

**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, California 92101-8893*

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516 Industry Way  
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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

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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

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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

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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.

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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

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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.

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