STATE OF NEW YORK: DEPARTMENT OF HEALTH	
In the Matter of	X :
JEANETTE BREEN, CNM	:
Baldwin Midwifery Service	:
Town of Hempstead, Nassau County, New York	:
	X

STIPULATION AND ORDER

WHEREAS, Jeanette Breen ("Breen") was a licensed midwife who was authorized by the New York State Department of Health (the "Department" or "DOH") to provide information to the New York State Immunization Information System ("NYSIIS");

WHEREAS, the Department conducted an investigation of purported vaccination information that Breen provided to NYSIIS from July 2020 through December 2022;

WHEREAS, the investigation determined that Breen violated Article 21, Title 6, Section 2168 of the Public Health Law (the "Immunization Registry Law") by unreasonably and in bad faith providing false information about 12,449 purported vaccinations that never occurred and 1,452 purported vaccinees who were not vaccinated;

WHEREAS, the Commissioner of Health (the "Commissioner") is responsible for enforcing the Public Health Law ("PHL") and has the authority to bring enforcement proceedings, levy monetary penalties, seek injunctive relief, and refer criminal charges against parties that have violated PHL and associated regulations; and

WHEREAS, before beginning an enforcement action, the Department and Breen engaged in settlement discussions and wish to resolve the matter by means of a Stipulation and Order.

NOW THEREFORE, in connection with an agreement to resolve this matter without further proceedings, the Department finds as follows:

THE DEPARTMENT'S FINDINGS

Breen and Baldwin Midwifery Service

- 1. Breen was a midwife licensed and certified with prescriptive privilege by the New York State Education Department (Lic. No. 000045). She did business as Baldwin Midwifery Service and operated Baldwin Midwifery, a private women's healthcare center located in the town of Hempstead, Nassau County, New York.
- 2. At Baldwin Midwifery, Breen provided traditional as well as alternative healthcare. She described her care as "holistic with the appropriate use of technology as well as alternatives to traditional health care" and advertised offering, among other things, "healthcare counseling and screening including the use of Herbs, Homeopathics, and traditional Medicine [sic]."

History of Assisting Patient Attempts to Evade a Vaccination Requirement

3. Beyond practicing alternative medicine, Breen had a history of helping patients try to avoid mandatory immunization. For example, in fall 2017 she wrote a request for exemption on behalf of a patient who was required to be vaccinated under an employer's influenza-vaccination policy. At the time of the exemption request, Breen had met the patient only once. She based the request on the patient's uncomplicated pregnancy, as if being pregnant were itself a medical contraindication to the flu vaccine. This was contrary to guidance from the American College of Obstetricians and Gynecologists and the Centers for Disease Control (the "CDC"), both of which recommend that people who are pregnant during flu season get vaccinated. Accordingly, the patient's employer—a New York hospital with an Influenza Vaccine Exemption Review Board—rejected Breen's assessment as "personal opinion" and denied the exemption request.

Repeal of Non-medical Exemptions from Mandatory School Vaccinations

4. In June 2019, legislation ending non-medical exemptions from New York's school vaccine requirements took effect. Families of unvaccinated and undervaccinated children who had previously qualified for non-medical exemption were, for the first time, required to show proof of age-appropriate vaccination to attend any school or day care in the state.

The Real Immunity Homeoprophylaxis Program

- 5. In September 2019, less than three months after the change in law and at the start of the next school year, Breen began supplying patients with the Real Immunity Homeoprophylaxis Program ("Real Immunity"), a series of oral pellets marketed online by an out-of-state homeopath as an alternative to vaccination. No prescription was required for the self-administered program and, as with all products labeled as homeopathic, Real Immunity was not reviewed or authorized by the U.S. Food and Drug Administration. Likewise, it was neither recommended nor approved by the CDC or the Department as an immunizing agent against any disease.
- 6. Unlike her obstetric and gynecologic patients, Breen's Real Immunity patients were almost all school-aged children. Most lived on Long Island, but many were from New York City and other communities across the state including Cattaraugus, Columbia, Dutchess, Erie, Greene, Orange, Putnam, Rensselaer, Rockland, Saratoga, Schenectady, Schoharie, Sullivan, Tompkins, Ulster, Warren, Washington, and Westchester counties.
 - 7. In total, Breen supplied Real Immunity to at least 1,452 patients throughout New York.

 The New York State Immunization Information System ("NYSIIS")
- 8. In April 2020, approximately six months after she began distributing Real Immunity,

 Breen enrolled in NYSIIS, the public-health database run by the Department and used to collect,

store, and disclose vaccination records in New York.

