First Regular Session Seventy-fourth General Assembly STATE OF COLORADO

REVISED

This Version Includes All Amendments Adopted on Second Reading in the Second House

LLS NO. 23-0428.01 Kristen Forrestal x4217

HOUSE BILL 23-1002

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A BILL FOR AN ACT

101 CONCERNING THE AFFORDABILITY OF EPINEPHRINE AUTO-INJECTORS, 102 AND, IN CONNECTION THEREWITH, MAKING AN APPROPRIATION.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at http://leg.colorado.gov.)

Effective January 1, 2024, the bill creates an epinephrine auto-injector affordability program (program) to provide low-cost epinephrine auto-injectors to individuals who:

- Are residents of this state;
- Are not enrolled in the state medicaid program or the federal medicare program;

SENATE Amended 2nd Reading April 20, 2023

> HOUSE ord Reading Unamended March 8, 2023

HOUSE Amended 2nd Reading March 7, 2023

Shading denotes HOUSE amendment. <u>Double underlining denotes SENATE amendment.</u>

Capital letters or bold & italic numbers indicate new material to be added to existing law.

Dashes through the words or numbers indicate deletions from existing law.

- Have a prescription for an epinephrine auto-injector; and
- Are not enrolled in prescription drug coverage that limits the total amount of cost sharing that the enrollee is required to pay for an epinephrine auto-injector.

The bill requires the division of insurance in the department of regulatory agencies (division) to create an application for the program and requires the division and the department of health care policy and financing to make the application available on their websites and to promote the availability of the program.

The bill requires a carrier that provides coverage for prescription epinephrine auto-injectors to cap the total amount that a covered person is required to pay for all covered prescription epinephrine auto-injectors at an amount not to exceed \$60 for a 2-pack of epinephrine auto-injectors.

A pharmacy that dispenses epinephrine auto-injectors is authorized to collect a copayment not to exceed \$60 from the individual to cover the pharmacy's costs of processing and dispensing a 2-pack of epinephrine auto-injectors.

A manufacturer of epinephrine auto-injectors:

- Is required to make epinephrine auto-injectors available to individuals through the program; and
- May be required to reimburse the dispensing pharmacy an amount that covers the difference between the pharmacy's wholesale acquisition cost for the number of epinephrine auto-injectors dispensed through the program and the amount the recipients of the epinephrine auto-injectors paid for the same number of epinephrine auto-injectors or send the pharmacy a replacement supply of the same number of epinephrine auto-injectors.

If a manufacturer fails to comply with the requirements of the bill, the manufacturer may be subject to a fine.

Be it enacted by the General Assembly of the State of Colorado:

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2 **SECTION 1. Legislative declaration.** (1) The general assembly finds and declares that:

(a) Individuals who have moderate to severe allergies, severe asthma, or genetic conditions such as angioedema are at risk of reactions that can occur within seconds or minutes and that can lead to anaphylaxis, a potentially fatal reaction;

(b) Epinephrine works quickly to improve breathing, stimulate the

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- 1 heart, raise dropping blood pressure, prevent airways from closing, 2 prevent or decrease shock, reverse hives, and reduce swelling of the face, 3 lips, and throat; 4 (c) Delay in appropriate treatment for anaphylaxis almost certainly 5 contributes to death in individuals, so it is critical that all anaphylaxis 6 reactions are treated as a medical emergency; 7 (d) In Colorado, there are approximately 565,824 individuals with 8 life-threatening food allergies, which is more than the population of 9 Colorado Springs; of these individuals, 101,848 are under 18 years of age, 10 which means that the number of children with food allergies in Colorado 11 is larger than the population of Longmont; 12 (e) Epinephrine auto-injectors are essential because they are the 13 easiest and most efficient way to potentially save the life of an individual 14 exhibiting symptoms of or experiencing anaphylactic shock; 15 Many individuals are unable to afford an epinephrine 16
 - (f) Many individuals are unable to afford an epinephrine auto-injector because they cannnot pay the copayment amount required under their insurance plan or, if they are uninsured, the cost of an epinephrine auto-injector; these individuals risk their lives every day by not having access to this life-saving medicine if faced with an allergic reaction; and

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- (g) Rising costs of epinephrine auto-injectors make this life-saving medication difficult or impossible to obtain for many people, even those with private health insurance or who are enrolled in a public health benefit program.
- (2) Therefore, it is the intent of the general assembly to establish an epinephrine auto-injector affordability program to ensure Colorado residents have greater access to epinephrine.

