States' audit(s) and civil investigation(s) of matters covered by this Stipulation;
  - (3) Progenity's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with matters covered by this Stipulation (including attorneys' fees);
  - (4) the negotiation and performance of this Stipulation;
  - (5) any payment Progenity makes to the United States pursuant to this Stipulation and any payment Progenity may make to the Relator, including expenses, costs, and attorneys' fees; and
  - (6) the negotiation of, and obligations undertaken pursuant to the CIA to:
    - (i) retain an independent review organization to perform annual reviews as described in the CIA; and (ii) prepare and submit reports to the OIG-HHS, are unallowable costs for government contracting purposes (hereinafter referred to as "Unallowable Costs").
- b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Progenity, and Progenity shall not

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charge such Unallowable Costs directly or indirectly to any contracts with the United States.

- c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Stipulation, Progenity shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs (as defined in this Paragraph) included in payments previously sought by Progenity from the United States. Progenity agrees that the United States, at a minimum, shall be entitled to recoup from Progenity any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. Any payments due shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States, including the Department of Justice and/or the affected agencies, reserves its right to audit, examine, or re-examine Progenity's books and records and to disagree with any calculation submitted by Progenity or any of Progenity's subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Progenity, or the effect of any such Unallowable Costs on the amounts of such payments.
- d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Progenity's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

23. This Stipulation is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity except as otherwise provided herein.

24. Progenity agrees that it waives and shall not seek payment for any of the health care billings covered by this Stipulation from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Miscoding Covered Conduct and Kickback Covered Conduct.

25. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation; provided, however, nothing in this Stipulation shall preclude the Relator from seeking to recover her expenses or attorneys' fees and costs from Progenity pursuant to 31 U.S.C. § 3730(d). Defendant's payment to the Relator for expenses, attorney's fees, and costs pursuant to 31 U.S.C. § 3730(d) shall be addressed by separate agreement.

26. Any failure by the Government to insist upon the full or material performance of any of the provisions of this Stipulation shall not be deemed a waiver of any of the provisions hereof, and the Government, notwithstanding that failure, shall have the right thereafter to insist upon the full or material performance of any and all of the provisions of this Stipulation.

27. This Stipulation is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Stipulation is the United States District Court for the Southern District of New York. For purposes of construing this Stipulation, this Stipulation shall be deemed to have been drafted by all Parties to this Stipulation and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

28. This Stipulation constitutes the complete agreement between the Parties with respect to the subject matter hereof. This Stipulation may not be amended except by written consent of the Parties.

29. The undersigned counsel and other signatories represent and warrant that they are fully authorized to execute this Stipulation on behalf of the persons and the entities indicated below.

30. This Stipulation is binding on Progenity's successors, transferees, heirs, and assigns.

31. This Stipulation is binding on the Relator's successors, transferees, heirs, and assigns.

32. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. E-mails that attach signatures in PDF form or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

33. Any notice pursuant to this Stipulation shall be in writing and shall, unless expressly provided otherwise herein, be delivered by hand, express courier, or e-mail transmission followed by postage-prepaid mail, and shall be addressed as follows:

TO THE UNITED STATES:  
Jeffrey K. Powell, Esq.  
Kirti Vaidya Reddy, Esq.  
Assistant United States Attorneys  
United States Attorney's Office  
Southern District of New York  
86 Chambers Street, Third Floor  
New York, New York 10007

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TO DEFENDANT PROGENITY, INC.:  
M. Kendall Day, Esq.  
Jonathan M. Phillips, Esq.  
Gibson, Dunn & Crutcher LLP  
1050 Connecticut Avenue, N.W.  
Washington, D.C. 20036-5306

TO RELATOR:  
Robert W. Sadowski, Esq.  
800 Third Avenue, 28<sup>th</sup> Floor  
New York, NY 10022

34. The effective date of this Stipulation is the date upon which the Stipulation is approved by the Court (the "Effective Date").

Agreed to by:

**THE UNITED STATES OF AMERICA**

Dated: July 21, 2020

AUDREY STRAUSS  
Acting United States Attorney for the  
Southern District of New York

By: /s/ Kirti Vaidya Reddy

Jeffrey K. Powell  
Kirti Vaidya Reddy  
Assistant United States Attorneys  
86 Chambers Street, Third Floor  
New York, New York 10007

Dated: July 20, 2020

Office of the Inspector General, the U.S.  
Department of Health and Human Services

By: /s/ Lisa M. Re

Lisa M. Re  
Assistant Inspector General  
for Legal Affairs

**DEFENDANT**

Dated: July 21, 2020

DEFENDANT PROGENITY, INC.

