First Regular Session Seventy-third General Assembly STATE OF COLORADO

REREVISED

This Version Includes All Amendments Adopted in the Second House

LLS NO. 21-0292.03 Yelana Love x2295

HOUSE BILL 21-1307

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A BILL FOR AN ACT

101 CONCERNING MEASURES TO INCREASE ACCESS TO PRESCRIPTION 102 INSULIN FOR PERSONS WITH DIABETES.

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.)

The bill:

- Provides that the current law establishing a \$100 cap on a person's 30-day supply of prescription insulin is for the person's entire insulin supply, regardless of the number of prescriptions a person may have;
- Provides eligible individuals access to one emergency

SENATE d Reading Unamended

SENATE Amended 2nd Reading June 2, 2021

HOUSE 3rd Reading Unamended May 24, 2021

HOUSE Amended 2nd Reading May 22, 2021

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 statute.

Dashes through the words indicate deletions from existing statute.

- prescription insulin supply within a 12-month period at a cost not to exceed \$35 for a 30-day supply; and
- Creates the insulin affordability program in the division of insurance through which eligible individuals may obtain prescription insulin for 12 months at a cost of not more than \$50 for a 30-day supply.

I	Be it enacted by the General Assembly of the State of Colorado:
2	SECTION 1. Legislative declaration. (1) The general assembly
3	hereby finds and declares that:
4	(a) Approximately 300,000 Coloradans live with type 1 or type 2
5	diabetes, with as many as 110,000 additional undiagnosed diabetes
6	patients. Around 73,800 Coloradans rely on insulin to manage their
7	<u>diabetes.</u>
8	(b) Access to this critical life-saving drug is cost-prohibitive for
9	many Coloradans, as the average dosage unit cost of all insulin types
10	increased roughly 280% between 2010 and 2018;
11	(c) The inability to afford insulin has resulted in individuals
12	attempting to ration or underdose their insulin supply. In one study of 354
13	eligible patients at the Yale Diabetes Center in Connecticut, 25.5% of
14	patients reported cost-related insulin underuse.
15	(d) Rationing or underdosing insulin is dangerous for a person
16	with diabetes and can result in the deadly condition of diabetic
17	ketoacidosis;
18	(e) It is necessary to protect the public health, safety, and welfare
19	of Colorado citizens by providing affordable and emergency
20	life-sustaining insulin to those who need it; and
21	(f) This act does not require the state to physically appropriate
22	insulin for its own use; rather, this act governs the reimbursement of

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1	insulin provided through the programs created in this act.
2	SECTION 2. In Colorado Revised Statutes, 10-16-151, amend
3	(2) as follows:
4	10-16-151. Cost sharing in prescription insulin drugs - limits
5	- definition - rules. (2) A carrier that provides coverage for prescription
6	insulin drugs pursuant to the terms of a health coverage plan the carrier
7	offers shall cap the total amount that a covered person is required to pay
8	for a ALL covered prescription insulin drug DRUGS at an amount not to
9	exceed one hundred dollars per for the covered person's entire
10	thirty-day supply of insulin, regardless of the amount or type of insulin
11	needed to fill the covered person's prescription OR THE NUMBER OF
12	PRESCRIPTIONS.
13	SECTION 3. In Colorado Revised Statutes, add 12-280-137 and
14	12-280-138 as follows:
15	12-280-137. Insulin affordability program - record keeping -
16	$\textbf{reimbursement-definitions.} \ (1) \ As \ \text{USED IN THIS SECTION AND SECTION}$
17	12-280-138, UNLESS THE CONTEXT OTHERWISE REQUIRES:
18	(a) "Consumer price index" means the United States
19	DEPARTMENT OF LABOR'S BUREAU OF LABOR STATISTICS CONSUMER PRICE
20	INDEX FOR DENVER-AURORA-LAKEWOOD FOR ALL ITEMS PAID BY ALL
21	URBAN CONSUMERS, OR ITS APPLICABLE PREDECESSOR OR SUCCESSOR
22	INDEX.
23	(b) "DIVISION OF INSURANCE" MEANS THE DIVISION OF INSURANCE
24	IN THE DEPARTMENT OF REGULATORY AGENCIES, CREATED IN SECTION
25	10-1-103.
26	(c) "MANUFACTURER" MEANS A PERSON:
27	(I) ENGAGED IN THE MANUFACTURING OF INSULIN THAT IS

