

SENATE, No. 1186

STATE OF NEW JERSEY
219th LEGISLATURE

INTRODUCED FEBRUARY 3, 2020

Sponsored by:

Senator NILSA CRUZ-PEREZ

District 5 (Camden and Gloucester)

SYNOPSIS

Requires hospital laboratories and bio-analytical or clinical laboratories to offer test for hepatitis C to certain individuals; authorizes certain laboratories to perform rapid tests for hepatitis C.

CURRENT VERSION OF TEXT

As introduced.



1 **AN ACT** concerning hepatitis C testing and supplementing Title 26
2 and Title 45 of the Revised Statutes.

3
4 **BE IT ENACTED** *by the Senate and General Assembly of the State*
5 *of New Jersey:*

6
7 1. The Legislature finds and declares that:

8 a. According to the federal Centers for Disease Control and
9 Prevention (CDC), approximately 75 percent of the 3.2 million people
10 chronically infected with hepatitis C in the United States were born
11 between 1945 and 1965. The CDC estimates that people born during
12 these years are five times more likely than other adults to be infected
13 with hepatitis C.

14 b. The CDC notes that hepatitis C is the leading cause of both liver
15 cancer and liver transplants, and estimates that people born between
16 1945 and 1965 account for 73 percent of all hepatitis C-related
17 mortality.

18 c. Studies suggest that between 45 percent and 85 percent of people
19 infected with hepatitis C are unaware they are infected, and as many as
20 50 percent of hepatitis C infections may go undetected under the current
21 hepatitis C risk factor screening standards.

22 d. The CDC recommends one-time testing of all people born
23 between 1945 and 1965 for hepatitis C infection, suggesting that this
24 testing is likely to identify approximately 800,000 people infected with
25 hepatitis C.

26 e. Proactively testing for hepatitis C infection among persons born
27 between 1945 and 1965 may help stop progression of the disease,
28 increase the effectiveness of treatment, and reduce the duration of
29 therapy for those infected, potentially resulting in improved health
30 outcomes and significant cost reductions associated with treating liver
31 disease.

32 f. New Jersey can help promote efforts to diagnose and treat
33 hepatitis C infection by facilitating access to hepatitis C screening tests
34 at certain points of care for persons born between 1945 and 1965.

35
36 2. a. As used in this section:

37 "Carrier" means a carrier as defined in section 2 of P.L.1997,
38 c.192 (C.26:2S-2).

39 "Health benefits plan" means a health benefits plan as defined in
40 section 2 of P.L.1997, c.192 (C.26:2S-2), the State Health Benefits
41 Program established pursuant to the "State Health Benefits Program
42 Act," P.L.1961, c.49 (C.52:14-17.25 et seq.), and the School
43 Employees' Health Benefits Program established pursuant to the
44 "School Employees' Health Benefits Program Act," sections 31
45 through 41 of P.L.2007, c.103 (C.54:14-17.46.1 through C.52:14-
46 17.46.11).

1 “Hepatitis C screening test” means a test approved by the federal
2 Food and Drug Administration that detects the presence of hepatitis
3 C virus antibodies in the blood.

4 b. Pursuant to a standing order issued by its chief medical
5 officer, a general hospital licensed pursuant to P.L.1971,
6 c.136 (C.26:2H-1 et seq.), when providing laboratory services on an
7 outpatient basis to an individual who was born between January 1,
8 1945 and December 31, 1965, shall, upon registration, provide the
9 individual with a verbal and written statement of CDC policy
10 regarding hepatitis C screening, and offer to provide a hepatitis C
11 screening test to that individual. If the individual consents to undergo
12 a hepatitis C screening test pursuant to this subsection, the hospital
13 laboratory shall perform the hepatitis C screening test and transmit
14 the test results to the health care provider rendering the referral for
15 laboratory services. The standing order shall designate a process for
16 an appropriate member of the hospital staff to contact an individual
17 who tests positive for hepatitis C in a screening test performed
18 pursuant to this subsection, so as to advise the individual of the test
19 results and encourage the individual to seek appropriate follow-up
20 care.

