Filed November 24, 2025

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES

BIOBANKING COMPLIANCE PROGRAM

Licensure of Embryo Storage Facilities

Adopted New Rules: N.J.A.C. 8:77

Proposed: September 15, 2025, at 57 N.J.R. 2203(a).

Adopted: November 20, 2025, by Jeffrey A. Brown, Acting Commissioner, Department of Health.

Filed: November 20, 2025, as R.2025 d.155, with **non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 26:2A-23 through 31 (P.L. 2019, c. 268, P.L. 2022, c. 106).

Effective Date: December 15, 2025.

Expiration Date: December 15, 2032.

Summary of Public Comment and Agency Response:

A comment was received from David Lawyer, a resident of Columbus, New Jersey.

COMMENT: “VOTE NO”

RESPONSE: The Department of Health (Department) acknowledges the commenter’s submission; however, because the comment does not include any suggested changes to, or any specific, actionable criticism of the proposed new rules, which the Department is required to adopt pursuant to N.J.S.A. 26:2A-26, the Department takes no action with respect to this comment.

Federal Standards Statement

The Food and Drug Administration (FDA) has established standards to regulate "establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/Ps)," including a requirement at 21 CFR 1271.10(b) that the establishment register with the FDA and comply with certain other parts of 21 CFR 1271, as applicable to the particular operations of the establishment, primarily in an effort to prevent the transmission or spread of communicable disease by the operations of these establishments. “Manufacture” means “any or all steps in the recovery,

processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor." 21 CFR 1271.3(e). The adopted new rules require any applicant that is required by FDA regulation to register as an HCT/P establishment to submit proof of such registration with their application for Department licensure. The Department expects that some embryo storage facilities (ESFs), such as reproductive laboratories, are not subject to any of the requirements of 21 CFR 1271 because they do not meet the threshold definition of "manufacture." Additionally, the Department expects that some IVF facilities are not subject to any of the requirements of 21 CFR 1271 because they are establishments "that do not recover, screen, test, process, label, package, or distribute, but only receive or store HCT/Ps solely for implantation, transplantation, infusion, or transfer within your facility," pursuant to paragraph (c) of 21 CFR 1271.15. To the extent that some ESFs, due to their particular operations and activities, are required to comply with paragraph (c) of 21 CFR 1271.150 concerning Current Good Tissue Practice requirements and any of the Donor Eligibility requirements of Subpart C of 21 CFR 1271, those are separate and distinct from any standards imposed by these adopted new rules. There are no Federal standards for reproductive tissue that concern a facility's personnel, physical plant, equipment, emergency preparedness, or quality management.

In addition, the Department is adopting these rules under the authority of N.J.S.A. 26:2A-23 et seq. and not under the authority of, or to implement, comply with, or participate in, any program established under Federal law or a State law that incorporates or refers to any Federal law, standard, or requirement. Therefore, a Federal standards analysis is not required.

Full text of the adopted new rules follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

8:77-2.8 Provisional licensure

(a) The Department shall deem an existing ESF that is fully operational as of *[(the effective date of this rulemaking)]* ***December 15, 2025*** to be a provisionally licensed

ESF and thereby authorized to continue existing operations in the State without interruption; provided:

1.-2. (No change.)

3. The ESF submits to the BCP written notice of its intention to apply for licensure as an ESF by *[(30 days after the effective date of this rulemaking)]* ***January 15, 2026***, and submits evidence of its current accreditation by an accrediting body; and

4. The ESF applies to the BCP for licensure pursuant to N.J.A.C. 8:77-2.1 by *[(60 days after the effective date of this rulemaking)]* ***February 13, 2026***.

(b) Upon receipt of an ESF's notice of intention pursuant to (a)3 above, the BCP will issue a document evidencing provisional licensure to the ESF reflecting the ESF's status as a provisionally licensed ESF.

(c) Provisional licensure status shall remain effective until the earlier of either:

1. The BCP's issuance of a final determination on the ESF's application for licensure; or

2. The ESF's abandonment of an application for licensure pursuant to N.J.A.C. 8:77-2.1(b)3i.

(d) An existing ESF as described at (a) above that engages in the cryopreservation or storage of reproductive tissue in the State without having obtained provisional licensure, in accordance with this section, is subject to BCP enforcement action for violation of the Act pursuant to N.J.S.A. 26:2A-29 and this chapter.

(e) An ESF remains responsible to submit reportable events to the Department pursuant to N.J.A.C. 8:77-3.3 during the pendency of its provisional licensure status, notwithstanding its anticipated or actual submission of an application for licensure of the ESF.