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1	SELF-ADMINISTERED ON AN OUTPATIENT BASIS AND IS AVAILABLE FOR
2	PURCHASE BY RESIDENTS OF THIS STATE; AND
3	(II) THAT HAS ANNUAL GROSS REVENUE OF MORE THAN TWO
4	MILLION DOLLARS FROM THE SALE OF INSULIN IN THIS STATE.
5	(d) "PHARMACY" MEANS A PHARMACY OUTLET REGISTERED
6	PURSUANT TO THIS ARTICLE $\overline{280}$ WHERE PRESCRIPTIONS ARE COMPOUNDED
7	AND DISPENSED.
8	(e) "PROGRAM" MEANS THE INSULIN AFFORDABILITY PROGRAM
9	CREATED IN SUBSECTION (2) OF THIS SECTION.
10	(f) (I) "Wholesale acquisition cost" means a
11	MANUFACTURER'S LIST PRICE FOR INSULIN TO WHOLESALERS OR DIRECT
12	PURCHASERS IN THE UNITED STATES FOR THE MOST RECENT MONTH FOR
13	WHICH THE INFORMATION IS REPORTED IN WHOLESALE PRICE GUIDES OR
14	OTHER PUBLICATIONS OF DRUG OR BIOLOGICAL PRICING DATA.
15	(II) "WHOLESALE ACQUISITION COST" DOES NOT INCLUDE PROMPT
16	PAY OR OTHER DISCOUNTS, REBATES, OR REDUCTIONS IN PRICE.
17	(2) Effective January 1, 2022, the insulin affordability
18	PROGRAM IS HEREBY CREATED TO PROVIDE LOW-COST INSULIN TO
19	ELIGIBLE INDIVIDUALS. BY JANUARY 1, 2022, EACH MANUFACTURER
20	SHALL ESTABLISH PROCEDURES TO MAKE INSULIN AVAILABLE IN
21	ACCORDANCE WITH THIS SECTION TO ELIGIBLE INDIVIDUALS WHO NEED
22	ACCESS TO AN AFFORDABLE INSULIN SUPPLY.
23	(3) TO BE ELIGIBLE TO RECEIVE INSULIN UNDER THE PROGRAM, AN
24	INDIVIDUAL MUST:
25	(a) BE A RESIDENT OF COLORADO;
26	(b) NOT BE ELIGIBLE FOR OR ENROLLED IN ASSISTANCE PROVIDED
27	THROUGH THE "COLORADO MEDICAL ASSISTANCE ACT", ARTICLES 4 TO

