C3, J1 EMERGENCY BILL

0 lr 1574

By: Delegates Kipke, Adams, Anderton, Arikan, Chisholm, Clark, Hornberger, Krebs, Malone, McComas, Metzgar, Morgan, Reilly, Saab, and Szeliga

Introduced and read first time: January 29, 2020 Assigned to: Health and Government Operations

A BILL ENTITLED

| 1 | AN ACT concerning | | |
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Maryland Medical Assistance Program and Health Insurance – Specialty Drugs
 Definition

- 4 FOR the purpose of prohibiting the Secretary of Health from considering certain drugs to be specialty drugs for the purpose of providing services under the Maryland Medical 5 6 Assistance Program; excluding prescription drugs prescribed to treat certain medical conditions from the definition of "specialty drug" for the purposes of certain 7 8 provisions of law limiting the authority of certain insurers, nonprofit health service 9 plans, and health maintenance organizations to impose copayment and coinsurance 10 requirements; making conforming changes; providing for the application of this Act; 11 making this Act an emergency measure; and generally relating to specialty drugs.
- 12 BY repealing and reenacting, without amendments,
- 13 Article Health General
- 14 Section 15–101(a) and (h)
- 15 Annotated Code of Maryland
- 16 (2019 Replacement Volume)
- 17 BY adding to
- 18 Article Health General
- 19 Section 15–118.1
- 20 Annotated Code of Maryland
- 21 (2019 Replacement Volume)
- 22 BY repealing and reenacting, with amendments,
- 23 Article Insurance
- 24 Section 15–847
- 25 Annotated Code of Maryland
- 26 (2017 Replacement Volume and 2019 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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(4)

(i)

| $1\\2$ | SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows: | | | | |
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| 3 | Article – Health – General | | | | |
| 4 | 15–101. | | | | |
| 5 | (a) In | n this title | the fol | llowing words have the meanings indicated. | |
| 6 | (h) " | "Program" means the Maryland Medical Assistance Program. | | | |
| 7 | 15–118.1. | | | | |
| 8 9 10 | DIABETES, H | HIV, OR | AIDS | Y NOT CONSIDER DRUGS PRESCRIBED TO TREAT TO BE SPECIALTY DRUGS FOR THE PURPOSE OF R THE PROGRAM. | |
| 11 | | | | Article – Insurance | |
| 12 | 15–847. | | | | |
| 13 | (a) (i | 1) In th | is secti | on the following words have the meanings indicated. | |
| 14 15 | (2 behavioral, or | 2) (i) developme | | aplex or chronic medical condition" means a physical, condition that: | |
| 16 | | | 1. | may have no known cure; | |
| 17 | | | 2. | is progressive; or | |
| 18 19 | undertreated. | | 3. | can be debilitating or fatal if left untreated or | |
| 20 | | (ii) | "Com | plex or chronic medical condition" includes: | |
| 21 | | | 1. | multiple sclerosis; | |
| 22 | | | 2. | hepatitis C; and | |
| 23 | | | 3. | rheumatoid arthritis. | |
| 24 25 26 27 | that an insure to review and | r, a nonpro | ofit hea orize d | care system" means a system of cost containment methods alth service plan, or a health maintenance organization uses rugs prescribed by a health care provider for a covered a quality, and claims. | |

"Rare medical condition" means a disease or condition that

| 1 | affects fewer than: | | | |
|----------------|--|---------------------------|---|--|
| 2 | | 1. | 200,000 individuals in the United States; or | |
| 3 | | 2. | approximately 1 in 1,500 individuals worldwide. | |
| 4 | (ii) | "Rare | e medical condition" includes: | |
| 5 | | 1. | cystic fibrosis; | |
| 6 | | 2. | hemophilia; and | |
| 7 | | 3. | multiple myeloma. | |
| 8 | (5) (I) | "Spec | cialty drug" means a prescription drug that: | |
| 9 10 | [(i)] medical condition or a r | 1. are med | is prescribed for an individual with a complex or chronic dical condition; | |
| 11 | [(ii)] | 2. | costs \$600 or more for up to a 30-day supply; | |
| 12 | [(iii) |] 3. | is not typically stocked at retail pharmacies; and | |
| 13 14 15 | [(iv) delivery to the patient the drug; or | _ | 4. A. requires a difficult or unusual process of oreparation, handling, storage, inventory, or distribution of | |
| 16 17 18 | or support, beyond thos of the drug. | [2.] I e requir | 3. requires enhanced patient education, management, red for traditional dispensing, before or after administration | |
| 19 20 | (II) DRUG PRESCRIBED TO | | ECIALTY DRUG" DOES NOT INCLUDE A PRESCRIPTION T DIABETES, HIV, OR AIDS. | |
| 21 | (b) This section | n applie | es to: | |
| 22 23 24 | (1) insurers and nonprofit health service plans that provide coverage for prescription drugs under individual, group, or blanket health insurance policies or contracts that are issued or delivered in the State; and | | | |
| 25 26 27 | (2) head prescription drugs under State. | | aintenance organizations that provide coverage for idual or group contracts that are issued or delivered in the | |
| 28 | (c) (1) Sub | ject to j | paragraph (2) of this subsection, an entity subject to this | |

