COMMONWEALTH OF MASSACHUSETTS
Office of Consumer Affairs and Business Regulation
DIVISION OF INSURANCE
One Federal Street, Suite 700 • Boston, MA 02110
(617) 521-7794 • Toll-free (877) 563-4467
http://www.mass.gov/doi

MAURA T. HEALEY
GOVERNOR

KIMBERLEY DRISCOLL
LIEUTENANT GOVERNOR

MICHAEL T. CALJOUW
COMMISSIONER OF INSURANCE

FILING GUIDANCE NOTICE 2025-E

TO: Commercial Health Insurers; Blue Cross Blue Shield of Massachusetts, Inc.; and Health Maintenance Organizations Offering or Renewing Insured Health Products in Massachusetts ("Carriers") subject to M.G.L. c. 176O

FROM: Kevin P. Beagan, Deputy Commissioner, Health Care Access Bureau

DATE: March 4, 2025

RE: Prescription Benefits for Chronic Conditions Pursuant to Sections 32-36 of Chapter 342 of the Acts of 2024

The Division of Insurance ("Division") distributes this Filing Guidance Notice 2025-E to inform insured health carriers ("Carriers") regarding the filing requirements associated with Chapter 342 of the Acts of 2024 ("Chapter 342"), which amends Massachusetts laws to add M.G.L. c. 175, §47CCC; M.G.L. c. 176A, §8DDD; M.G.L. c. 176B, §4DDD; M.G.L. c. 176G, §4VV, and M.G.L. c. 176O, §30. The new sections establish new requirements for prescription drug coverage in insured health benefit plans issued or renewed within or without Massachusetts. As noted in Section 39 of Chapter 342, these provisions are effective for all insured health plan contracts entered into or renewed on or after July 1, 2025.

Prescription Drug Coverage

Within Chapter 342, the following terms are as defined as follows:

"Brand name drug", a drug that is: (i) produced or distributed pursuant to an original new drug application approved under 21 U.S.C. 355(c) except for:

(A) any drug approved through an application submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that is pharmaceutically equivalent, as that term is defined by the United States Food and Drug Administration, to a drug approved under 21 U.S.C. 355(c);

(B) an abbreviated new drug application that was approved by the United States Secretary of Health and Human Services under section 505(c) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the date of the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585; or

(C) an authorized generic drug as defined in 42 C.F.R. 447.502;

(ii) produced or distributed pursuant to a biologics license application approved under 42 U.S.C. 262(a)(2)(C); or

(iii) identified by the health benefit plan as a brand name drug based on available data resources, including Medi-Span.

"Generic drug", a retail drug that is: (i) marketed or distributed pursuant to an abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic drug as defined in 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962 and was not originally marketed under a new drug application; or (iv) identified by the health benefit plan as a generic drug based on available data resources, including Medi-Span.

Insured health benefit plans issued, delivered, or renewed in Massachusetts "shall identify 1 generic drug and 1 brand name drug [where available] used to treat each of the following chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 2 most prevalent heart conditions among its enrollees." It is also noted that the Carrier "shall identify insulin as the drug used to treat diabetes. In determining the 1 generic drug and 1 brand name drug used to treat each chronic condition, the "carrier shall consider whether the drug is:

(i) of clear benefit and strongly supported by clinical evidence to be cost-effective;
(ii) likely to:
  (A) reduce hospitalizations or emergency department visits;
  (B) reduce future exacerbations of illness progression; or
  (C) improve quality of life;
(iii) cost effective for the carrier and its enrollees;
(iv) at low risk for overutilization, abuse, addiction, diversion or fraud; and
(v) one of the most widely utilized as a treatment for the chronic condition."

When making the determination of the generic and the brand name drug, Carriers may make changes in its selection of these drugs not more than annually, except that, in the instances where a drug is taken off the market by the drug manufacturer or if the price is substantially changed by the drug manufacturer, a Carrier may notify the Division in writing of a material change, which the Division will then review. Carriers are expected to publicly identify all drugs selected as generic and brand-name drugs.

It is further noted that "[c]overage for the identified generic drugs [for chronic conditions] shall not be subject to cost-sharing, including co-payments and co-insurance and shall not be subject to any deductible; provided, however, that cost-sharing shall be required if the applicable plan is governed by the Internal Revenue Code and would lose its tax-exempt status as a result of the prohibition on cost-sharing under this section. Coverage for identified brand name drugs [for chronic conditions] shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply. Coverage for 1 brand name insulin drug per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting and premixed under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply."

It is further noted that, for plans subject to M.G.L. c. 176O, "On an annual basis, each carrier shall report to the division the drugs selected to be provided for chronic conditions with no or limited cost-sharing…[and t]he commissioner shall review the drugs to verify that the selected drugs meet the criteria identified in those sections…[and s]hould a selected drug be deemed by the commissioner to not meet the criteria, the commissioner may require a different drug to be

selected…[and t]he commissioner shall disclose the list of drugs selected by each entity annually on the division's website."

Filing Requirements

As required under 211 CMR 52.05(7), Carriers are to submit material change materials - including the Carrier's Evidence of Coverage as described in 211 CMR 52.05(4)(i) and the list of each prescription drugs selected to be provided for the statutory chronic conditions with no or limited cost-sharing - that are to be part of insured health coverage offered or renewed in Massachusetts. Please forward all form filings to update the Evidence of Coverage on file and the list of prescription drugs, using SERFF (the System for Electronic Rate and Form Filing), with the SERFF Project Name: Chapter 342 of the Acts of 2024.

Carriers are expected to review requests for the required services according to the medically necessary requirements identified in M.G.L. c. 176O and 211 CMR 52.00, including required review of utilization requests within statutory timeframes, notification of all utilization review decisions, and notification to members regarding their rights to internal and external appeals when there has been an adverse determination of a request for services. In order to comply with 211 CMR 52.05(7) for utilization management systems, please forward a signed certification via SERFF that the Carrier will continue to comply with utilization management procedures for the review of prescription services subject to Chapter 342 in accordance with M.G.L. c. 176O and 211 CMR 52.00.

As noted in 211 CMR 52.13(6), Carriers are required to provide "to at least one adult Insured in each household residing in Massachusetts, or in the case of a group policy, to the group representative, notice of all Material Changes to the Evidence of Coverage." Carriers are also required to describe all continuation of coverage provisions for the drugs selected to be provided for chronic conditions with no or limited cost-sharing. In order to comply with 211 CMR 52.05(7) material change requirements regarding continuation of coverage, Carriers should forward via SERFF the document that will be used to explain continuation of coverage provisions for chronic care prescription services when an individual newly enrolls in the Carrier.

If you have any questions about Filing Guidance Notice 2025-E, please contact Niels Puetthoff at Niels.Puetthoff@mass.gov.