

ASSEMBLY, No. 4671

STATE OF NEW JERSEY

218th LEGISLATURE

INTRODUCED OCTOBER 22, 2018

Sponsored by:
Assemblyman HERB CONAWAY, JR.
District 7 (Burlington)

SYNOPSIS

Permits terminally ill patients to access investigational therapies; allows corporation business tax credit and gross income tax credit for certain investigational therapies available to terminally ill patients.

CURRENT VERSION OF TEXT

As introduced.



1 AN ACT concerning the availability of investigational therapies to
2 certain patients and supplementing Title 26 of the Revised
3 Statutes, P.L.1945, c.162 (C.54:10A-1 et seq.), and Title 54A of
4 the New Jersey Statutes.

5
6 **BE IT ENACTED** *by the Senate and General Assembly of the State*
7 *of New Jersey:*

8
9 1. a. As used in this section:

10 “Eligible patient” means an individual who:

11 (1) has a terminal illness, attested to by the individual’s treating
12 physician;

13 (2) has considered all other treatment options currently
14 approved by the United States Food and Drug Administration in
15 consultation with the individual’s treating physician;

16 (3) has received a recommendation from the individual’s
17 treating physician for the use of an investigational therapy; and

18 (4) has provided, or has had a parent or legal guardian provide,
19 informed consent for the use of the investigational therapy.

20 “Investigational therapy” means any drug, biological product,
21 device, or other treatment or therapy that has successfully
22 completed Phase I of a clinical trial but has not yet been approved
23 for general use by the United States Food and Drug Administration
24 and which remains under investigation or in a clinical trial approved
25 by the United States Food and Drug Administration.

26 “Informed consent” shall have the same meaning as in section 4
27 of P.L.2007, c.316 (C.26:14-4).

28 “Terminal illness” means a medical condition that may result in a
29 patient’s life expectancy being 12 months or less as determined by a
30 physician.

31 b. A manufacturer of an investigational therapy may make the
32 investigational therapy available to eligible patients.

33 c. The State Board of Medical Examiners shall not revoke a
34 license, fail to renew a license, or take any other disciplinary action
35 under Title 45 of the Revised Statutes against a physician solely
36 based on the physician’s recommendation, prescription, or
37 treatment of an eligible patient with an investigational therapy.

38
39 2. a. As used in this section, “eligible patient” and
40 “investigational therapy” shall have the same meanings as set forth
41 in section 1 of P.L. , c. (C.) (pending before the Legislature
42 as this bill).

43 b. In privilege periods commencing after the effective date of
44 P.L. , c. (C.) (pending before the Legislature as this bill), the
45 director shall allow a taxpayer a credit against the tax imposed
46 pursuant to section 5 of P.L.1945, c.162 (C.54:10A-5) in an amount
47 equal to 25 percent of the cost incurred by the taxpayer in

1 manufacturing an investigational therapy that is made available to
2 eligible patients.

3 c. A taxpayer shall apply the credit awarded against the
4 taxpayer's liability under section 5 of P.L.1945, c.162 (C.54:10A-5)
5 for the current privilege period as of the date of the credit's
6 approval. A taxpayer may carry forward an unused credit resulting
7 from the limitations of subsection d. of this section, if necessary, for
8 use in the seven privilege periods following the privilege period for
9 which the credit is allowed.

10 d. The director shall prescribe the order of priority of the
11 application of the credit allowed under this section and any other
12 credits allowed by law against the tax imposed under section 5 of
13 P.L.1945, c.162 (C.54:10A-5). The amount of the credit applied
14 under this section against the tax imposed pursuant to section 5 of
15 P.L.1945, c.162 (C.54:10A-5) for a privilege period, together with
16 any other credits allowed by law, shall not exceed 50 percent of the
17 tax liability otherwise due and shall not reduce the tax liability to an
18 amount less than the statutory minimum provided in subsection (e)
19 of section 5 of P.L.1945, c.162 (C.54:10A-5).

20 e. The director shall not allow a taxpayer a credit pursuant to
21 this section for the value of an investigational therapy made
22 available by the taxpayer to eligible patients that is included in the
23 calculation of a credit allowed against the "New Jersey Gross
24 Income Tax Act," N.J.S.54A:1-1 et seq., allowed pursuant to
25 section 3 of P.L. , c. (C.) (pending before the Legislature as
26 this bill).