section may not impose a copayment or coinsurance requirement on a covered specialty

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1 drug that exceeds \$150 for up to a 30-day supply of the specialty drug.

- (2) On July 1 of each year, the limit on the copayment or coinsurance requirement on a covered specialty drug shall increase by a percentage equal to the percentage change from the preceding year in the medical care component of the March Consumer Price Index for All Urban Consumers, Washington Metropolitan Area, from the U.S. Department of Labor, Bureau of Labor Statistics.
- 7 (d) Subject to § 15–805 of this subtitle and notwithstanding § 15–806 of this 8 subtitle, nothing in this article or regulations adopted under this article precludes an entity 9 subject to this section from requiring a covered specialty drug to be obtained through:
- 10 (1) a designated pharmacy or other source authorized under the Health Occupations Article to dispense or administer prescription drugs; or
- 12 (2) a pharmacy participating in the entity's provider network, if the entity 13 determines that the pharmacy:
- (i) meets the entity's performance standards; and
- 15 (ii) accepts the entity's network reimbursement rates.
- 16 (e) (1) A pharmacy registered under § 340B of the federal Public Health
 17 Services Act may apply to an entity subject to this section to be a designated pharmacy
 18 under subsection (d)(1) of this section for the purpose of enabling the pharmacy's patients
 19 with [HIV, AIDS, or] hepatitis C to receive the copayment or coinsurance maximum
 20 provided for in subsection (c) of this section if:
- 21 (i) the pharmacy is owned by a federally qualified health center, as 22 defined in 42 U.S.C. § 254B;
- 23 (ii) the federally qualified health center provides integrated and 24 coordinated medical and pharmaceutical services to [HIV positive, AIDS, and] hepatitis C 25 patients; and
- 26 (iii) the prescription drugs are covered specialty drugs for the 27 treatment of [HIV, AIDS, or] hepatitis C.
- 28 (2) An entity subject to this section may not unreasonably withhold 29 approval of a pharmacy's application under paragraph (1) of this subsection.
- 30 (f) An entity subject to this section may provide coverage for specialty drugs 31 through a managed care system.
- 32 (g) (1) A determination by an entity subject to this section that a prescription 33 drug is not a specialty drug is considered a coverage decision under § 15–10D–01 of this 34 title.

| $\frac{1}{2}$ | (2) For complaints filed with the Commissioner under this subsection, if the entity made its determination that a prescription drug is not a specialty drug on the | | | | | |
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| 3 | basis that the prescription drug did not meet the criteria listed in subsection (a)(5)(i) of this | | | | | |
| 4 | section: | | | | | |
| 5 | (i) the Commissioner may seek advice from an independent review | | | | | |
| 6 | organization or medical expert on the list compiled under § 15–10A–05(b) of this title; and | | | | | |
| 7 | (ii) the expenses for any advice provided by an independent review | | | | | |
| 8 | organization or medical expert shall be paid for as provided under § 15–10A–05(h) of this | | | | | |
| 9 | title. | | | | | |
| 10 | SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all | | | | | |
| 11 | policies, contracts, and health benefit plans issued, delivered, amended, or renewed in the | | | | | |
| $\overline{12}$ | State on or after the effective date of this Act. | | | | | |
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| 13 | SECTION 3. AND BE IT FURTHER ENACTED, That this Act is an emergency | | | | | |

measure, is necessary for the immediate preservation of the public health or safety, has

been passed by a yea and nay vote supported by three—fifths of all the members elected to each of the two Houses of the General Assembly, and shall take effect from the date it is

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enacted.