21 c. Pursuant to a standing order issued by its chief medical officer
22 or an equivalent officer, a bio-analytical or clinical laboratory, when
23 providing laboratory services to an individual born between January
24 1, 1945 and December 31, 1965 who was referred for laboratory
25 services by a health care professional licensed pursuant to Title 45 of
26 the Revised Statutes, shall, upon registration, provide the individual
27 with a verbal and written statement of CDC policy regarding hepatitis
28 C screening and offer to provide a hepatitis C screening test to that
29 individual. If the individual consents to undergo a hepatitis C
30 screening test pursuant to this subsection, the laboratory shall
31 perform the hepatitis C screening test and transmit the test results to
32 the health care professional who provided the referral for laboratory
33 services.

34 d. This section shall not affect the scope of practice of any health
35 care professional or diminish any authority or legal or professional
36 obligation of any health care professional to offer a hepatitis C
37 screening test, or to provide services or health care for the individual
38 who is subject to a hepatitis C screening test.

39 e. A hospital, bio-analytical, or clinical laboratory shall not be
40 required to provide an individual with a statement of CDC policy
41 regarding hepatitis C screening and offer to provide a hepatitis C
42 screening test to the individual pursuant to this section if, upon a
43 review of the laboratory’s records, it is determined the individual has
44 already been tested for hepatitis C.

45 f. (1) In the event that a laboratory that performs a hepatitis C
46 screening test pursuant to subsection b. or c. of this section is out-of-
47 network with respect to a covered person’s health benefits plan, the
48 carrier shall reimburse the laboratory for the cost of the screening test

1 at the carrier's in-network rate, or in any other reasonable amount as
2 agreed upon by the laboratory and the carrier, less any applicable
3 copayment, coinsurance, or deductible. In no case shall the
4 laboratory bill the covered person for the screening test, except for
5 the covered person's applicable copayment, coinsurance, or
6 deductible.

7 (2) Paragraph (1) of this subsection shall not apply to a hepatitis
8 C screening test that is performed on a covered person in the event
9 that, prior to the performance of the screening test:

10 (a) a check of laboratory records pursuant to subsection e. of this
11 section determines that the covered person was previously tested for
12 hepatitis C;

13 (b) the covered person is advised that, because the person was
14 previously tested for hepatitis C, the person may be liable for all or
15 part of the cost of the screening test in the event the person's health
16 benefits plan does not provide coverage for the test; and

17 (c) the person, voluntarily and in writing, requests or agrees to
18 undergo the hepatitis C screening test.

19 g. The Commissioner of Health shall evaluate the impact of the
20 provisions of this section with respect to the number of individuals
21 who are screened for hepatitis C and the number of individuals who
22 have accessed care following a positive test. No later than one year
23 after the effective date of this act, the Commissioner of Health shall
24 submit a report of the evaluation to the Governor and, pursuant to
25 section 2 of P.L.1991, c.164 (C.52:14-19.1), to the Legislature.

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27 3. The Commissioner of Health, in consultation with the Public
28 Health Council in the Department of Health, shall adopt regulations,
29 pursuant to the "Administrative Procedure Act," P.L.1968, c.410
30 (C.52:14B-1 et seq.), to permit any laboratory site that has a current
31 Clinical Laboratory Improvement Amendments Certificate of Waiver
32 issued by the federal Centers for Medicare & Medicaid Services to
33 perform rapid point-of-care tests for hepatitis C virus licensed by the
34 federal Food and Drug Administration.

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36 4. The Commissioner of Health, pursuant to the "Administrative
37 Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), shall adopt
38 rules and regulations necessary to effectuate the purposes of this act.

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40 5. This act shall take effect on the first day of January next
41 following the date of enactment, except that the Commissioner of
42 Health may take such anticipatory administrative action in advance of
43 the effective date as shall be necessary for the implementation of this
44 act.

