

In the Matter of

**Oxford Health Insurance, Inc.,
UnitedHealthcare Insurance Company of New York,
and
UnitedHealthcare of New York, Inc.**

Assurance No.: 24-044

**ASSURANCE OF DISCONTINUANCE
UNDER EXECUTIVE LAW
SECTION 63, SUBDIVISION 15**

As authorized by Article 22-A of the General Business Law and Executive Law § 63(12), Letitia James, Attorney General of the State of New York, conducted an investigation into the policies and practices of Oxford Health Insurance, Inc., UnitedHealthcare Insurance Company of New York, and UnitedHealthcare of New York, Inc. (hereinafter collectively referred to as “UnitedHealthcare or UHC”) regarding contraception coverage. Based upon that investigation, the Office of the Attorney General has made the following findings, and UnitedHealthcare has agreed to modify and discontinue—and/or has previously modified and discontinued—certain of its policies and practices, and now assures its compliance with the following provisions of this Assurance of Discontinuance (“Assurance”).

DEFINITIONS

1. The following terms as used throughout this Assurance are defined as follows:
 - a) “Health Plan” shall mean a person, natural or corporate, or any groups of such persons, authorized as health insurers or managed care organizations under New York Insurance Law to offer comprehensive health coverage.
 - b) “Consumer” shall mean an enrollee, member, covered person, or subscriber of a Health Plan.
 - c) “Contraception” shall include, in addition to contraceptive drugs, devices, products, and procedures secured by a prescription, over-the-counter contraception, sterilization, and emergency contraception, as well as patient education and counseling on contraception, and follow-up services related to

contraceptive drugs, devices, products, and procedures.

ATTORNEY GENERAL'S INVESTIGATION

2. As part of United Health Group Incorporated, the nation's largest health insurer, UnitedHealthcare provides prescription drug coverage and other benefits in New York.

3. The Health Care Bureau of the Office of the New York State Attorney General ("OAG") received a complaint from a Consumer who was prescribed a progestin-only oral contraceptive, Slynd, by her health care provider. Her UnitedHealthcare health plan denied coverage for the contraceptive.

4. In response to an appeal, UnitedHealthcare initially maintained its denial, citing "safety concerns" and the need for Prior Authorization and Step Therapy, or an exception process. These denials continued despite being queried by both the OAG and the New York State Department of Financial Services, who cited the New York State Comprehensive Contraception Coverage Act (CCCA), which requires coverage with no cost sharing and no restrictions or delay for all FDA-approved contraception without a covered FDA therapeutic equivalent.¹

5. Such denials and medical management not only violate the CCCA but are additionally problematic because such hurdles to filling prescriptions for oral contraceptives impose unnecessary and unwarranted costs, restrict equitable access, and reduce utilization by Consumers, and Consumers might delay or skip care due to financial barriers leading to risk of unintended pregnancy. [Committee on Oversight and Reform, U.S. House of Representatives, Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance, October 25, 2022, [2022-10-25.COR PBM-Insurer Report.pdf \(house.gov\)](#), pp 1-6 (hereinafter "Committee Report").]

6. UnitedHealthcare's ostensible reasons for imposing restrictions and delay to its coverage of Slynd also failed to account for the benefits of progestin-only contraception, for those patients for whom estrogen is contraindicated—such as people with certain health conditions, including high blood pressure, migraines, and a family history of breast cancer, or being a current or former smoker. Moreover, Slynd is the only progestin-only pill that does

¹ More specifically, where the FDA has approved one or more therapeutic and pharmaceutical equivalent versions of a contraceptive drug, device, or product, the issuer is not required to include all of the therapeutic and pharmaceutical equivalent versions in its formulary, so long as at least one is included and covered without cost-sharing and without restriction and delay. ([Supplement No. 3 to Insurance Circular Letter No. 1 \(2003\): Health Insurance Coverage for Contraceptive Services | Department of Financial Services \(ny.gov\)](#))

not need to be taken at the same time every day, which may be particularly beneficial for people with irregular work schedules. [Committee Report. p 11.]

7. In addition, barriers and delays to coverage for newer forms of FDA-approved contraceptive drugs and devices, through mechanisms such as step therapy and prior authorization, impede dissemination and growth of market share for those drugs and devices. This in turn stifles innovation in development of newer contraceptive drugs and devices—a field that has long been underdeveloped.