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1	SECTION 2. In Colorado Revised Statutes, add 10-16-158 as
2	follows:
3	10-16-158. Cost sharing - prescription epinephrine - limits -
4	rules - definition. (1) As used in this section, unless the context
5	OTHERWISE REQUIRES, "EPINEPHRINE AUTO-INJECTOR" HAS THE SAME
6	MEANING AS SET FORTH IN SECTION 12-280-141 (1)(c).
7	(2) FOR HEALTH BENEFIT PLANS ISSUED OR RENEWED ON OR AFTER
8	JANUARY 1, 2024, IF A CARRIER PROVIDES COVERAGE FOR PRESCRIPTION
9	EPINEPHRINE AUTO-INJECTORS, THE CARRIER SHALL CAP THE TOTAL
10	<u>AMOUNT</u> THAT A COVERED PERSON IS REQUIRED TO PAY FOR ALL COVERED
11	PRESCRIPTION EPINEPHRINE AUTO-INJECTORS AT AN AMOUNT NOT TO
12	EXCEED SIXTY DOLLARS FOR A TWO-PACK OF EPINEPHRINE
13	AUTO-INJECTORS, REGARDLESS OF THE AMOUNT OR TYPE OF EPINEPHRINE
14	NEEDED TO FILL THE COVERED PERSON'S PRESCRIPTION.
15	(3) NOTHING IN THIS SECTION PREVENTS A CARRIER FROM
16	REDUCING A COVERED PERSON'S COST SHARING TO AN AMOUNT THAT IS
17	LOWER THAN THE AMOUNT SPECIFIED IN SUBSECTION (2) OF THIS SECTION.
18	(4) The coverage required by this section may be offered
19	THROUGH A HIGH DEDUCTIBLE PLAN THAT QUALIFIES FOR A HEALTH
20	SAVINGS ACCOUNT PURSUANT TO 26 U.S.C. SEC. 223 OF THE FEDERAL
21	"Internal Revenue Code of 1986"; except that a carrier may
22	APPLY DEDUCTIBLE AMOUNTS FOR THE REQUIRED COVERAGE IF THE
23	COVERAGE IS NOT CONSIDERED BY THE UNITED STATES DEPARTMENT OF
24	THE TREASURY TO BE PREVENTIVE OR TO HAVE AN ACCEPTABLE
25	DEDUCTIBLE AMOUNT.
26	(5) The commissioner may use any of the commissioner's
27	ENFORCEMENT POWERS TO OBTAIN A CARRIER'S COMPLIANCE WITH THIS

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2	(6) THE COMMISSIONER MAY PROMULGATE RULES AS NECESSARY
3	TO IMPLEMENT AND ADMINISTER THIS SECTION AND TO ALIGN WITH
4	FEDERAL REQUIREMENTS.
5	SECTION 3. In Colorado Revised Statutes, add 12-280-141 as
6	follows:
7	12-280-141. Epinephrine auto-injector affordability program
8	- record keeping - reimbursement - definitions. (1) AS USED IN THIS
9	SECTION:
10	(a) "Consumer price index" means the United States
11	DEPARTMENT OF LABOR'S BUREAU OF LABOR STATISTICS CONSUMER PRICE
12	INDEX FOR DENVER-AURORA-LAKEWOOD FOR ALL ITEMS PAID BY ALL
13	URBAN CONSUMERS, OR ITS APPLICABLE PREDECESSOR OR SUCCESSOR
14	INDEX.
15	(b) "DIVISION OF INSURANCE" MEANS THE DIVISION OF INSURANCE
16	IN THE DEPARTMENT OF REGULATORY AGENCIES, CREATED IN SECTION
17	10-1-103.
18	(c) "Epinephrine auto-injector" means an automatic
19	INJECTION DEVICE FOR INJECTING A MEASURED DOSE OF EPINEPHRINE
20	BASED ON THE WEIGHT OF THE PERSON WHO IS TO RECEIVE THE INJECTION.
21	(d) "MANUFACTURER" MEANS A PERSON ENGAGED IN
22	MANUFACTURING EPINEPHRINE AUTO-INJECTORS THAT ARE AVAILABLE
23	FOR PURCHASE IN THIS STATE.
24	(e) "Pharmacy" means a pharmacy outlet registered
25	PURSUANT TO THIS ARTICLE 280 WHERE PRESCRIPTIONS ARE COMPOUNDED
26	AND DISPENSED.
27	(f) "Program" means the epinephrine auto-injector

