SB0357/443427/1

BY: Finance Committee

AMENDMENT TO SENATE BILL 357
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike "**and Feldman**" and substitute "**, Feldman , and Hester**"; in line 2, strike "**for Upper Payment Limits**" and substitute "**and Stakeholder Council Membership**"; in line 4, after "of" insert "altering the membership of the Prescription Drug Affordability Stakeholder Council;"; in line 5, strike "all"; and in line 10, after "Board;" insert "requiring the Board to confer with the Maryland Medical Assistance Program before establishing an upper payment limit that applies to the Program;"; in line 14, after "21–2C–01," insert "21–2C–04,"; in line 19, after "Section" insert "21–2C–09(c) and"; and after line 21, insert:

"BY adding to
Article - Health - General
Section 21-2C-09(d) and (e) and 21-2C-16
Annotated Code of Maryland
(2023 Replacement Volume and 2024 Supplement)".

On pages 1 and 2, strike in their entirety the lines beginning with line 27 on page 1 through line 4 on page 2, inclusive.

AMENDMENT NO. 2

On page 3, after line 10, insert:

"21–2C–04.

(a) There is a Prescription Drug Affordability Stakeholder Council.

(b) The purpose of the Stakeholder Council is to provide stakeholder input to assist the Board in making decisions as required under this subtitle.

(c) (1) The Stakeholder Council consists of **[**26**]** members appointed in accordance with this subsection.

(2) The Speaker of the House of Delegates shall appoint:

(i) One representative of generic drug corporations;

(ii) One representative of nonprofit insurance carriers;

(iii) One representative of a statewide health care advocacy coalition;

(iv) One representative of a statewide advocacy organization for seniors;

(v) One representative of a statewide organization for diverse communities;

(vi) One representative of a labor union;

(vii) **ONE REPRESENTATIVE OF THE RARE DISEASE COMMUNITY;**

(VIII) One health services researcher specializing in prescription drugs; and

[(viii)**]** **(IX)** One public member at the discretion of the Speaker of the House of Delegates.

(3) The President of the Senate shall appoint:

(i) One representative of brand name drug corporations;

(ii) One representative of physicians;

(iii) One representative of nurses;

(iv) One representative of hospitals;

(v) One representative of dentists;

(vi) **ONE REPRESENTATIVE OF ONCOLOGISTS;**

(VII) One representative of managed care organizations;

[(vii)**] (VIII)** One representative of the Department of Budget and Management;

[(viii)**] (IX)** One clinical researcher; and

[(ix)**] (X)** One public member at the discretion of the President of the Senate.

(4) The Governor shall appoint:

(i) One representative of brand name drug corporations;

(ii) One representative of generic drug corporations;

(iii) One representative of biotechnology companies;

(iv) One representative of for–profit health insurance carriers;

(v) One representative of employers;

(vi) One representative of pharmacy benefits managers;

(vii) One representative of pharmacists;

(viii) One pharmacologist; **[**and**]**

(ix) **ONE REPRESENTATIVE OF A PATIENT ADVOCACY ORGANIZATION; AND**

(X) One public member at the discretion of the Governor.

(5) Collectively, the members of the Stakeholder Council shall have knowledge of the following:

(i) The pharmaceutical business model;

(ii) Supply chain business models;

(iii) The practice of medicine or clinical training;

(iv) Consumer or patient perspectives;

(v) Health care costs trends and drivers;

(vi) Clinical and health services research; or

(vii) The State's health care marketplace.

(6) To the extent practicable and consistent with federal and State law, the membership of the Stakeholder Council shall reflect the racial, ethnic, and gender diversity of the State.

(7) From among the membership of the Stakeholder Council, the Board chair shall appoint two members to be cochairs of the Stakeholder Council.

(d) (1) The term of a member is 3 years.

(2) The initial members of the Stakeholder Council shall serve staggered terms as required by the terms provided for members on October 1, 2019.

(e) A member of the Stakeholder Council:

(1) May not receive compensation as a member of the Stakeholder Council; but

(2) Is entitled to reimbursement for expenses under the Standard State Travel Regulations, as provided in the State budget.

