

**ASSEMBLY CONCURRENT
RESOLUTION No. 120**

STATE OF NEW JERSEY

219th LEGISLATURE

INTRODUCED FEBRUARY 20, 2020

Sponsored by:

Assemblyman GARY S. SCHAER

District 36 (Bergen and Passaic)

SYNOPSIS

Urges federal government to allow additional entities to retain pharmaceutical products beyond expiration date.

CURRENT VERSION OF TEXT

As introduced.



1 **A CONCURRENT RESOLUTION** urging the federal government to
2 allow additional entities to retain pharmaceutical products
3 beyond expiration date.
4

5 **WHEREAS**, The federal Food and Drug Administration (FDA) requires
6 that all pharmaceutical products include an expiration date, which is
7 intended to reflect the maximum period of time for which the
8 manufacturer guarantees the product will remain at least 90 percent
9 effective; and

10 **WHEREAS**, Manufacturers determine pharmaceutical expiration dates
11 using stability testing, which involves exposing the product to
12 extreme heat and moisture to determine how it degrades under
13 stress and over time; and

14 **WHEREAS**, Manufacturers submit a proposed expiration date to the
15 FDA, which will approve the date after confirming that it is
16 supported by the available data. Expiration dates are typically set at
17 one to five years after the date of manufacture; and

18 **WHEREAS**, Even after a pharmaceutical product is launched,
19 manufacturers continue to test the product to confirm that the
20 approved expiration date reflects a period during which the
21 medication continues to be at least 90 percent effective. However,
22 they do not currently evaluate whether expiration dates can be
23 extended; and

24 **WHEREAS**, Generally, federal law requires pharmacies, government
25 agencies, and other entities that maintain stockpiles of
26 pharmaceutical products to dispose of products that have reached
27 the labeled expiration date; and

28 **WHEREAS**, In 1986, as a cost-saving measure, the FDA and the
29 Department of Defense (DOD) created the Shelf Life Extension
30 Program to determine whether the expiration dates for various
31 drugs could be extended. At least one study conducted under the
32 program determined that approximately two-thirds of the 122 drugs
33 tested remained stable past the approved expiration date, and, on
34 average, these drugs remained at least 90 percent effective for more
35 than four years after the expiration date; and

36 **WHEREAS**, As a result of the study, a number of federal entities,
37 including the federal Centers for Disease Control and Prevention,
38 the Department of Veterans Affairs, and the military, are permitted
39 to retain stockpiles of certain medications beyond the approved
40 expiration date; and

41 **WHEREAS**, According to one estimate, retaining pharmaceutical
42 products beyond their expiration dates saves the federal government
43 between \$600 million and \$800 million per year. Moreover, one
44 DOD official reported that the Shelf Life Extension Program cost
45 the DOD approximately \$3.1 million to run in 2016, while netting
46 cost savings of \$2.1 billion, representing \$677 in savings for each
47 \$1 spent; and

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6 **WHEREAS**, Requiring pharmacies and other entities to dispose of
7 pharmaceutical supplies according to the labeled expiration date
8 results in wasted product, drives up the cost of doing business for
9 pharmacies, increases operational costs for law enforcement
10 agencies, emergency medical services providers, and local and
11 county health departments, and results in inflated prices that
12 adversely affect health insurers and consumers alike; and

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20 **BE IT RESOLVED** *by the General Assembly of the State of New*
21 *Jersey (the Senate concurring):*

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32 2. Copies of this resolution, as filed with the Secretary of State,
33 shall be transmitted by the Clerk of the General Assembly or the
34 Secretary of the Senate to the President and Vice President of the
35 United States, the Commissioner of Food and Drugs, the Majority
36 and Minority Leaders of the United States Senate, the Speaker and
37 Majority and Minority Leaders of the United States House of
38 Representatives, and each member of the United States Congress
39 elected from New Jersey.

44 This concurrent resolution respectfully urges the federal Food
45 and Drug Administration (FDA) and the Congress and President of
46 the United States to take appropriate measures to allow entities that
47 maintain stockpiles of pharmaceutical products to retain those
48 products beyond the expiration date under the same terms and

1 conditions as currently apply to various federal entities, including
2 the federal Centers for Disease Control and Prevention, the
3 Department of Veterans Affairs, and the military.

4 Currently, pharmaceutical manufacturers propose expiration
5 dates to the FDA that are intended to reflect the time period during
6 which the product will remain at least 90 percent effective; the FDA
7 approves these dates upon confirming they are supported by the
8 available data. Pharmacies, government agencies, emergency
9 medical response squads, county and local health departments, and
10 other entities that stockpile pharmaceutical products are required to
11 dispose of any products that have reached their expiration date.

12 In 1986, the FDA and the Department of Defense began the
13 Shelf Life Extension Program, which found that many
14 pharmaceutical products remain at least 90 percent effective for
15 several years past the labeled effective date. In light of this, the
16 federal government has allowed certain federal entities, including
17 the Centers for Disease Control and Prevention, the Department of
18 Veterans Affairs, and the military, to retain pharmaceutical products
19 beyond the labeled expiration date, resulting in significant cost
20 savings. However, this approval has not been extended to entities
21 outside the federal government, which are still required to dispose
22 of any product that has reached its expiration date. This results in
23 products that are still safe and effective for use being wasted, and
24 increases costs for pharmacies, consumers, insurers, and the various
25 entities that maintain pharmaceutical stockpiles.

26 Allowing additional entities to retain stockpiles of
27 pharmaceutical products beyond their expiration dates, consistent
28 with current studies and on the same terms as various federal
29 entities are authorized to do, would be a significant step in helping
30 realize cost savings in the pharmaceutical market, both within New
31 Jersey and throughout the nation.