SENATE DOCKET, NO. 2739 FILED ON: 8/25/2021

SENATE . . . . . No. 2537

The Commonwealth of Massachusetts

PRESENTED BY:

Patrick M. O'Connor

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to an insulin patient assistance program.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Patrick M. O'Connor	*Plymouth and Norfolk*

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By Mr. O'Connor, a petition (accompanied by bill, Senate, No. 2537) (subject to Joint Rule 12) of Patrick M. O'Connor for legislation relative to an insulin patient assistance program. Financial Services.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Second General Court
(2021-2022)

An Act relative to an insulin patient assistance program.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

Chapter 111N as appearing in the 2020 official edition is hereby amended by inserting at the end thereof the following new section:-

Section 9. MINIMUM STANDARDS FOR INSULIN PATIENT ASSISTANCE

(a) DEFINITIONS. For purposes of this section, the following definitions apply:

(1) MANUFACTURER. The term ‘manufacturer’ refers to a company engaged in the manufacture, sale, and marketing of insulin in the United States that is self-administered on an outpatient basis; and

(2) INSULIN PATIENT ASSISTANCE PROGRAM. The term ‘Insulin Patient Assistance Program’ or “PAP’ means assistance in the form of insulin free of charge for a specified duration provided by a manufacturer to an eligible individual, as more specifically set forth in Section (b)(2)(D), for example directly to an eligible individual’s licensed practitioner

for dispensing, to an eligible individual through a single-use card that can be used at a pharmacy when accompanied with a prescription, or any other similar means.

(b) MINIMUM STANDARDS FOR INSULIN PATIENT ASSISTANCE. Each manufacturer with a Medicaid drug rebate agreement under 42 U.S.C. 1396r–8 shall ensure their patient assistance offerings for insulin operate in accordance with this Section:

(1) ACCESS TO URGENTLY NEEDED INSULIN. Each manufacturer shall ensure that there exists an option as part of its insulin patient assistance offerings for individuals who urgently need insulin and are at risk of rationing to obtain a one-time annually, 30-day supply of insulin at no cost, provided they have a prescription and attest to financial need in writing. For the purposes of this subsection, the term 'urgently needed insulin' means having readily available for use less than a seven-day supply of insulin, and thus, likelihood of rationing because will not be able to obtain insulin without grant of this urgent need offering. Manufacturers may implement processes to provide urgently needed insulin to patients, for example through a single use voucher that is redeemable at any retail pharmacy with a prescription.

(2) ADMINISTRATION OF INSULIN PATIENT ASSISTANCE PROGRAM (PAP). Each manufacturer of insulin shall establish procedures to ensure that participation in its manufacturer-administered Insulin PAP is available to individuals who satisfy manufacturer-defined eligibility criteria consistent with the requirements below. These procedures shall include, at a minimum:

(A) Making freely available an application form for the manufacturer's insulin PAP on the manufacturer's website or a website specific to the insulin PAP;

(B) Following receipt of the application, in a reasonable timeframe, issuing a written notice to the individual disclosing that the manufacturer has determined that the individual is eligible, ineligible, or that more information is needed for determination of eligibility;

(C) Upon determination that an individual is eligible for the Insulin PAP, the manufacturer will enroll such individual for 12 months from the date the manufacturer issued a notice of eligibility unless the individual acquires government sponsored health insurance at any time during the 12 month term; and

(D) Considering an individual eligible if he or she:

(i) Is a U.S. citizen or legal resident;

(ii) Has a family income that is equal to or less than 400 percent of the federal poverty guidelines;

(iii) Does not have private prescription drug coverage such as an HMO or PPO; and

(iv) Is not eligible to receive prescription drug benefits through a federally funded program or through the Department of Veterans Affairs, except that an individual who is enrolled in Medicare Part D may be eligible for a manufacturer's insulin patient assistance program if they meet all other eligibility requirements and agree to all applicable manufacturer-set program terms and conditions.

(c) PENALTY. If a manufacturer fails to comply with this section, an administrative penalty of $10,000.00 per month of noncompliance will apply. Manufacturers may appeal penalties for non-compliance through an administrative review process. This chapter shall be enforced by the Department of Public Health.

(d) EFFECTIVE DATE. This section is effective upon enactment.