STATUTORY AND REGULATORY VIOLATIONS

8. New York State's Comprehensive Contraception Coverage Act (CCCA), effective January 1, 2020, requires plans to cover without cost sharing all FDA-approved contraceptives without an FDA therapeutic equivalent. In addition, health plans may impose no restrictions or delay. Improper restrictions or delay include prior authorization, step therapy requirements, and exception processes. If there is more than one therapeutically equivalent version, as defined by the FDA, health plans must cover at least one therapeutically unique version. N.Y. Insurance Law §§ 3216, 3221, 4303.

9. Under the CCCA, therapeutic equivalence is determined by the FDA. The FDA considers drugs to be therapeutically equivalent if they meet these criteria:

- they are pharmaceutical equivalents (contain the same active ingredient(s); dosage form and route of administration; and strength.)
- they are assigned by FDA the same therapeutic equivalence codes starting with the letter "A ." To receive a letter "A", FDA
 - designates a brand name drug or a generic drug to be the Reference Listed Drug (RLD).
 - assigns therapeutic equivalence codes based on data that a drug sponsor submits in an ANDA to scientifically demonstrate that its product is bioequivalent (i.e., performs in the same manner as the Reference Listed Drug).

[Drugs@FDA Glossary of Terms | FDA](#)

10. Accordingly, a health plan must cover contraceptives such as Slynd without prior authorization and other restrictions, and without delays such as an exception process, as long as there is no other covered therapeutic equivalent.

11. Other provisions of New York State law also prohibit UnitedHealthcare's contraception coverage practices, including:

- a) Executive Law § 63(12), which prohibits repeated fraudulent or illegal acts in the transaction of business; and
- b) Article 22-A of the New York State General Business Law, which prohibits “deceptive acts and practices in the conduct of any business, trade or

commerce or in the furnishing of any service in this state....” General Business Law § 349[a].

12. Based on the findings of the Attorney General’s investigation, the Attorney General has determined that UnitedHealthcare’s coverage policies and practices have violated the CCCA, Executive Law § 63(12), and General Business Law Article 22-A.

WHEREAS, UnitedHealthcare neither admits nor denies the OAG’s Findings above, and the Attorney General is willing to accept the terms of this Assurance under Executive Law § 63(15) and to discontinue this investigation; the parties each believe that the obligations imposed by this Assurance are prudent and appropriate; and the Attorney General has determined that this Assurance is in the public interest.

IT IS HEREBY UNDERSTOOD AND AGREED, by and between the parties that:

PROSPECTIVE RELIEF

13. UnitedHealthcare agrees to modify its contraception coverage practices, procedures, and policies to comply fully with all New York State and federal laws, regulations, and guidance, including but not limited to N.Y. Insurance Law §§ 3216, 3221, and 4303, and the requirements of this Assurance. It has already made such modifications with respect to the Slynd contraceptive. UnitedHealthcare shall cover with no cost sharing and no restrictions or delay all FDA-approved contraception without an FDA therapeutic equivalent on its formulary.

14. UnitedHealthcare shall provide training to relevant staff involved in contraception coverage determinations to ensure compliance with the requirements of this Assurance and all New York State and federal laws, regulations, and guidance. All relevant personnel shall be trained on the materials within a reasonable time, but not more than thirty (30) business days from the Effective Date of this Assurance. Thereafter, new relevant personnel involved in contraceptive coverage determinations will be trained within thirty (30) business days of commencing their duties.

CONSUMER RESTITUTION

15. UnitedHealthcare has reviewed and identified contraceptive drugs that are FDA approved and have no therapeutic equivalent that are either 1) not on any UnitedHealthcare prescription drug list; or 2) on a UnitedHealthcare prescription drug list, but for which UnitedHealthcare imposed Prior Authorization, Step Therapy, Exception Processes, or other restrictions or delay. Such drugs include but are not limited to Slynd

(drospirenone), Nextsellis (estetrol monohydrate and drospirenone), and Phexxi Gel (citric acid; lactic acid; potassium bitartrate).

16. UnitedHealthcare shall pay full restitution plus twelve (12) percent interest per annum to those Consumers of New York Health Plans, who 1) had a claim for contraception that should have been covered pursuant to the CCCA without cost sharing and without restrictions or delay, at any time from June 1, 2020 through the present; and 2) who paid any amount (including but not limited to copayments, coinsurance or deductible) on the contraception or alternate covered contraceptive. The consumers who meet these conditions will be called “Eligible Consumers.” UHC shall make best efforts to identify all Eligible Consumers within thirty (30) business days of the Effective Date of this Assurance as follows:

a) UnitedHealthcare will use claim history to identify Consumers of New York Health Plans who had a claim for contraception that should have been covered pursuant to the CCCA without cost sharing and without restrictions or delay, at any time from June 1, 2020 through the present;

b) For each Consumer identified:

(1) If the claim history indicates that cost share was applied either on the contraceptive or an alternate covered contraceptive, then the Consumer will be deemed an Eligible Consumer and restitution will be sent to the Consumer.