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SECTION.

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I	AFFORDABILITY PROGRAM CREATED IN SUBSECTION (2) OF THIS SECTION
2	(g) "PROOF OF RESIDENCY" MEANS A CURRENT AND VALID
3	DOCUMENT THAT IS IN ENGLISH, OR IS TRANSLATED INTO ENGLISH AND IS
4	UNALTERED, AND THAT INCLUDES THE INDIVIDUAL'S, OR IN THE CASE OF
5	A MINOR, THE MINOR'S PARENT'S OR GUARDIAN'S, PRINTED NAME AND
6	COLORADO RESIDENTIAL ADDRESS. DOCUMENTS THAT MAY BE USED FOR
7	PROOF OF RESIDENCY ARE:
8	(I) A COLORADO-ISSUED DRIVER'S LICENSE OR COLORADO
9	IDENTIFICATION CARD;
10	(II) A PRINTED BILL, INCLUDING A UTILITY, TELEPHONE, INTERNET
11	CABLE, INSURANCE, MORTGAGE, RENT, WASTE DISPOSAL, WATER OR
12	SEWER, MEDICAL, OR OTHER BILL;
13	(III) A CREDIT CARD OR BANK STATEMENT;
14	(IV) A PAY STUB OR EARNINGS STATEMENT;
15	(V) A PIECE OF POST-MARKED FIRST-CLASS MAIL OR UNITED
16	STATES POSTAL SERVICE CHANGE OF ADDRESS CONFIRMATION;
17	(VI) A PRINTED RENT RECEIPT OR RESIDENTIAL LEASE;
18	(VII) A TRANSCRIPT OR REPORT CARD FROM AN ACCREDITED
19	SCHOOL;
20	(VIII) A VEHICLE TITLE OR REGISTRATION;
21	(IX) AN INSURANCE POLICY;
22	(X) A GOVERNMENT-ISSUED LETTER OR STATE OR FEDERAL
23	GOVERNMENT-ISSUED CHECK; OR
24	(XI) A RECORD OF MEDICAL SERVICE FROM A SHELTER.
25	TREATMENT FACILITY, OR ASSISTED LIVING FACILITY, INCLUDING A
26	HOMELESS SHELTER, WOMEN'S SHELTER, OTHER NONPROFIT SHELTER,
27	HALFWAY HOUSE, NURSING HOME, OR REHABILITATION FACILITY.