- 9. Under the Immunization Registry Law, healthcare providers are required to submit information to NYSIIS about any vaccination administered to a child and may, with the consent of the vaccinee, submit information about vaccinations administered to adults. Once submitted, the information is used by medical professionals, public-health officials, school administrators, and other authorized NYSIIS users responsible for reducing illness, disability, and death caused by vaccine-preventable disease.
- 10. From July 2020, when she first submitted information to NYSIIS, until December 2022, when the Department suspended her NYSIIS account, Breen reported information about 12,450 ostensible vaccinations administered to 1,453 patients.

Misreporting Vaccination Information to NYSIIS

- 11. Of all the supposed vaccinations that Breen reported to NYSIIS, however, only one involved administration of an actual vaccine: a flu vaccination that Breen gave to an adult vaccinee in October 2021. Information about it alone was appropriate for submission to NYSIIS, assuming the patient consented. For the other 12,449 purported vaccinations, including all purported vaccinations required for school attendance, no vaccine was administered. Instead, Breen used distribution of Real Immunity—a homeopathic *non*-vaccine—as pretext to report that 1,452 patients had altogether received thousands of vaccinations when they in fact had not.
- 12. In addition to submitting information about purported "vaccinees" who had not received any vaccine and about "vaccine types" when no vaccine of any type had been administered,

 Breen falsely reported and omitted various other required NYSIIS elements. For example, she misreported supposed vaccinations as "historical" (i.e., administered by another provider) rather than as having been administered by her despite being the source of the non-vaccinations herself

(as she indicated on paper immunization records), provided vaccine administration dates that did not correlate with administration of any vaccine, and failed to submit tradenames and lot numbers which would have existed for any true vaccine. Moreover, on 407 occasions Breen falsely reported administering Adacel, a Tdap booster approved by the CDC that she had never actually possessed let alone administered to any patient.

Violations of Law

13. Breen did not report to NYSIIS information about vaccinees and vaccinations, submit to NYSIIS information in a format prescribed by the Commissioner, submit to NYSIIS the national immunization program data elements and other elements required by the Commissioner, or otherwise report to NYSIIS reasonably and in good faith, in violation of PHL §§ 2168(3)(a)(i), (5)(a), and (14) and 10 NYCRR § 66-1.2(c)(1).

NOW THEREFORE, to resolve this matter without further proceedings, the Department and Breen stipulate and agree to the following terms and conditions:

SETTLEMENT PROVISIONS

Monetary Penalty

14. Pursuant to PHL §§ 12(a)(1) and 206(4), Breen is assessed a monetary penalty of Three Hundred Thousand Dollars (\$300,000.00). Breen shall pay One Hundred and Fifty Thousand Dollars (\$150,000.00) of such penalty within ten (10) business days of the effective date of this Stipulation and Order, as defined in Paragraph 32, by sending a certified check or money order in that amount, payable to the New York State Department of Health, to the New York State Department of Health, Bureau of Accounts Management, Room 2748, Corning Tower, Empire State Plaza, Albany, New York 12237-0016. The remainder of the penalty shall be suspended contingent upon Breen achieving and maintaining full compliance with the PHL, associated

regulations, and all terms set forth in this Stipulation and Order.

- 15. If Breen fails to achieve and maintain full compliance with the PHL, associated regulations, and all terms set forth in this Stipulation and Order, she shall pay the full amount of the suspended monetary penalty within thirty (30) days of written demand by the Department. Such demand shall in no way bar the Department from pursuing any additional enforcement action pursuant to this Stipulation and Order and applicable to the new violation(s).
- 16. Any amount of the monetary penalty not paid by the dates prescribed herein shall be subject to all provisions of law related to debt collection by the State of New York. This includes, but is not limited to, the imposition of interest, late payment charges, and collection fees; referral to the New York State Department of Taxation and Finance for collection; and non-renewal of permits and licenses.

Remediation, Prohibitions, and Exclusion

Deletion of False Vaccination Information and Prohibition Against Further Acts

- 17. The Department shall, without delay, delete from NYSIIS all false immunization information that Breen submitted. As described above, this includes all vaccinations that Breen reported except for a single flu vaccination administered to an adult vaccinee (whose identity is known to the Department) in October 2021.
- 18. Breen shall in no way facilitate, aid, abet, endorse, recommend, advise, conspire, or otherwise participate in any scheme or attempt to misrepresent any individual as having received immunization that the individual in fact had not received. For clarification, this includes, but is not limited to, participating on behalf of any of her Real Immunity patients and their families in challenge to administrative action taken by a school, day care, college, business, or any other entity or institution as a result of the Department's Findings and providing any further assistance

to her Real Immunity patients in evading required vaccinations.