(2) If the claim history does not contain a record of cost sharing, then UnitedHealthcare will seek to determine if the Consumer is an Eligible Consumer by sending via the Consumer’s preferred method of communication a notice to such Consumer. The notice will read, in yellow highlighted and bold-face, fifteen-point or larger type:

Under New York law, health plans must cover contraception without cost-sharing and without restriction or delay. You may be owed money for payments you made if you were covered by health insurance at the time of securing contraception. If you paid for contraception that you believe should have been covered in full, please submit a claim to UnitedHealthcare at UHC_NYContraceptives_support@uhc.com, identifying the exact type of contraception, approximate date(s) of the claims for coverage, and the amount you believe you overpaid. UnitedHealthcare will review your claim and provide a refund if deemed appropriate.

This notice shall also be posted on the UHC website at new.york.required.state.notices@uhc.com. The notice shall remain on the website for one year after the Effective Date of this Assurance.

17. Within sixty (60) business days from the date that all Eligible Consumers are identified, UnitedHealthcare shall make best efforts to issue a restitution payment to each Eligible Consumer, which shall reimburse Eligible Consumers the amount they paid for contraception that should have been covered in full pursuant to the CCCA. The restitution payment shall also include twelve (12) percent interest per annum from the date the Consumer made the first payment to the date restitution is issued.

18. UnitedHealthcare shall send by regular mail the restitution payment to the last known address of the Eligible Consumer. UnitedHealthcare shall make reasonable efforts to ensure the restitution payments are received, which shall include but not be limited to contacting the United States Post Office for a possible forwarding address if the payment is returned.

19. UnitedHealthcare will review all claims received from Consumers in response to the notice described in paragraph 16, and make best efforts to issue refunds to Consumers within thirty (30) business days of receipt of the claim.

20. Within sixty (60) business days from the date all restitution payments are made (other than those payments made as a result of the notice process described in paragraph 16), United Healthcare shall submit to the OAG a restitution report that includes, for each contraception claim: the identity of the Eligible Consumer, the name, formulation, dosage, and type of contraception, the date(s) of claim, the restitution amount with an explanation as to how it was calculated, the date restitution was issued, the address to which the restitution was sent, and whether the payment was returned.

21. Within fourteen (14) months of the Effective Date of this Assurance, UnitedHealthcare shall submit to the OAG a report in the same format as paragraph 21 for each Consumer claim it received in response to the notice described in paragraph 16. The report shall also include whether the Consumer's claim was granted or rejected in whole or in part and if rejected, the reason.

22. UnitedHealthcare shall continue to cooperate with the OAG and promptly resolve all consumer complaints that the OAG submits to UHC, or that otherwise come to the attention of UHC, which shall include issuing appropriate restitution to Consumers. UnitedHealthcare further shall cooperate with all ongoing requests by the OAG for information related to this investigation and to ensure compliance with this Assurance.

23. United Healthcare shall bear all costs for the procedures set out in this section.

PENALTIES

24. UnitedHealthcare shall pay \$1,000,000.00 in full by wire transfer within thirty (30) business days of the Effective Date of this Assurance. The OAG shall provide transfer information to Respondents.

CORRESPONDENCE AND PAYMENT

25. All notices, reports, requests, and other communications to any party pursuant to this Assurance shall be in writing and shall be directed as follows:

If to the OAG to:

Carol Hunt
Assistant Attorney General
Office of the Attorney
General Health Care Bureau
28 Liberty Street, 19th Floor
New York, New York 10005
Carol.Hunt@ag.ny.gov

If to UnitedHealthcare to:

Susan Tully Abdo, Esquire
Senior Assoc. General Counsel
UnitedHealthcare
Susan_Tully_Abdo@uhc.com

MISCELLANEOUS

Successors and Third Parties

26. This Assurance and all obligations imposed on or undertaken by UnitedHealthcare herein, will be binding upon and enforceable against UnitedHealthcare and its officers, directors, agents, employees and assignees, and any subsequent owner or operator (whether by merger, transfer of control, contractual arrangements, or other means) of UnitedHealthcare.

UnitedHealthcare's Representations

27. The OAG has agreed to the terms of this Assurance based on, among other things, the representations made to the OAG by UnitedHealthcare and the OAG's own factual investigation. To the extent that any material representations are later found to be inaccurate or misleading, this Assurance is voidable by the OAG in its sole discretion.