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2	(2) (a) Effective January 1, 2024, the epinephrine				
3	AUTO-INJECTOR AFFORDABILITY PROGRAM IS CREATED TO PROVIDE				
4	LOW-COST EPINEPHRINE AUTO-INJECTORS TO ELIGIBLE INDIVIDUALS. BY				
5	JANUARY 1, 2024, EACH MANUFACTURER SHALL ESTABLISH PROCEDURES				
6	TO AND SHALL MAKE EPINEPHRINE AUTO-INJECTORS AVAILABLE IN				
7	ACCORDANCE WITH THIS SECTION TO ELIGIBLE INDIVIDUALS WHO HOLD A				
8	VALID PRESCRIPTION FOR EPINEPHRINE AUTO-INJECTORS. THE				
9	COMMISSIONER OF INSURANCE MAY DETERMINE THAT A MANUFACTURER				
10	MEETS THE REQUIREMENTS OF THIS SECTION IF THE MANUFACTURER:				
11	(I) HAS A PATIENT ASSISTANCE PROGRAM THAT HAS BEEN				
12	REVIEWED AND APPROVED BY THE DIVISION;				
13	(II) Provides Colorado patients with epinephrine				
14	AUTO-INJECTORS AT THE COST OF SIXTY DOLLARS OR LESS FOR EACH				
15	TWO-PACK OF EPINEPHRINE AUTO-INJECTORS; AND				
16	(III) CONTINUES TO MAKE THE PATIENT ASSISTANCE PROGRAM				
17	AVAILABLE TO COLORADO PATIENTS WHO MEET THE ELIGIBILITY CRITERIA				
18	OUTLINED IN SUBSECTION (3) OF THIS SECTION.				
19	(b) The commissioner of insurance shall develop a form				
20	FOR MANUFACTURERS TO USE IN SEEKING SUCH DETERMINATION.				
21	(c) If a manufacturer discontinues its approved patient				
22	ASSISTANCE PROGRAM, THE MANUFACTURER MUST IMMEDIATELY				
23	IMPLEMENT A PROGRAM TO COMPLY WITH THE REQUIREMENTS OF THIS				
24	SECTION FOR QUALIFYING COLORADO PATIENTS.				
25	(3) To be eligible to receive epinephrine auto-injectors				
26	THROUGH THE PROGRAM, AN INDIVIDUAL MUST:				
27	(a) DEMONSTRATE PROOF OF RESIDENCY IN COLORADO:				

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1	(b) NOT BE ELIGIBLE FOR ASSISTANCE PROVIDED THROUGH THE
2	"COLORADO MEDICAL ASSISTANCE ACT", ARTICLES 4 TO 6 OF TITLE 25.5,
3	OR THE FEDERAL "HEALTH INSURANCE FOR THE AGED ACT", TITLE XVIII
4	OF THE FEDERAL "SOCIAL SECURITY ACT", 42 U.S.C. SEC. 1395 ET SEQ.,
5	AS AMENDED;
6	(c) HAVE A VALID EPINEPHRINE AUTO-INJECTOR PRESCRIPTION;
7	AND
8	(d) NOT BE ENROLLED IN PRESCRIPTION DRUG COVERAGE THAT
9	LIMITS THE TOTAL AMOUNT OF COST SHARING THAT THE ENROLLEE IS
10	REQUIRED TO PAY FOR A COVERED PRESCRIPTION TO NOT MORE THAN
11	SIXTY DOLLARS FOR A TWO-PACK OF EPINEPHRINE AUTO-INJECTORS,
12	REGARDLESS OF THE AMOUNT OR TYPE OF EPINEPHRINE NEEDED TO FILL
13	THE PRESCRIPTION.
14	(4) (a) The division of insurance shall develop an
15	APPLICATION FORM TO BE USED BY AN INDIVIDUAL WHO IS SEEKING
16	EPINEPHRINE AUTO-INJECTORS THROUGH THE PROGRAM. AT A MINIMUM,
17	THE APPLICATION FORM MUST:
18	$(I)\ Provide information related to program eligibility and$
19	COVERAGE IN ENGLISH, SPANISH, AND IN EACH LANGUAGE SPOKEN BY AT
20	LEAST TWO AND ONE-HALF PERCENT OF THE POPULATION OF ANY COUNTY
21	IN WHICH SUCH POPULATION SPEAKS ENGLISH LESS THAN VERY WELL, AS
22	DEFINED BY THE UNITED STATES BUREAU OF THE CENSUS AMERICAN
23	COMMUNITY SURVEY OR COMPARABLE CENSUS DATA, AND SPEAKS A
24	SHARED MINORITY LANGUAGE AT HOME; AND
25	(II) REQUIRE THE INDIVIDUAL TO SHOW PROOF THAT THE
26	INDIVIDUAL MEETS THE REQUIREMENTS OF SUBSECTION (3) OF THIS
27	SECTION

