

HOUSE No. 3481

The Commonwealth of Massachusetts

PRESENTED BY:

Edward F. Coppinger

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 to ensure the fair, transparent and patient-focused use of health technology assessments by the Commonwealth.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Edward F. Coppinger</i>	<i>10th Suffolk</i>	<i>1/15/2019</i>
<i>Paul McMurtry</i>	<i>11th Norfolk</i>	<i>1/31/2019</i>
<i>José F. Tosado</i>	<i>9th Hampden</i>	<i>2/1/2019</i>

HOUSE No. 3481

By Mr. Coppinger of Boston, a petition (accompanied by bill, House, No. 3481) of Edward F. Coppinger, Paul McMurtry and José F. Tosado relative to the use of health technology assessments. Public Health.

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-First General Court
(2019-2020)**

An Act to ensure the fair, transparent and patient-focused use of health technology assessments by the Commonwealth.

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

1 SECTION 1. Chapter 118E of the General Laws is hereby amended by inserting after
2 section 12 the following section:

3 Section 12A. (a) As used in this section, the following words shall have the following
4 meanings unless the context clearly requires otherwise:

5 “Executive office” means the executive office of health and human services.

6 “External expert” means an individual who possesses scientific or medical training that
7 the executive office lacks with respect to a disease or therapeutic area that is the subject of a
8 health technology assessment.

9 “Health technology assessment” means any third-party evaluation of the clinical,
10 economic or public health value of medical innovations, including prescription drugs.

11 “Prescription Drug” means a drug as defined in 21 U.S.C. section 321(g)(1) and approved
12 by the Federal Food and Drug Administration for the treatment of disease in humans.

13 “Rare disease” means any disease that affects fewer than 200,000 people in the United
14 States, which has status as an "orphan" disease for research purposes, or is known to be
15 substantially underdiagnosed and unrecognized as a result of lack of adequate diagnostic and
16 research information.

17 (b) The executive office shall not rely in whole or in part on any health technology
18 assessment to support any negotiations for supplemental rebate agreements with respect to any
19 prescription drug (1) if the third party conducting such health technology assessment has within
20 twenty-four months prior to the completion of the health technology assessment received (i) any
21 funding or other support from any health insurance company, pharmaceutical manufacturing
22 company or pharmacy benefit manager or (ii) more than fifty percent of its total funding from
23 any one source or (2) if the health technology assessment was not conducted and completed
24 independently and free from any collaboration with or influence by the executive office or any
25 other agency, department, board or commission of the commonwealth.

26 (c) The executive office shall disclose whether it has relied on any health technology
27 assessment in whole or in part as support for supplemental rebate agreement negotiations with
28 respect to a prescription drug thirty days after the commencement of such negotiations through
29 publication on the executive office’s website. Such publication shall include:

- 30 (1) the identity of the third party that conducted the health technology assessment;
- 31 (2) a complete list of the governance and advisory board members of such third party;

32 (3) a complete list of all of the third party's sources of funding and funding amounts
33 from each such source;

34 (4) the identity of the prescription drug that is the subject of supplemental rebate
35 agreement negotiations;

36 (5) a summary of all reports, records, methodologies, data and all other documents
37 relied upon by the third party in support of the health technology assessment;

38 (6) a summary of all feedback and other contributions solicited or received by the
39 third party in support of the health technology assessment, including any such feedback and
40 contributions provided by the manufacturer of the prescription drug that is the subject of the
41 health technology assessment to the extent that the manufacturer permits the public disclosure of
42 such information or documentation, and the methodology by which such feedback or other
43 contributions were incorporated, calculated or quantified; and

44 (7) the identity of any external experts consulted by the third party in support of the
45 health technology assessment and a summary of any expert reports or other information
46 produced by such experts relative to the health technology assessment.

47 (d) The executive office shall provide advance notice to any manufacturer of a
48 prescription drug that is the subject of any health technology assessment on which the executive
49 office intends to rely in whole or in part in support of supplemental rebate agreement
50 negotiations. Such notice shall be confidential and not a public record under clause twenty-sixth
51 of section 7 of chapter 4 or under chapter 66, and shall be delivered in writing no later than forty-
52 five days prior to the commencement of such negotiations. Such notice shall identify with
53 reasonable detail the health technology assessment on which the executive office intends to rely.

54 To the extent that such health technology assessment incorporates any non-public model or
55 methodologies, such notice shall provide that documents describing such non-public model or
56 methodologies shall be disclosed in reasonable detail to the manufacturer no later than ten days
57 after a request for such documents is made.

58 (e) The executive office shall not rely in whole or in part on any health technology
59 assessment in support of any supplemental rebate agreement negotiations with respect to any
60 prescription drug unless such health technology assessment is:

61 (1) supported by meaningful input from patients and caregivers affected by the
62 condition or disease being studied, and any other input or variables that should reasonably be
63 considered in connection with a fair and balanced health technology assessment, including
64 without limitation caregiver burden, the value of treating patients with unmet medical needs, the
65 severity of the disease being studied, and any other non-health related issues including but not
66 limited to societal impact;

67 (2) supported by meaningful input from external experts on the following topics,
68 without limitation: (i) the impact of particular coverage, cost-sharing, tiering, utilization
69 management, prior authorization, medication therapy management, or other utilization
70 management policies on adherence by patients to the prescription drug, and on access to the
71 prescription drug; (ii) the demographics and the clinical description of patient populations treated
72 by the prescription drug; and (iii) to the extent the prescription drug is approved for the treatment
73 of a rare disease, the severity of and the unmet medical need associated with the rare disease, the
74 benefits and risks of the prescription drug as a treatment for the rare disease, and factors that may

75 be limiting access by patients requiring treatment from or consultation with a rare disease
76 specialist; and

77 (3) validated in writing by third parties unrelated to the third party that conducted the
78 health technology assessment, including without limitation external experts and academics and
79 physicians with knowledge of and expertise in the disease area being studied.

80 (f) Nothing in this section shall be construed to authorize the executive office to deny
81 access by any Medicaid recipient to any prescription drug that is covered under a Medicaid drug
82 rebate agreement.