By: /s/ Clarke Neumann

Clarke Neumann  
General Counsel  
GIBSON, DUNN & CRUTCHER LLP

By: /s/ M. Kendall Day

M. Kendall Day  
Jonathan M. Phillips  
1050 Connecticut Avenue, N.W.  
Washington, D.C. 20036-5306

*Attorneys for Progenity, Inc.*

RELATOR

Dated: July 20, 2020

DEMETRIA KATSANOS

By: /s/ Demetria Katsanos  
Demetria Katsanos

ROBERT W. SADOWSKI PLLC

By: /s/ Robert W. Sadowski  
Robert W. Sadowski, Esq.  
800 Third Avenue, 28<sup>th</sup> Floor  
New York, NY 10022

*Attorney for Relator*

SO ORDERED:

/s/ Loretta A. Preska  
HON. LORETTA A. PRESKA  
UNITED STATES DISTRICT JUDGE

Dated: July 23, 2020  
New York, New York

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Defense Health Agency (“DHA”), acting on behalf of the TRICARE Program (“TRICARE”), and the Office of Personnel Management (“OPM”), which administers the Federal Employees Health Benefits Program (“FEHBP”), (collectively, “the United States”), and Progenity, Inc. (“Progenity”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. At relevant times herein, Progenity was organized as a corporation under the laws of the State of Delaware, was a participating provider in federally-funded health care programs including TRICARE and FEHBP, and specialized in providing genetic testing laboratory services.

B. The United States contends that Progenity submitted or caused to be submitted claims for payment to TRICARE, 10 U.S.C. §§ 1071-1110b, and the FEHBP, 5 U.S.C. §§ 8901-8914.

C. The United States contends that it has certain civil claims against Progenity arising from the submission of claims for reimbursement to TRICARE and FEHBP for medical services, as follows:

1. Progenity specializes in providing cell-free DNA technology or non-invasive prenatal genetic testing (“NIPT”) services to screen for chromosomal disorders including Down Syndrome.

2. Between April 1, 2013 and April 30, 2016, there existed an established Current Procedural Terminology (“CPT”) code of 88271 for genetic testing procedures known as

“FISH” (fluorescence in situ hybridization) procedures. FISH procedures “map” the genetic material in a person’s cells while NIPT conducts testing on fragments of DNA in maternal plasma. During this time period, NIPT was not a covered service of TRICARE or FEHBP, as it was considered a laboratory-developed test and did not have FDA approval.

3. Until January 2, 2015, there was no CPT code specific to NIPT. On January 2, 2015, a new CPT code, 81420 (Genomic Sequencing Procedures and Other Molecular Multianalyte Assays) became active.

4. Between April 1, 2013 and April 30, 2016, Progenity knowingly submitted false claims for payment to TRICARE and FEHBP by using CPT code 88271 to obtain reimbursement for NIPTs. Progenity used CPT code 88271, a FISH code, despite knowing that its NIPTs are not FISH procedures. Progenity also misrepresented the number of units of service when it submitted claims under CPT code 88271 in order to receive a higher reimbursement rate.

5. Progenity continued to knowingly submit false claims to TRICARE and FEHBP using the 88271 code after the new CPT code 81420 became active in order to receive higher reimbursement amounts.

The conduct described above in Recital C is referred to below as the “Covered Conduct.”

D. This Settlement Agreement is neither an admission of liability by Progenity nor a concession by the United States that its claims are not well founded.

E. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Progenity shall pay to the United States Sixteen Million, Four Hundred Thousand Dollars (\$16,400,000), plus any interest in accordance with Paragraph 1.a. and 1.b. below and the Note referenced therein (the "Settlement Amount"), of which Nine Million, Nine Hundred Eighty-Seven Thousand, and Six Hundred and Ninety-Three Dollars (\$9,987,693) constitutes restitution to the United States. Progenity will make a payment in the amount of Seven Million, Six Hundred and Sixty-Eight Thousand, One Hundred and Thirty-Five Dollars and Thirty Cents (\$7,668,135.30) no later than ten days after the effective date of this agreement by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Southern District of California.

a. Over a period of 5 years, Progenity will pay the remaining Eight Million, Seven Hundred Thirty-One Thousand, Eight Hundred Sixty-Four Dollars and Seventy Cents (\$8,731,864.70), plus interest at 1.25% per annum, pursuant to the promissory note (Note) in the form of Appendix A, that Progenity agrees to execute contemporaneously with this settlement agreement.

b. The Note shall be partially secured pursuant to the Guaranty Agreement, in the form of Appendix B, that Progenity agrees to cause to be issued contemporaneously with this Settlement Agreement. Progenity may, with the prior written approval of the United States, cause to be issued a substitute Guaranty Agreement of like terms and conditions. If the Guaranty Agreement expires before the entire outstanding balance due under the Note is paid, Progenity shall cause to be issued a substitute Guaranty Agreement of like terms and conditions.

c. Interest shall accrue on the unpaid settlement amount as indicated in the Note.

2. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Progenity's full payment of the Settlement Amount and subject to Paragraph 23, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the United States releases Progenity from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. In consideration of the obligations of Progenity set forth in this Agreement, and conditioned upon Progenity's full payment of the Settlement Amount, and except as expressly reserved in this Paragraph and in Paragraph 5 (concerning excluded claims), DHA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from TRICARE against Progenity under 32 C.F.R. § 199.9 for the Covered Conduct. DHA expressly reserves authority to exclude Progenity from TRICARE under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or TRICARE from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 5, below.

4. In consideration of the obligations of Progenity in this Agreement, and conditioned upon Progenity's full payment of the Settlement Amount, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from FEHBP against Progenity under 5 U.S.C. § 8902a or 5 C.F.R. Part 890 Subpart J or Part 919 for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 5 (concerning excluded claims), below, and except if excluded by the OIG-HHS pursuant to 42

U.S.C. § 1320a-7(a). OPM expressly reserves all rights to comply with any statutory obligation to debar Progenity from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 5, below.

5. Notwithstanding the releases given in paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement; and
- f. Any liability of individuals.

6. Progenity has provided sworn financial disclosure statements (Financial Statements) to the United States and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. Progenity warrants that the Financial Statements are complete, truthful, and accurate. If the United States learns of asset(s) in which Progenity had an interest at the time of this Agreement that were not disclosed in the Financial Statements, or if the United States learns of any misrepresentation by Progenity on, or in connection with, the Financial Statements, and if such nondisclosure or

misrepresentation changes the estimated net worth set forth in the Financial Statements by 5% or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct, or (b) let the Agreement stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth of Progenity previously undisclosed. Progenity agrees not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorney's fees and expenses.

7. In the event that the United States, pursuant to Paragraph 6 (concerning disclosure of assets), above, opts to rescind this Agreement, Progenity agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 60 calendar days of written notification to Progenity that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on August 31, 2019.

8. Progenity waives and shall not assert any defenses Progenity may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

9. Progenity fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Progenity has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and

servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

10. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any TRICARE carrier or payer, or any FEHB carrier or payer related to the Covered Conduct; and Progenity agrees not to resubmit to any TRICARE carrier or payer or any FEHB carrier or payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

11. Progenity agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Progenity, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and any Plea Agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Progenity's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement and any Plea Agreement; and

- (5) the payment Progenity makes to the United States pursuant to this Agreement and any payments that Progenity may make to Relator, including costs and attorneys' fees.

are unallowable costs for government contracting purposes and under TRICARE and FEHBP (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Progenity, and Progenity shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Progenity or any of its subsidiaries or affiliates to TRICARE or FEHBP.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Progenity further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable TRICARE fiscal intermediaries, carriers, and/or contractors, and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Progenity or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Progenity agrees that the United States, at a minimum, shall be entitled to recoup from Progenity any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Progenity or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Progenity or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Progenity's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

12. Progenity agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Progenity shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Progenity further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

13. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 14 (waiver for beneficiaries paragraph), below.

14. Progenity agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents,

sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

15. Progenity warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Progenity, within the meaning of 11 U.S.C. § 547(c)(1), and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Progenity was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

16. If within 91 days of the Effective Date of this Agreement or of any payment made under this Agreement, Progenity commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of Progenity's debts, or seeking to adjudicate Progenity as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Progenity or for all or any substantial part of Progenity's assets, Progenity agrees as follows:

a. Progenity's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and Progenity shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) Progenity's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) Progenity was insolvent at the time this Agreement was

entered into, or became insolvent as a result of the payment made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Progenity.

b. If Progenity's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Progenity for the claims that would otherwise be covered by the releases provided in Paragraph 2 above. Progenity agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceedings described in the first clause of this Paragraph, and Progenity shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) Progenity shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the United States within 30 calendar days of written notification to Progenity that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on August 31, 2019; and (iii) the United States has a valid claim against Progenity in the amount of \$29,963,079, and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

c. Progenity acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

17. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

18. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Southern District of California. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

20. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

21. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

23. This Agreement is binding on Progenity's successors, transferees, heirs, and assigns.

24. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

25. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

**THE UNITED STATES OF AMERICA**

DATED: July 21, 2020

BY: /s/ Paul Starita  
Paul Starita  
Assistant United States Attorney  
United States Attorney's Office  
for the Southern District of California

DATED: July 23, 2020

BY: /s/ Paul Nicholas Bley  
For: Salvatore M. Maida  
General Counsel  
Defense Health Agency  
United States Department of Defense

DATED: July 20, 2020

BY: /s/ Edward M. Deharde  
Edward M. Deharde  
Assistant Director of Federal Employee  
Insurance Operations  
Healthcare and Insurance  
United States Office of Personnel Management

DATED: July 20, 2020

BY: /s/ Paul St. Hillaire  
Paul St. Hillaire  
Assistant Inspector General  
for Legal & Legislative Affairs  
Office of the Inspector General  
United States Office of Personnel Management

**DEFENDANT**

DATED: July 21, 2020

BY: /s/ Clarke Neumann

Clarke Neumann, Esq.  
Senior Vice President, General Counsel and Secretary  
Progenity, Inc.  
4330 La Jolla Village Drive Suite 200  
San Diego, CA 92122

DATED: July 21, 2020

BY: /s/ M. Kendall Day

M. Kendall Day, Esq.  
Jonathan Phillips, Esq.  
Gibson, Dunn, & Crutcher  
1050 Connecticut Avenue, N.W.  
Washington, DC 20036-5306  
Attorneys for Progenity, Inc.