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1	(b) THE DIVISION OF INSURANCE AND THE DEPARTMENT OF HEALTH
2	CARE POLICY AND FINANCING SHALL MAKE THE APPLICATION FORM
3	AVAILABLE ON EACH AGENCY'S WEBSITE. THE DIVISION OF INSURANCE
4	SHALL ALSO MAKE THE APPLICATION FORM AVAILABLE TO PHARMACIES,
5	HEALTH-CARE PROVIDERS, AND HEALTH FACILITIES THAT PRESCRIBE OR
6	DISPENSE EPINEPHRINE AUTO-INJECTORS.
7	(5) To access epinephrine auto-injectors through the
8	PROGRAM, AN INDIVIDUAL MUST PRESENT, AT A PHARMACY, A
9	COMPLETED, SIGNED, AND DATED APPLICATION FORM WITH PROOF OF
10	RESIDENCY. IF THE INDIVIDUAL IS UNDER EIGHTEEN YEARS OF AGE, THE
11	INDIVIDUAL'S PARENT OR LEGAL GUARDIAN MAY PROVIDE THE
12	PHARMACIST WITH PROOF OF RESIDENCY.
13	(6) (a) Upon receipt of an individual's proof of residency
14	AND COMPLETED, SIGNED, AND DATED APPLICATION FORM
15	DEMONSTRATING THAT THE INDIVIDUAL IS ELIGIBLE PURSUANT TO
16	SUBSECTION (3) OF THIS SECTION, A PHARMACIST SHALL DISPENSE THE
17	PRESCRIBED EPINEPHRINE AUTO-INJECTORS. AN INDIVIDUAL WHO IS
18	ELIGIBLE TO RECEIVE EPINEPHRINE AUTO-INJECTORS THROUGH THE
19	PROGRAM MAY RECEIVE EPINEPHRINE AUTO-INJECTORS AS PRESCRIBED
20	FOR TWELVE MONTHS.
21	$(b)\ The\ pharmacist\ is\ encouraged\ to\ inform\ the\ individual:$
22	(I) That the individual may be eligible for medical
23	ASSISTANCE PROGRAMS PURSUANT TO THE "COLORADO MEDICAL
24	Assistance Act", articles 4 to 6 of title 25.5, or an affordable
25	INSURANCE PRODUCT ON THE HEALTH BENEFIT EXCHANGE CREATED IN
26	SECTION 10-22-104; AND
27	(II) OF ANY MANUFACTURER-SPONSORED PROGRAMS THAT ASSIST

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1	INDIVIDUALS WHO	CANNOT	AFFORD	THEIR	PRESCRIPTION	EPINEPHRINE
2	AUTO-INJECTORS.					

- (c) THE PHARMACIST SHALL RETAIN A COPY OF THE APPLICATION FORM SUBMITTED BY THE INDIVIDUAL FOR TWO YEARS AFTER THE DATE THE EPINEPHRINE AUTO-INJECTOR WAS INITIALLY DISPENSED.
- (7) A PHARMACY THAT DISPENSES EPINEPHRINE AUTO-INJECTORS PURSUANT TO SUBSECTION (6)(a) OF THIS SECTION MAY COLLECT A COPAYMENT FROM THE INDIVIDUAL TO COVER THE PHARMACY'S COSTS OF PROCESSING AND DISPENSING THE EPINEPHRINE AUTO-INJECTOR, WHICH COPAYMENT AMOUNT MUST NOT EXCEED SIXTY DOLLARS FOR EACH TWO-PACK OF EPINEPHRINE AUTO-INJECTORS THAT THE PHARMACY DISPENSES TO THE INDIVIDUAL.
 - (8) (a) EXCEPT AS PROVIDED IN SUBSECTION (8)(d) OF THIS SECTION, UNLESS THE MANUFACTURER AGREES TO SEND TO THE PHARMACY A REPLACEMENT SUPPLY OF THE SAME NUMBER OF EPINEPHRINE AUTO-INJECTORS DISPENSED THROUGH THE PROGRAM, THE PHARMACY MAY SUBMIT TO THE MANUFACTURER OF THE DISPENSED EPINEPHRINE AUTO-INJECTORS, DIRECTLY OR THROUGH THE MANUFACTURER'S DELEGATED REPRESENTATIVE, SUBCONTRACTOR, OR OTHER VENDOR, AN ELECTRONIC CLAIM FOR PAYMENT THAT IS MADE IN ACCORDANCE WITH THE NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS' STANDARDS FOR ELECTRONIC CLAIMS PROCESSING.
 - (b) By January 1, 2024, Each Manufacturer shall develop a process for a pharmacy to submit an electronic claim for reimbursement, including an accessible online application for reimbursement claims from pharmacies under the program, as provided in subsection (8)(a) of this section.

