

ASSEMBLY, No. 959

STATE OF NEW JERSEY

219th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2020 SESSION

Sponsored by:

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District 7 (Burlington)

Assemblywoman ANGELA V. MCKNIGHT

District 31 (Hudson)

Assemblyman BENJIE E. WIMBERLY

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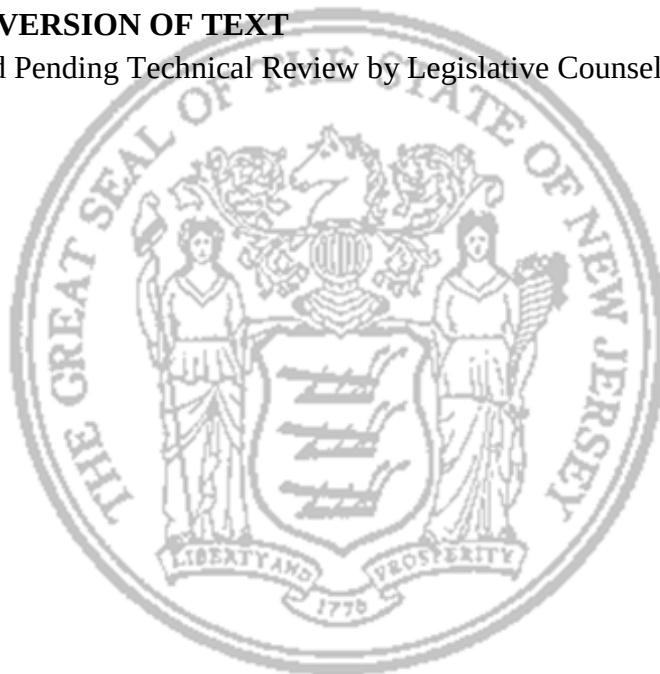
Assemblyman Verrelli

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

Introduced Pending Technical Review by Legislative Counsel.



(Sponsorship Updated As Of: 3/5/2020)

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
15 liver cancer and liver transplants, and estimates that people born
16 between 1945 and 1965 account for 73 percent of all hepatitis C-
17 related mortality.

18 c. Studies suggest that between 45 percent and 85 percent of
19 people infected with hepatitis C are unaware they are infected, and as
20 many as 50 percent of hepatitis C infections may go undetected under
21 the current 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
27 born 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
12 undergo a hepatitis C screening test pursuant to this subsection, the
13 hospital laboratory shall perform the hepatitis C screening test and
14 transmit the test results to the health care provider rendering the
15 referral for laboratory services. The standing order shall designate
16 a process for an appropriate member of the hospital staff to contact
17 an individual who tests positive for hepatitis C in a screening test
18 performed pursuant to this subsection, so as to advise the individual
19 of the test results and encourage the individual to seek appropriate
20 follow-up care.

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

34 d. This section shall not affect the scope of practice of any
35 health care professional or diminish any authority or legal or
36 professional obligation of any health care professional to offer a
37 hepatitis C screening test, or to provide services or health care for
38 the individual 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
44 has 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-
47 of-network with respect to a covered person’s health benefits plan,
48 the carrier shall reimburse the laboratory for the cost of the

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

26
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,
30 c.410 (C.52:14B-1 et seq.), to permit any laboratory site that has a
31 current Clinical Laboratory Improvement Amendments Certificate
32 of Waiver issued by the federal Centers for Medicare & Medicaid
33 Services to perform rapid point-of-care tests for hepatitis C virus
34 licensed by the federal Food and Drug Administration.

35
36 4. The Commissioner of Health, pursuant to the
37 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et
38 seq.), shall adopt rules and regulations necessary to effectuate the
39 purposes of this act.

40
41 5. This act shall take effect on the first day of January next
42 following the date of enactment, except that the Commissioner of
43 Health may take such anticipatory administrative action in advance of
44 the effective date as shall be necessary for the implementation of this
45 act. Section 1 of this act shall expire and be deemed repealed on
46 January 1 of the fifth year next following the date of enactment.

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, upon registration, provide 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. This bill provides that a standing order for hospital laboratories to offer hepatitis C screening tests is to designate a process for an appropriate member of the hospital staff to contact individuals whose screening test results are positive for hepatitis C, so as to advise them of the positive test results and to encourage them to seek appropriate follow-up care. This bill provides that the requirement to provide individuals with a statement of the federal Centers for Disease Control and Prevention policy concerning hepatitis C screenings, and offer a hepatitis C screening test to the person, will not apply if a check of laboratory records indicates that the individual has already been tested for hepatitis C.

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, upon registration, provide 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 laboratory is to perform the test and transmit the test results to the health care professional who provided the referral for laboratory services.

This bill provides that, in the event that a laboratory performing a hepatitis C screening test is out-of-network with respect to a covered person's health benefits plan, the carrier will provide reimbursement for the test to the laboratory at the in-network rate, or at any other reasonable amount as agreed upon by the carrier and the laboratory, less any applicable copayment, coinsurance, or deductible. The laboratory will be prohibited from billing the covered person for the screening test, except for any applicable copayment, coinsurance, or deductible. The prohibition against balance billing will not apply in the event that, prior to the performance of a hepatitis C screening test, a records check determines that the individual has already been tested

1 for hepatitis C, the individual is advised that the individual was already
2 tested for hepatitis C and may consequently be liable for any costs of
3 the test that are not covered by the individual's health benefits plan,
4 and the individual, voluntarily and in writing, requests or agrees to
5 undergo the screening test.

6 The bill requires the Commissioner of Health to evaluate the
7 impact of the bill with respect to the number of individuals who are
8 screened for hepatitis C and the number of individuals who access
9 follow-up care, and to submit a report of this evaluation to the
10 Governor and the Legislature no later than one year following the
11 effective date of the bill.

12 Nothing in the bill will affect the scope of practice of any health
13 care professional or diminish any authority or legal or professional
14 obligation of any health care professional to offer a hepatitis C
15 screening or diagnostic test, or to provide services or health care for an
16 individual who is subject to a hepatitis C test.

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

24 The bill will take effect on the first day of January next following
25 the date of enactment, and the provisions concerning the hepatitis C
26 screening requirements will expire and be deemed repealed on January
27 1 of the fifth year next following the date of enactment.

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