21–2C–09.

(c) On or before December 31, 2020, and each December 31 thereafter, the Board shall submit to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2–1257 of the State Government Article, a report that includes:

(1) Price trends for prescription drug products;

(2) The number of prescription drug products that were subject to Board review and the results of the review; and

(3) Any recommendations the Board may have on further legislation needed to make prescription drug products more affordable in the State.

(D) IF THE BOARD SETS A NEW UPPER PAYMENT LIMIT, THE BOARD SHALL INCLUDE IN THE FIRST REPORT THAT IS REQUIRED UNDER SUBSECTION (C) OF THIS SECTION AFTER THE UPPER PAYMENT LIMIT HAS BEEN IN EFFECT

FOR 1 YEAR INFORMATION ON THE EFFECTS OF THE UPPER PAYMENT LIMIT, BASED ON AVAILABLE TIMELY DATA, FOR THE FOLLOWING:

(1) PATIENT OUT-OF-POCKET COSTS INCLUDING WHETHER THE UPPER PAYMENT LIMIT WAS ASSOCIATED WITH INCREASES OR DECREASES IN WHAT PATIENTS PAY FOR PRESCRIPTION DRUG PRODUCTS;

(2) PATIENT HEALTH INSURANCE PREMIUMS, INCLUDING WHETHER THE UPPER PAYMENT LIMIT IS ASSOCIATED WITH INCREASES OR DECREASES IN HEALTH INSURANCE COSTS FOR PATIENTS;

(3) PHARMACIES OPERATING IN THE STATE, INCLUDING THE IMPACT ON REIMBURSEMENT RATES AND FINANCIAL VIABILITY OF RETAIL AND INDEPENDENT PHARMACIES;

(4) PATIENT HEALTH INSURANCE FORMULARIES, INCLUDING WHETHER THE PRESCRIPTION DRUG PRODUCT SUBJECT TO THE UPPER PAYMENT LIMIT REMAINED ON FORMULARIES;

(5) PROVIDER–ADMINISTERED MEDICATIONS SUBJECT TO THE UPPER PAYMENT LIMIT, INCLUDING WHETHER PROVIDERS WERE ABLE TO ACQUIRE THE PRESCRIPTION DRUG PRODUCT SUBJECT TO THE UPPER PAYMENT LIMIT AT A RATE TO ACCOUNT FOR ACQUISITION COSTS AND WHETHER THERE WAS AN IMPACT ON PROVIDER REIMBURSEMENT;

(6) PATIENT ACCESS TO THE PRESCRIPTION DRUG PRODUCT SUBJECT TO THE UPPER PAYMENT LIMIT, WHICH MAY INCLUDE:

(I) WHETHER PRESCRIPTION DRUG PRODUCT SHORTAGES OR OTHER SUPPLY DISRUPTIONS OCCURRED AFTER THE UPPER PAYMENT LIMIT TOOK EFFECT;

(II) WHETHER FORMULARY PLACEMENT OR PLAN DESIGN CHANGES MADE THE PRESCRIPTION DRUG PRODUCT SUBJECT TO THE UPPER LIMIT MORE DIFFICULT FOR PATIENTS TO ACCESS, INCLUDING IF INSURANCE

PLANS PREFERRED A PRESCRIPTION DRUG PRODUCT WITHOUT AN UPPER PAYMENT LIMIT OVER A PRESCRIPTION DRUG PRODUCT SUBJECT TO AN UPPER PAYMENT LIMIT;

(III) WHETHER THE DISTRIBUTION AND DELIVERY OF SPECIALTY OR RARE DISEASE MEDICATIONS FROM OUT-OF-STATE PHARMACIES TO PROVIDERS, PHARMACIES, OR PATIENTS WAS IMPACTED;

(IV) WHETHER PATIENTS IN COMMUNITIES OF COLOR, PATIENTS WHO ARE WOMEN, PATIENTS WITH A RARE DISEASE, OR PATIENTS IN RURAL AREAS EXPERIENCED DISPROPORTIONATE ACCESS CHALLENGES; AND