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1	(c) If the Pharmacy Submits an electronic claim to the
2	MANUFACTURER PURSUANT TO SUBSECTION (8)(a) OF THIS SECTION, THE
3	MANUFACTURER OR THE MANUFACTURER'S DELEGATED REPRESENTATIVE,
4	SUBCONTRACTOR, OR OTHER VENDOR SHALL, WITHIN THIRTY DAYS AFTER
5	RECEIPT OF THE CLAIM, EITHER:
6	(I) REIMBURSE THE PHARMACY IN AN AMOUNT THAT THE
7	PHARMACY PAID FOR THE NUMBER OF EPINEPHRINE AUTO-INJECTORS
8	DISPENSED THROUGH THE PROGRAM; OR
9	(II) SEND THE PHARMACY A REPLACEMENT SUPPLY OF THE SAME
10	NUMBER OF EPINEPHRINE AUTO-INJECTORS IN AN AMOUNT EQUAL TO OR
11	GREATER THAN THE NUMBER OF EPINEPHRINE AUTO-INJECTORS DISPENSED
12	THROUGH THE PROGRAM PURSUANT TO SUBSECTION (6) OF THIS SECTION.
13	(9) THE DIVISION OF INSURANCE AND THE DEPARTMENT OF HEALTH
14	CARE POLICY AND FINANCING SHALL PROMOTE THE AVAILABILITY OF THE
15	PROGRAM TO COLORADANS. THE PROMOTIONAL MATERIAL MUST INCLUDE
16	INFORMATION ABOUT EACH MANUFACTURER'S CONSUMER EPINEPHRINE
17	AUTO-INJECTOR PROGRAM, AS APPLICABLE. EACH AGENCY MAY SEEK AND
18	ACCEPT GIFTS, GRANTS, AND DONATIONS TO FULFILL THE REQUIREMENTS
19	OF THIS SUBSECTION (9).
20	(10) A MANUFACTURER'S REIMBURSEMENT PURSUANT TO
21	SUBSECTION (8)(c) OF THIS SECTION IS NOT A KICKBACK.
22	(11) A MANUFACTURER THAT FAILS TO COMPLY WITH THE
23	REQUIREMENTS OF THIS SECTION:
24	(a) Is subject to a fine of ten thousand dollars for each
25	MONTH OF NONCOMPLIANCE; AND
26	(b) Engages in a deceptive trade practice under section
27	6-1-105 (1)(uuu).

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1	SECTION 4. In Colorado Revised Statutes, 6-1-105, amend
2	(1)(uuu) as follows:
3	6-1-105. Unfair or deceptive trade practices. (1) A person
4	engages in a deceptive trade practice when, in the course of the person's
5	business, vocation, or occupation, the person:
6	(uuu) FAILS TO COMPLY WITH THE REQUIREMENTS OF SECTION
7	12-280-141.
8	SECTION 5. Appropriation. For the 2023-24 state fiscal year,
9	\$77,632 is appropriated to the department of regulatory agencies for use
10	by the division of insurance. This appropriation is from the division of
11	insurance cash fund created in section 10-1-103 (3), C.R.S. To implement
12	this act, the division may use this appropriation as follows:
13	(a) \$68,112 for personal services, which amount is based on an
14	assumption that the division will require an additional 1.0 FTE; and
15	(b) $$9,520$ for operating expenses.
16	SECTION 6. Act subject to petition - effective date. This act
17	takes effect at 12:01 a.m. on the day following the expiration of the
18	ninety-day period after final adjournment of the general assembly; except
19	that, if a referendum petition is filed pursuant to section 1 (3) of article V
20	of the state constitution against this act or an item, section, or part of this
21	act within such period, then the act, item, section, or part will not take
22	effect unless approved by the people at the general election to be held in
23	November 2024 and, in such case, will take effect on the date of the
24	official declaration of the vote thereon by the governor.

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