STATEMENT

This bill sets forth certain requirements for hepatitis C screenings for individuals born between January 1, 1945 and December 31, 1965 who, according to the federal Centers for Disease Control and Prevention (CDC), are at increased risk for hepatitis C infection and associated liver diseases.

Specifically, pursuant to a standing order issued by its chief medical officer, a general hospital will be required, when providing laboratory services on an outpatient basis to an individual born between 1945 and 1965, to provide, upon registration, the individual with a verbal and written statement of CDC policy regarding hepatitis C screening, and offer to provide the individual with a hepatitis C screening test. If the individual consents to a hepatitis C screening test, the hospital laboratory will be required to perform the test and transmit the test results to the health care provider who referred the individual for laboratory services. The standing order is to designate a process for an appropriate member of the hospital staff to contact individuals who test positive for hepatitis C, so as to advise the individual of the test results and encourage the individual to seek appropriate follow-up care.

Similarly, when providing laboratory services to an individual born between 1945 and 1965 upon referral by a health care professional, a bio-analytical or clinical laboratory, pursuant to a standing order issued by its chief medical officer or an equivalent officer, will be required to provide the individual, upon registration, with a verbal and written statement of CDC policy regarding hepatitis C screening and offer to provide the individual with a hepatitis C screening test. If the individual consents to a hepatitis C screening test, the laboratory is to perform the test and transmit the test results to the health care professional who provided the referral for laboratory services.

The requirement for laboratories to provide individuals with a statement of CDC policy regarding hepatitis C screening and offer to provide a hepatitis C screening test will not apply if a check of laboratory records indicates the individual has already been tested for hepatitis C.

The bill provides that, in the event that a laboratory is out-of-network with respect to an individual's health benefits plan, the person's health benefits carrier is to reimburse the laboratory at the carrier's in-network rate, or in any other reasonable amount as agreed upon by the laboratory and the carrier, less any applicable copayment, coinsurance, or deductible, and the laboratory will be prohibited from billing the covered person for the screening test, other than for the applicable copayment, coinsurance, or deductible. This prohibition will not apply in situations in which: (1) the laboratory checks its records and determines that the covered person was previously screened for hepatitis C; (2) the person is advised

1 that, because of the prior test, the person may be liable for the full
2 cost of a subsequent test if the person's health benefits plan does not
3 provide coverage for the test; (3) and the person, voluntarily and in
4 writing, requests or agrees to undergo the subsequent test.

5 Nothing in the bill will affect the scope of practice of any health
6 care professional or diminish any authority or legal or professional
7 obligation of any health care professional to offer a hepatitis C
8 screening or diagnostic test, or to provide services or health care for
9 the individual who is subject to a hepatitis C test.

10 The commissioner will be required to evaluate the impact of the
11 bill with respect to the number of hepatitis C screenings and the
12 number of individuals who access care following a positive test, and
13 submit a report of the evaluation to the Governor and to the
14 Legislature within one year of the effective date of the bill.

15 The commissioner will also be required to adopt regulations, in
16 consultation with the Public Health Council in the Department of
17 Health, to permit any laboratory site that has a current Clinical
18 Laboratory Improvement Amendments Certificate of Waiver issued
19 by the federal Centers for Medicare & Medicaid Services to perform
20 rapid point-of-care tests for hepatitis C virus licensed by the federal
21 Food and Drug Administration.

22 The bill will take effect on the first day of January next following
23 the date of enactment, and the provisions concerning the hepatitis C
24 screening requirements will expire and be deemed repealed on
25 January 1 of the fifth year next following the date of enactment.

26 The CDC has suggested that one-time testing of persons born
27 between 1945 and 1965 for hepatitis C will help identify additional
28 cases of hepatitis C infection that may otherwise go undetected,
29 potentially improving health care outcomes and reducing the impact
30 of liver disease among this population.