**Promissory Note**

1. For value received, and pursuant to a Settlement Agreement dated July 21, 2020 attached hereto (Settlement Agreement), Progenity, Inc., (“Progenity” or “Maker”), for itself and its successors and assigns, promises to pay to the United States of America (“Holder”), or its assignee, the full principal sum of \$16,400,000.00, together with interest accruing at the rate of 1.25% per annum through year 5 (“Outstanding Balance”) as set forth below.

**Schedule of Payments (including interest)**

	<b>Payment Number</b>	<b>Date Due</b>	<b>Payment</b>	<b>Principal</b>	<b>Interest (1.25%)</b>	<b>Balance</b>
<b>Down Payment</b>		7/31/2020	\$ 7,668,135.30	\$ 7,668,135.30		\$8,731,864.70
	1	12/31/2020	\$ 1,384,253.97	\$ 1,338,775.51	\$ 45,478.46	\$7,393,089.19
	2	12/31/2021	\$ 1,765,883.00	\$ 1,673,469.39	\$ 92,413.61	\$5,719,619.80
	3	12/31/2022	\$ 2,414,352.39	\$ 2,342,857.14	\$ 71,495.25	\$3,376,762.66
	4	12/31/2023	\$ 2,719,760.55	\$ 2,677,551.02	\$ 42,209.53	\$ 699,211.64
	5	12/31/2024	\$ 707,951.79	\$ 699,211.64	\$ 8,740.15	\$ 0.00
<b>Total, All Years</b>			\$16,660,337.00	\$16,400,000.00	\$260,337.00	

2. Payments will be made by wire transfer as indicated pursuant to written instructions provided by the United States Attorney’s Office for the Southern District of California. If there is any change in the method or instructions of payment, the Holder shall inform the Maker at least 5 business days before payment is due.

3. This Note may be prepaid, in whole or in part, without penalty or premium. Partial payment does not alter the interest rate applicable each year as reflected in paragraph 1 of this Note.

4. **Acceleration Windfall Clause:** In the event that, during any calendar year from 2020 through 2023, Progenity receives any civil settlements, damages awards, or tax refunds which exceed the aggregate value of \$5,000,000 in a calendar year (referred to herein as a “Windfall Event”), Progenity shall pay to the United States 22% of the value of the Windfall Event. This payment shall be made within 15 days of the occurrence of the Windfall Event, and Progenity shall promptly notify the United States of the Windfall Event and its value prior to making the payment. Each payment made pursuant to this provision will proportionately reduce the amount due in the last remaining installment payment set forth in Paragraph 1 above. (For example, if Progenity were to receive \$10,000,000 from a future Windfall Event that occurred in calendar year 2020, Progenity would be required to pay \$2,200,000 to the United States within 15 days of the occurrence of the Windfall Event, and this payment would proportionately reduce future installment payments so that Progenity would no longer need to make the payment required on 12/31/2024 in Paragraph 1 above, and the payment required on 12/31/2023 in Paragraph 1 above

would be reduced to \$1,227,712.34 plus applicable interest.) The aggregate amount of accelerated payments made pursuant to this Paragraph for the life of Settlement Agreement shall not exceed \$3,449,400. This provision shall no longer be operative after the Settlement Amount due under Paragraph 1 of the Terms and Conditions of the Settlement Agreement has been fully paid (\$16,400,000 plus applicable interest).

5. Maker is in default of this Note on the date of occurrence of any of the following events (“Events of Default”).

- A. Maker’s failure to pay any amount provided for in this Note within ten days of when such payment is due and payable; provided, however, that an Event of Default does not occur if because of events outside of Maker’s control, the Holder does not receive the paid amount after transmission by Maker. Maker will make its best efforts to ensure Holder’s receipt of the paid amount.
- B. As provided in Paragraph 6 of the Terms and Conditions in the Settlement Agreement.
- C. If prior to making the full payment of the amount due under this Note, any case, proceeding, or other action is instituted:
  - a. under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, seeking to have any order for relief of debtors, or seeking to adjudicate Maker as bankrupt or insolvent; or
  - b. seeking appointment of a receiver, trustee, custodian or other similar official for Progenity or for all or any substantial part of Maker’s assets.

6. The Maker shall provide the United States written notice of an Event of Default falling under Paragraph 5.C within two (2) business days of such event by overnight mail, delivered to the Office of the United States Attorney for the Southern District of California (USAO), at 880 Front Street, Suite 6293, San Diego, CA 92101.