19. Breen shall, upon the effective date of this Stipulation and Order, cease using DOH Immunization Record and Signature Cards and any similar documents generally intended to record immunization. Any record that Breen provides to or on behalf of patients regarding Real Immunity or any other product or treatment intended or alleged to effect immunity shall include a clear and conspicuous disclaimer that accurately discloses the nature of the product or treatment and the fact that it is not recognized by the government as an alternative to conventional vaccination.

Exclusion from NYSIIS

20. Breen shall, upon the effective date of this Stipulation and Order, be permanently excluded from NYSIIS. Specifically, she shall be barred from directly accessing, or attempting to directly access, NYSIIS in any way and for any purpose; applying for, or attempting to apply for, a NYSIIS account or NYSIIS access; and permitting any individual or entity to apply for, or attempt to apply for, a NYSIIS account or NYSIIS access on her behalf. Any access or attempted access by Breen, or an agent acting on her behalf, shall be unauthorized, trespassory, and in violation of this Stipulation and Order and any applicable law, regulation, order, or term of use.

Prohibition Against Administering Certain Vaccinations

21. Breen shall, upon the effective date of this Stipulation and Order, permanently refrain from administering any immunization that must be reported to NYSIIS.

Assessment of Penalties

22. In assessing the penalty for Breen's violations of the Immunization Registry Law, the Department has considered factors that include, without limitation, the extent to which Breen has cooperated with the Department in its investigation of her conduct; the nature and gravity of the

violations; and such other matters as justice, public health, and the public interest may require.

23. The Department acknowledges Breen's cooperation with its investigation.

Evidence of PHL Violations

24. To resolve this administrative matter, Breen admits to the existence of substantial evidence in violation of PHL §§ 2168(3)(a)(i), (5)(a), and (14) and 10 NYCRR § 66-1.2(c)(1). Notwithstanding any other provision of this Stipulation and Order, the admission is without prejudice to Breen's rights, defenses, and claims in any other proceeding, action, hearing, investigation, or litigation not involving the Department or any of its boards or councils authorized by the PHL.

Full and Complete Cooperation

25. Breen commits and agrees that she will fully cooperate with the Department regarding all terms of this Stipulation and Order.

Further Action by the Department

26. Provided that Breen complies with the terms of this Stipulation and Order, this matter is settled and discontinued with prejudice. The Department shall not pursue administrative, civil, or criminal enforcement against Breen pursuant to PHL §§ 12-a and/or § 12-b and 10 NYCRR Part 51, or on any other basis, in connection with Breen's NYSIIS activity from April 2020, when her NYSIIS account was first activated, to December 2022, when it was suspended.

Waiver of Rights

- 27. Breen submits to the jurisdiction of the Department.
- 28. Breen understands and agrees that no provision of this Stipulation and Order is subject to review in any court, tribunal, or agency outside of the Department.
 - 29. Breen and the Department further stipulate and agree that there exist valid and sufficient

grounds, as a matter of fact and law, for the issuance of this Stipulation and Order under the PHL and Breen consents to its issuance, accepts its terms and conditions, and waives any right to challenge it in any action or proceeding including, but not limited to, a proceeding pursuant to Article 78 of the Civil Practice Law and Rules.

Parties Bound

30. This Stipulation and Order is binding on Breen and the Department. It does not bind any other state agency, federal agency, or law enforcement authority.

Public Record

31. This Stipulation and Order is a public record. Notwithstanding any other provision of this Stipulation and Order, the Department may publish, distribute, provide, and otherwise disclose it and its contents to any and all third parties at its discretion and without limitation.

Effective Date

32. This Stipulation and Order shall become effective upon service on Breen or her attorney by certified or registered mail.

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IN WITNESS WHEREOF, the parties have caused this Stipulation and Order to be signed on the dates set forth below.

NEW YORK STATE DEPARTMENT OF HEALTH

By: <u>Joe Giovannetti</u>
JOSEPH A. GIOVANNETTI, ESQ.
Director, Bureau of Investigations

Division of Legal Affairs

November 27, 2023

KATHY MARKS

General Counsel
Division of Legal Affairs

November 27, 2023

JEANETTE BREEN, CNM d/b/a BALDWIN MIDWIFERY SERVICE

JEANETTE BREEN, CNM

Baldwin Midwifery Service Baldwin Midwifery

November 14, 2023

DAVID M. ESKEW

Attorney for Jeanette Breen Abell Eskew Landau LLP

November 14, 2023

THE FOREGOING IS HEREBY APPROVED. IT IS SO ORDERED.

JAMES VI MCDON Commissioner of Health

New York State Department of Health

November \mathcal{L} , 2023