27
28 3. a. As used in this section, "eligible patient" and
29 "investigational therapy" shall have the same meanings as set forth
30 in section 1 of P.L. , c. (C.) (pending before the Legislature
31 as this bill).

32 b. In taxable years commencing after the effective date of
33 P.L. , c. (C.) (pending before the Legislature as this bill), the
34 director shall allow a taxpayer a credit against the tax otherwise due
35 pursuant to the "New Jersey Gross Income Tax Act," N.J.S.54A:1-1
36 et seq., in an amount equal to 25 percent of the cost incurred by the
37 taxpayer in manufacturing an investigational therapy that is made
38 available to eligible patients.

39 c. A taxpayer shall apply the credit awarded against the
40 taxpayer's liability under N.J.S.54A:1-1 et seq. for the current
41 taxable year as of the date of the credit's approval. A taxpayer may
42 carry forward an unused credit resulting from the limitations of
43 subsection d. of this section, if necessary, for use in the seven
44 taxable years following the taxable year for which the credit is
45 allowed.

46 d. The director shall prescribe the order of priority of the
47 application of the credit allowed under this section and any other
48 credits allowed by law against the tax imposed under N.J.S.54A:1-1

1 et seq. The amount of the credit applied under this section against
2 the tax imposed pursuant to N.J.S.54A:1-1 et seq. for a taxable year,
3 together with any other credits allowed by law, shall not exceed 50
4 percent of the tax liability otherwise due and shall not reduce the
5 tax liability to an amount less than zero.

6 e. The director shall not allow a taxpayer a credit pursuant to
7 this section for the value of an investigational therapy made
8 available by the taxpayer to eligible patients that is included in the
9 calculation of a credit against the tax imposed pursuant to section 5
10 of P.L.1945, c.162 (C.54:10A-5), allowed pursuant to section 2 of
11 P.L. , c. (C.) (pending before the Legislature as this bill).

12
13 4. This act shall take effect immediately, and sections 2 and 3
14 shall apply to taxable years or privilege periods commencing on or
15 after January 1 next following the date of enactment.

16 17 18 STATEMENT

19
20 This bill would permit patients who are terminally ill to access
21 investigational therapies that the United States Food and Drug
22 Administration (FDA) has not yet approved. The bill also allows
23 corporation business tax credits and gross income tax credits for a
24 portion of the cost incurred in manufacturing certain investigational
25 therapies made available to terminally ill patients.

26 The bill permits only eligible patients, as defined by the bill, to
27 access investigational therapies. An eligible patient has a medical
28 condition that results in a life expectancy of less than 12 months.
29 Additionally, to be an eligible patient, an individual must have
30 consulted with a physician and considered all other treatment
31 options currently approved by the FDA; received a prescription or
32 recommendation from the individual's treating physician for the
33 investigational therapy; and provided informed consent to use of the
34 investigational therapy.

35 The bill defines "investigational therapy" as any drug, biological
36 product, device, or other treatment or therapy that has successfully
37 completed Phase I of a clinical trial but has not yet been approved
38 by the FDA for general use and which remains under investigation
39 or in a clinical trial approved by the FDA.

40 The bill would prohibit the State Board of Medical Examiners
41 from revoking a license, failing to renew a license, or taking any
42 other disciplinary action against a physician solely based on the
43 physician's recommendation, prescription, or treatment of an
44 eligible patient with an investigational therapy.

45 Moreover, this bill allows a corporation business tax and gross
46 income tax credit for manufacturing an investigational therapy
47 made available to eligible patients. The bill enables a taxpayer
48 under either tax to take a credit equal to 25 percent of the cost

1 incurred by the taxpayer in manufacturing an investigational
2 therapy, which is made available to an eligible patient. The credits
3 created by this bill under the corporation business tax and gross
4 income tax are mutually exclusive such that no taxpayer may take a
5 credit under both impositions for the production of the same
6 investigational therapy. The credits afforded under this bill will be
7 available in the privilege period and taxable year commencing after
8 the effective date, but the bill allows a taxpayer to carry over certain
9 unused credits to future privilege periods or taxable years.