7. With regard to an Event of Default under Paragraph 5.A (failure to timely pay), the Government shall provide written notice to the Maker of any such Event of Default. The Maker shall then have an opportunity to cure the Event of Default within ten (10) calendar days from the date of delivery of the notice of Default. In the event that an Event of Default under Paragraph 5.A is not fully cured within ten (10) calendar days of the delivery of the notice of the Event of Default (“Uncured Event of Default”), interest shall accrue at the rate of 12 per cent per annum compounded daily on the remaining unpaid principal balance of the settlement amount set forth in Paragraph 1 above, beginning ten (10) calendar days after mailing of the notice of Default.

8. Upon the occurrence of an Event of Default under Paragraph 5.B and Paragraph 5.C, or in the event of an Uncured Event of Default under Paragraph 5.A and Paragraph 7, without further notice or presentment and demand by the United States:

- A. The portion of the Outstanding Balance secured by this Note shall become immediately due and payable (“Default Amount”). Interest shall accrue on the default amount from the date of the Event of Default at 12 per cent per annum, compounded daily.
- B. The United States may take any and all actions provided under law and equity, or provided by the Settlement Agreement, to collect the Outstanding Balance pursuant to this Note.
- C. The United States retains any and all other rights and remedies it has or may have under law and equity, and may exercise those rights or remedies.
- D. No failure or delay on the part of the United States to exercise any right or remedy shall operate as a waiver of the United States’ rights. No partial or single exercise by the United States of any right or remedy shall operate as a waiver of the United States’ rights.
- E. Maker will pay the United States all reasonable costs of collection, including reasonable attorneys’ fees and expenses.

9. Waiver by the Holder of any default by Maker, its successors, or assigns will not constitute a waiver of a subsequent default. Failure by the Holder to exercise any right, power, or privilege which it may have by reason of default will not preclude the exercise of such right, power, or privilege so long as such default remains uncured or if a subsequent default occurs.

10. This Note shall be governed and construed according to the laws of the United States of America.

11. Maker acknowledges that it is entering into this Note, freely, voluntarily and with no degree of compulsion whatsoever.

12. Any notice to the Maker pursuant to this Note shall be in writing and shall be delivered by hand, express courier, or e-mail transmission followed by postage-prepaid mail, and shall be addressed as follows:

M. Kendall Day, Esq.  
Jonathan M. Phillips, Esq.  
Gibson, Dunn & Crutcher LLP  
1050 Connecticut Avenue, N.W.  
Washington, D.C. 20036-5306

IN WITNESS THEREOF, Maker intending to be legally bound hereby and so bind its successors and assigns, has caused this Note to be executed by its proper corporate officer, duly attested this 21<sup>st</sup> day of July, 2020.

PROGENITY, INC.

by:

/s/ Clarke Neumann

Clarke Neumann

General Counsel, Progenity

July 21, 2020

**U.S. Department of Justice**

**ROBERT S. BREWER, JR.**  
*United States Attorney  
Southern District of California*

*VALERIE H. CHU*

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*San Diego County Office  
Federal Office Building  
880 Front Street, Room 6293  
San Diego, California 92101-8893*

*Imperial County Office  
516 Industry Way  
Suite C  
Imperial County, California 92251-5782*

July 2, 2020

Via Electronic Mail

M. Kendall Day  
Gibson, Dunn & Crutcher LLP  
1050 Connecticut Avenue, N.W.  
Washington, DC 20036-5306  
[KDay@gibsondunn.com](mailto:KDay@gibsondunn.com)

Re: Progenity, Inc.

Dear Mr. Day:

On the understandings specified below, the Office of the United States Attorney for the Southern District of California ("this Office") will not criminally prosecute Progenity, Inc. for any crimes (except for criminal tax violations, as to which this Office cannot and does not make any agreement) related to the fraudulent billing of non-invasive-prenatal tests ("NIPT") using the incorrect Current Procedure Terminology ("CPT") Code 88271, further described in Appendix A to this letter, which is incorporated by reference herein.

The Office enters into this Non-Prosecution Agreement based on the individual facts and circumstances presented by this case and the Company. Among the facts considered were the following: (a) Progenity has engaged in extensive remediation, including terminating the employment of officers and employees responsible for the corrupt payments; enhancing its compliance program, including creating a Compliance Committee independent from the Board composed of senior personnel, instituting third-party review of Progenity's CPT code selection, and conducting regular audits of claims to government payors; (b) Progenity's cooperation with the Office in the ongoing investigation of the conduct of Progenity, and its offer to cooperate in any investigation of the conduct of Progenity's officers, directors, employees, agents, and consultants relating to the violations set forth in Appendix A; (c) the significant collateral consequences to health care beneficiaries and the public from further criminal prosecution of Progenity; and (d) Progenity's payment of civil monetary penalties as a result of the conduct described in Appendix A.