No Deprivation of the Public's Rights

28. Nothing herein shall be construed to deprive any person of any private

right under law or equity.

No Blanket Approval by the Attorney General of UnitedHealthcare's Practices

29. Acceptance of this Assurance by the OAG shall not be deemed or construed as approval by the OAG of any of UnitedHealthcare's acts or practices, and UnitedHealthcare shall make no representation to the contrary.

Monitoring by the OAG

30. To the extent not already provided under this Assurance, UnitedHealthcare shall, upon request by the OAG, provide all documentation and information necessary for the OAG to verify compliance with this Assurance, at UnitedHealthcare's expense. This Assurance does not in any way limit the OAG's right to obtain, by subpoena or by any other means permitted by law, documents, testimony, or other information.

No Limitation on the Attorney General's Authority & UnitedHealthcare's Duty to Honor Investigation and Obligations

31. Nothing in this Assurance in any way limits the OAG's ability to investigate or take other action with respect to any non-compliance at any time by UnitedHealthcare with respect to this Assurance, or UnitedHealthcare's noncompliance with any applicable law with respect to any matters.

Nondisparagement of Assurance

32. UnitedHealthcare shall not take any action or make any statement denying, directly or indirectly, the propriety of this Assurance or expressing the view that this Assurance is without factual basis. Nothing in this paragraph affects UnitedHealthcare's (a) testimonial obligations or (b) right to take legal or factual positions in defense of litigation or other legal proceedings to which OAG is not a party.

Governing Law; Effect of Violation of Assurance of Discontinuance

33. Under Executive Law § 63(15), evidence of a violation of this Assurance shall constitute prima facie proof of a violation of the applicable law in any action or proceeding thereafter commenced by the OAG.

34. This Assurance shall be governed by the laws of the State of New York without regard to any conflict of laws principles.

35. If a court of competent jurisdiction determines that UnitedHealthcare has breached this Assurance, UnitedHealthcare shall pay to the OAG the cost, if any, of such determination and of enforcing this Assurance, including without limitation legal fees,

expenses, and court costs.

36. In the event that any one or more of the provisions contained in this Assurance shall for any reason be held to be invalid, illegal, or unenforceable in any respect, in the sole discretion of the OAG such invalidity, illegality, or unenforceability shall not affect any other provision of this Assurance.

37. Any failure by the OAG to enforce this entire Assurance or any provision thereof with respect to any deadline or any other provision herein shall not be construed a waiver of the OAG's right to enforce other deadlines and provisions of this Assurance.

Entire Agreement; Amendment

38. No representation, inducement, promise, understanding, condition, or warranty not set forth in this Assurance has been made to or relied upon by UnitedHealthcare in agreeing to this Assurance.

39. This Assurance contains an entire, complete, and integrated statement of each and every term and provision agreed to by and among the parties, and the Assurance is not subject to any condition not provided for herein. This Assurance supersedes any prior agreements or understandings, whether written or oral, between the OAG and UnitedHealthcare regarding the subject matter of this Assurance.

40. This Assurance may not be amended or modified except in an instrument in writing signed on behalf of all the parties to this Assurance.

41. The division of this Assurance into sections and subsections and the use of captions and headings in connection herewith are solely for convenience and shall have no legal effect in construing the provisions of this Assurance.

Binding Effect

42. This Assurance is binding on and inures to the benefit of the parties to this Assurance and their respective successors and assigns, provided that no party, other than the OAG, may assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without prior written consent of the OAG. UnitedHealthcare represents and warrants, through the signatures below, that the terms and conditions of this Assurance are duly approved, and execution of this Assurance is duly authorized.

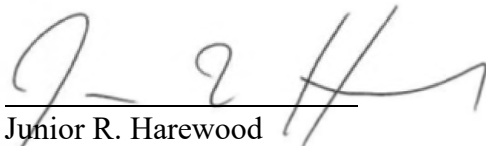
Effective Date

43. This Assurance is effective on the date that it is signed by the Attorney

General or his authorized representative (the “Effective Date”), and the document may be executed in counterparts, which shall all be deemed an original for all purposes.


AGREED TO BY THE PARTIES:

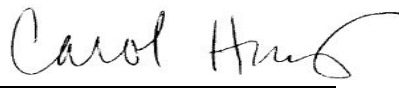
UnitedHealthcare

By: 
Junior R. Harewood
CEO, New York Health Plan
UnitedHealthcare
junior_r_harewood@uhc.com

CONSENTED TO:

LETITIA JAMES
Attorney General of the State of New York


By: _____
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Dated: June 12, 2024