(V) WHETHER COST DIFFERENCES AS A RESULT OF THE UPPER PAYMENT LIMIT AFFECTED PATIENTS, PHARMACIES, OR PROVIDERS AND, IF THE COST DIFFERENCE RESULTED IN AN INCREASE IN COSTS, WHO WAS ULTIMATELY RESPONSIBLE FOR BEARING THE INCREASED COST;

(7) COVERED ENTITY PROVIDERS PARTICIPATING IN THE 340B DRUG DISCOUNT PROGRAM, INCLUDING THE IMPACT OF THE UPPER PAYMENT LIMIT ON THE OPERATIONS OF THE PROVIDERS AND THEIR CONTRACTED PHARMACIES; AND

(8) THE BIOTECHNOLOGY INDUSTRY IN THE STATE, INCLUDING THE IMPACT ON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, INVESTMENT, AND JOB GROWTH.

(E) (1) THE BOARD MAY REQUEST INFORMATION NECESSARY TO COMPLETE THE REPORT REQUIRED UNDER SUBSECTIONS (C) AND (D) OF THIS SECTION FROM AN AFFECTED ENTITY.

(2) THE ENTITY FROM WHICH INFORMATION WAS REQUESTED UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL MAKE A GOOD FAITH EFFORT TO PROVIDE THE REQUESTED INFORMATION.";

and in line 29, after "**DRUGS**" insert "**;**

(4) FOR AN UPPER PAYMENT LIMIT ON A DRUG THAT IS DESIGNATED AS A DRUG FOR A RARE DISEASE OR CONDITION, THE IMPACT OF THE UPPER PAYMENT LIMIT ON PATIENTS WITH RARE DISEASES".

On page 4, in line 1, strike "**(4)**" and substitute "**(5)**".

On page 6, in line 21, strike "**ALL**".

On page 7, in lines 4 and 18, in each instance, strike "**ALL**"; after line 12, insert:

"**(3) BEFORE ESTABLISHING AN UPPER PAYMENT LIMIT THAT APPLIES TO THE MARYLAND MEDICAL ASSISTANCE PROGRAM, THE BOARD SHALL CONFER WITH THE MARYLAND MEDICAL ASSISTANCE PROGRAM TO APPROVE THE APPLICATION OF THE UPPER PAYMENT LIMIT BY ASSESSING WHETHER THE PROPOSED UPPER PAYMENT LIMIT WILL:**

(I) CONFLICT WITH THE MEDICAID DRUG REBATES PROGRAM, THE COVERED OUTPATIENT DRUG RULE (CMS–2345–FC), OR ANY OTHER FEDERAL REQUIREMENTS AS APPLICABLE; AND

(II) REQUIRE ADDITIONAL FUNDING TO BE ALLOCATED TO THE MARYLAND MEDICAL ASSISTANCE PROGRAM BUDGET.";

in line 17, after "**(C)**" insert "**(1)**"; in the same line, strike "**IF**" and substitute "**SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, IF**"; after line 20, insert:

"**(2) THIS SUBSECTION DOES NOT APPLY WITH RESPECT TO:**

(I) PAYOR REIMBURSEMENTS UNDER MEDICARE PART C AND D PLANS;

(II) PURCHASES UNDER THE FEDERAL 340B DRUG PRICING PROGRAM; AND

(III) PURCHASES AND PAYOR REIMBURSEMENTS UNDER FEDERAL PROGRAMS THAT ARE PREEMPTED BY FEDERAL LAW INCLUDING:

1. THE DEPARTMENT OF DEFENSE;

2. THE DEPARTMENT OF VETERANS AFFAIRS;

3. THE PUBLIC HEALTH SERVICE;

4. THE UNITED STATES COAST GUARD;

5. TRICARE;

6. THE FEDERAL EMPLOYEES HEALTH BENEFIT PLAN; AND

7. ANY OTHER EXCLUSIVE FEDERAL PROGRAM AS APPLICABLE.";

and in line 30, strike "September 31" and substitute "September 30".

On page 8, in line 2, strike "December 31" and substitute "September 30".