Progenity admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as set forth in the Statement of Facts

attached hereto as Appendix A and incorporated by reference into this Agreement, and that the facts described in Appendix A are true and accurate. Progenity also admits, accepts, and acknowledges that the facts described in Attachment A implicate Title 18, United States Code, Section 1347. Progenity expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents or any other person authorized to speak for Progenity, make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by the Progenity set forth above or the facts described in the Statement of Facts attached hereto as Appendix A. It is further understood that Progenity and the Office may disclose this Agreement to the public. Progenity agrees that if it issues a press release or holds any press conference in connection with this Agreement, the Progenity shall first consult the Office to determine (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the Office and the Progenity; and (b) whether the Office has any objection to the release.

This Agreement shall have a term of 12 months from the date this Agreement is executed by all parties ("Term"). For the Term of the Agreement, Progenity shall: (a) commit no crimes whatsoever; (b) truthfully and completely disclose relevant information with respect to the activities of Progenity, its officers and employees, and others concerning all matters, relating to the conduct described in Appendix A, about which this Office inquires of it, which information can be used for any purpose, except as otherwise limited in this Agreement; and (c) bring to this Office's attention all criminal conduct by, or criminal investigations of, Progenity or any of its employees that could bind Progenity and that comes to the attention of Progenity or its senior management, as well as any administrative proceeding or civil action brought by any governmental authority that alleges fraud by Progenity. The parties agree that, during the Term, the Office may unilaterally, upon notice to Progenity, extend the Term of the Agreement in 6-month increments, for a maximum total Term of 24 months (that is, two 6-month extensions).

Until the date upon which all investigations and prosecutions arising out of the conduct described in this Agreement are concluded, whether or not they are concluded within the Term specified in the preceding paragraph, Progenity shall: (a) cooperate fully with this Office, the Federal Bureau of Investigation, the Defense Criminal Investigative Service, and any other law enforcement agency designated by this Office, in connection with any investigation related to the matters described in Appendix A; (b) use its best efforts promptly to secure the attendance and truthful statements or testimony of any officer, agent or employee at any meeting or interview or before the grand jury or at any trial or other court proceeding as requested by this Office; and (c) provide this Office, upon request, all relevant information, documents, records, or other tangible evidence about which this Office or any designated law enforcement agency inquires. Cooperation pursuant to this Paragraph is subject to applicable law and regulations, and does not require the Company to waive any valid claims of attorney-client privilege or attorney work product doctrine.

As a further condition of this Agreement, Progenity agrees to pay restitution to TRICARE and the Federal Employee Health Care Employee Benefits Program ("FEHBP"). The amount of restitution to TRICARE and FEHBP that shall satisfy this Agreement shall be the amount set forth in the settlement agreement between Progenity and the Civil Division of this Office, that is, \$7,955,437 as to TRICARE, and \$2,032,256 as to FEHBP. The parties agree that Progenity's payment of that settlement amount shall be wholly credited against the restitution amount required

under this Agreement. The parties intend that result, and do not intend that this Agreement require additional monetary payment beyond the restitution to TRICARE and FEHBP strictly for the billing fraud via fraudulent misuse of CPT Code 88271 for NIPT.

In addition, during the term of the Agreement, should Progenity learn of credible evidence or allegations of a violation of U.S. federal law by Progenity, Progenity shall promptly report such evidence or allegations to the Office. No later than thirty (30) days after the expiration of the term of this Agreement, Progenity, by its Chief Executive Officer and its Chief Financial Officer, will certify to the Office that Progenity has met its disclosure obligations pursuant to this Agreement. Such certification will be deemed a material statement and representation by Progenity to the executive branch of the United States for purposes of 18 U.S.C. § 1001.

Progenity represents that it has implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of 18 USC § 1347, and 42 U.S.C. 1320a-7b(b), and other applicable fraud and kickback laws throughout its operations. In addition, Progenity agrees that it will report to the Office within 6 months after the Agreement is executed regarding its remediation and implementation of the compliance measures, and any potential breach of this Agreement.

If, during the Term of this Agreement, Progenity (a) commits any felony under U.S. federal law; (b) provides in connection with this Agreement deliberately false, incomplete, or misleading information; (c) fails to cooperate as set forth in this Agreement; (d) fails to implement a compliance program; or (e) otherwise fails specifically to perform or to fulfill completely each of Progenity's obligations under the Agreement, regardless of whether the Office becomes aware of such a breach after the Term of the Agreement is complete, Progenity shall thereafter be subject to prosecution for any federal criminal violation of which the Office has knowledge, including, but not limited to, the conduct described in Appendix A, which may be pursued by the Office in the U.S. District Court for the Southern District of California or any other appropriate venue. Determination of whether Progenity has breached the Agreement and whether to pursue prosecution of Progenity shall be in the Office's sole discretion. Any such prosecution may be premised on information provided by Progenity. Any such prosecution relating to the conduct described in Appendix A or relating to conduct known to the Office prior to the date on which this Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against Progenity, notwithstanding the expiration of the statute of limitations, between the signing of this Agreement and the expiration of the Term plus one year. Thus, by signing this Agreement, Progenity agrees that the statute of limitations with respect to any such prosecution that is not time-barred on the date of the signing of this Agreement shall be tolled for the term plus one year. In addition, the Company agrees that the statute of limitations as to any violation of federal law that occurs during the Term will be tolled from the date upon which the violation occurs until the date upon which the Office is made aware of the violation.

In the event the Office determines that Progenity has breached this Agreement, the Office agrees to provide Progenity with written notice of such breach prior to instituting any prosecution resulting from such breach. Within thirty (30) days of receipt of such notice, Progenity shall have the opportunity to respond to the Office in writing to explain the nature and circumstances of such

breach, as well as the actions Progenity has taken to address and remediate the situation, which explanation the Office shall consider in determining whether to pursue criminal prosecution of Progenity.

In the event that the Office determines that the Company has breached this Agreement: (a) all statements made by or on behalf of Progenity to the Office, including Appendix A, and any testimony given by the Company before a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the Office against Progenity; (b) the Company shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule that any such statements or testimony made by or on behalf of Progenity prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible; and (c) Progenity agrees that the intended loss amount for sentencing purposes shall be determined pursuant to the November 2019 Sentencing Guidelines Manual (“Guidelines” or “USSG”), Section 2B1.1, and that amount of the intended loss enhancement shall be the amount set forth in the settlement agreement between Progenity and the Civil Division of the Office. Parties further agree that the culpability score shall be 2 (starting from 3 for involvement in criminal activity by high-level personnel, USSG § 8C2.5(b), and subtracting 1 for acceptance of responsibility, USSG § 8C2.5(g)). The decision whether conduct or statements of any current director, officer or employee, or any person acting on behalf of, or at the direction of, Progenity, will be imputed to Progenity for the purpose of determining whether Progenity has violated any provision of this Agreement shall be in the sole discretion of the Office.

Except as may otherwise be agreed by the parties in connection with a particular transaction, Progenity agrees that in the event that, during the Term of the Agreement, it undertakes any change in corporate form, including if it sells, merges, or transfers a substantial portion of its business operations as they exist as of the date of this Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. Progenity shall obtain approval from the Office at least thirty (30) days prior to undertaking any such sale, merger, transfer, or other change in corporate form, including dissolution, in order to give the Office an opportunity to determine if such change in corporate form would impact the terms or obligations of the Agreement.

This Agreement is binding on Progenity and the Office but specifically does not bind any other federal agencies, or any state, local or foreign law enforcement or regulatory agencies, or any other authorities, although the Office will bring the cooperation of Progenity and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by Progenity.

This Agreement sets forth all the terms of the agreement between the Company and the Office. No amendments, modifications or additions to this Agreement shall be valid unless they are in writing and signed by the Office, the attorneys for Progenity, and a duly authorized representative of Progenity.

Sincerely,

ROBERT S. BREWER, JR.  
United States Attorney  
Southern District of California

Date: July 2, 2020

BY: /s/ Valerie H. Chu  
VALERIE H. CHU  
Assistant United States Attorney

AGREED AND CONSENTED TO:

PROGENITY, INC.

Date: July 21, 2020

BY: /s/ Clarke Neumann  
CLARKE NEUMANN  
General Counsel  
PROGENITY, INC.

Date: July 21, 2020

BY: /s/ M. Kendall Day  
M. KENDALL DAY  
Gibson, Dunn, & Crutcher, LLP

**APPENDIX A**  
**STATEMENT OF FACTS**

The following Statement of Facts is incorporated by reference as part of the Non-Prosecution Agreement (the "Agreement"), dated July 2, 2020, between the United States Attorney's Office for the Southern District of California (the "Office") and Progenity, Inc. ("Progenity"). Progenity admits, accepts, and acknowledges, and Progenity and the Office stipulate, that the following information is true and accurate, and that Progenity is responsible for the acts set forth below.

1. At all times relevant to this Agreement, Progenity (formerly known as Ascendant MDx, Inc., with a name change on July 25, 2013 and amended certificate of incorporation filed August 21, 2013) operated a clinical laboratory. Progenity was headquartered first in Carlsbad, California and then in San Diego, California.

2. Progenity offered, among other genetic testing services, certain cell-free DNA sequencing-based noninvasive prenatal tests ("NIPT") for pregnant women. These NIPT tests provided methods of determining the risk that a fetus would be born with certain genetic disorders or abnormalities, through analysis of fetal DNA present in the woman's blood.

3. TRICARE is a health care program of the United States Department of Defense Military Health System. On March 6, 2013, Progenity (then under the name Ascendant MDx) ("Provider"), executed a Provider Services Agreement ("Services Agreement") with Humana Military Healthcare Services ("HMHS"), the support contractor for TRICARE Management Agency ("TMA"), with an effective date of April 1, 2013, permitting Provider to become a TRICARE program participating provider authorized to provide services to TRICARE beneficiaries. The Services Agreement states, in part, that the Provider:

- a. Agrees to provide health care services for beneficiaries in accordance with the TRICARE program regulations, policies, and procedures;
- b. Agrees to abide by all quality assurance, utilization management, grievance, appeals, rules, regulations and other policies and procedures including claims submission policies and TRICARE program payment methodologies applicable to the TRICARE program;
- c. Understands that no payment may be made to Provider for services rendered to beneficiaries which are, in the opinion of HMHS or TMA, not medically necessary, or not otherwise a covered benefit under the TRICARE program;
- d. Shall use the most current and applicable billing codes on all forms submitted with respect to its claims for payment for services provided to beneficiaries;
- e. Will abide by all TRICARE program and HMHS rules and guidelines for coding that are applicable (including inclusive procedure codes) to the services provided hereunder; and
- f. Agrees to be bound by and comply with the provisions of all applicable state and federal laws and regulations.

4. The Federal Health Care Employee Benefits Program ("FEHBP") was established by the Federal Employees Health Benefits Act (the ACT), enacted on September 28, 1959. The FEHBP was created to provide health insurance benefits for Federal employees, annuitants, and dependents. The provisions of the Act are implemented by the Office of Personnel Management through regulations, which are codified in Title 5, Chapter 1, Part 890 of the Code of Federal

Appendix A to Non-Prosecution Agreement between Progenity Inc. and United States

Regulations. Health insurance coverage is made available through contracts with various health insurance carriers.

5. Progenity submitted reimbursement claims for NIPT genetic testing services to TRICARE and the FEHBP. The reimbursement claims for these testing services identified them with a Current Procedural Terminology (“CPT”) code. CPT codes are part of a numerical coding system that describes defined health care procedures. CPT codes are used, *inter alia*, in billing for health care services. The CPT code used on a reimbursement claim can affect the reimbursement rate for the service, as procedures, and their corresponding codes, are reimbursed at rates that are assigned to them.

6. CPT code 88271 covers a range of fluorescence in situ hybridization (“FISH”) procedures. Cell-free DNA sequencing-based NIPT is not a FISH procedure.

7. Until January 2, 2015, there was no CPT code specific to NIPT. Prior to January 2, 2015, at various times, Progenity submitted NIPT claims to TRICARE and the FEHBP using the 88271 code.

8. On January 2, 2015, a new CPT code, 81420 (Genomic Sequencing Procedures and Other Molecular Multianalyte Assays) became active. Upon its implementation, 81420 became the correct code that Progenity should have used to bill for its basic and enhanced NIPT products. However, Progenity did not completely switch to the 81420 code when it billed TRICARE and the FEHBP for NIPT, and instead continued to bill for NIPT using the 88271 code, which represented to TRICARE and the FEHBP that the test being billed was a “FISH” procedure. Progenity knew that 88271 represented FISH procedures, and therefore was not the appropriate CPT code for NIPT, starting no later than January 2, 2015, and nevertheless Progenity knowingly and willfully

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continued using the incorrect 88271 CPT code to bill TRICARE and the FEHBP, at least in part, because of its reimbursement potential.

9. TRICARE and the FEHBP reimbursed some of Progenity's claims for NIPT using CPT code 88271, with dates of service after January 2, 2015.

10. As a result of the facts and practices described above, Progenity knowingly and willfully made false and misleading claims to TRICARE and the FEHBP using 88271 to misrepresent NIPT from January 2, 2015 through submission of a claim with a date of service in approximately March 2016, in order to obtain reimbursement from TRICARE and the FEHBP.

Appendix A to Non-Prosecution Agreement between Progenity Inc. and United States

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**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."

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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:

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- 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.

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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

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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.

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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

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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).

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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

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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.

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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);

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- 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

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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

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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.

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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

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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:

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- 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.

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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.

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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

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- 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

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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.

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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);

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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.

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## 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;

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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;

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- changes;
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;

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- 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:

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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

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

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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.

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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

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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.

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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

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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

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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

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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

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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,

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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.

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**ON BEHALF OF PROGENITY**

/s/ Clarke Neumann  
Clarke Neumann  
General Counsel, Progenity

July 21, 2020  
DATE

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

July 21, 2020  
DATE

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

/s/ Lisa M. Re

LISA M. RE

Assistant Inspector General for Legal Affairs

Office of Inspector General

U.S. Department of Health and Human Services

July 20, 2020

DATE

/s/ Tamar Terzian

TAMAR TERZIAN

Senior Counsel

Office of Inspector General

U.S. Department of Health and Human Services

July 21, 2020

DATE

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**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

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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;

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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

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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.

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## 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

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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

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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

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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

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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.

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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.

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## 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.

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- 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.

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- 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.

*Progenity, Inc. CIA*  
*Appendix C*