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1	6 OF TITLE 25.5, OR THE FEDERAL "HEALTH INSURANCE FOR THE AGED
2	ACT", TITLE XVIII OF THE FEDERAL "SOCIAL SECURITY ACT", 42 U.S.C.
3	SEC. 1395 ET SEQ., AS AMENDED;
4	(c) HAVE A VALID INSULIN PRESCRIPTION OR BE ELIGIBLE FOR AN
5	EMERGENCY SUPPLY AS PROVIDED IN SECTION 12-280-125.5; AND
6	(d) NOT BE ENROLLED IN PRESCRIPTION DRUG COVERAGE THAT
7	LIMITS THE TOTAL AMOUNT OF COST SHARING THAT THE ENROLLEE IS
8	REQUIRED TO PAY FOR A THIRTY-DAY SUPPLY OF INSULIN TO ONE HUNDRED
9	DOLLARS AS DESCRIBED IN SECTION 10-16-151.
10	(4) (a) The division of insurance shall develop an
11	APPLICATION FORM TO BE USED BY AN INDIVIDUAL WHO IS SEEKING
12	INSULIN UNDER THE PROGRAM. THE APPLICATION FORM MUST REQUIRE
13	THE INDIVIDUAL TO SHOW PROOF THAT THE INDIVIDUAL MEETS THE
14	REQUIREMENTS OF SUBSECTION (3) OF THIS SECTION.
15	(b) THE DIVISION OF INSURANCE AND THE DEPARTMENT OF HEALTH
16	CARE POLICY AND FINANCING SHALL MAKE THE APPLICATION FORM
17	AVAILABLE ON EACH AGENCY'S WEBSITE. THE DIVISION OF INSURANCE
18	SHALL ALSO MAKE THE APPLICATION FORM AVAILABLE TO PHARMACIES,
19	HEALTH-CARE PROVIDERS, AND HEALTH FACILITIES THAT PRESCRIBE OR
20	DISPENSE INSULIN.
21	(5) TO ACCESS INSULIN THROUGH THE PROGRAM, AN INDIVIDUAL
22	MUST PRESENT, AT A PHARMACY, A COMPLETED, SIGNED, AND DATED
23	APPLICATION FORM WITH PROOF OF THE INDIVIDUAL'S COLORADO
24	RESIDENCY. IF THE INDIVIDUAL IS UNDER EIGHTEEN YEARS OF AGE, THE
25	INDIVIDUAL'S PARENT OR LEGAL GUARDIAN MAY PROVIDE THE
26	PHARMACIST WITH PROOF OF RESIDENCY.
27	(6) (a) Upon receipt of an individual's completed, signed,

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1	AND DATED APPLICATION FORM DEMONSTRATING THAT THE INDIVIDUAL
2	IS ELIGIBLE PURSUANT TO SUBSECTION (3) OF THIS SECTION AND THE
3	INDIVIDUAL'S PROOF OF RESIDENCY, A PHARMACIST SHALL DISPENSE THE
4	PRESCRIBED INSULIN IN AN AMOUNT THAT WILL PROVIDE THE INDIVIDUAL
5	WITH A THIRTY-DAY SUPPLY. AN INDIVIDUAL WHO IS ELIGIBLE TO RECEIVE
6	INSULIN PURSUANT TO THIS SECTION MAY RECEIVE THE INSULIN FOR
7	TWELVE MONTHS.
8	(b) THE PHARMACIST IS ENCOURAGED TO INFORM THE INDIVIDUAL
9	THAT THEY MAY BE ELIGIBLE FOR THE "COLORADO MEDICAL ASSISTANCE
10	ACT", ARTICLES 4 TO 6 OF TITLE 25.5, OR AN AFFORDABLE INSURANCE
11	PRODUCT ON THE STATE-BASED MARKETPLACE.
12	(c) THE PHARMACIST IS ENCOURAGED TO NOTIFY THE INDIVIDUAL
13	OF ANY MANUFACTURER-SPONSORED PROGRAMS THAT ASSIST
14	INDIVIDUALS WHO CANNOT AFFORD THEIR PRESCRIPTION INSULIN.
15	(d) THE PHARMACIST SHALL RETAIN A COPY OF THE APPLICATION
16	FORM SUBMITTED BY THE INDIVIDUAL FOR TWO YEARS AFTER THE DATE
17	THE INSULIN WAS INITIALLY DISPENSED.
18	(7) A PHARMACY THAT DISPENSES INSULIN PURSUANT TO
19	SUBSECTION (6)(a) OF THIS SECTION MAY COLLECT A COPAYMENT FROM
20	THE INDIVIDUAL TO COVER THE PHARMACY'S COSTS OF PROCESSING AND
21	DISPENSING THE INSULIN IN AN AMOUNT NOT TO EXCEED FIFTY DOLLARS
22	FOR EACH THIRTY-DAY SUPPLY OF INSULIN DISPENSED.
23	(8) (a) Except as provided in subsection (8)(d) of this
24	SECTION, UNLESS THE MANUFACTURER AGREES TO SEND TO THE
25	PHARMACY A REPLACEMENT SUPPLY OF THE SAME INSULIN DISPENSED IN
26	THE AMOUNT DISPENSED THROUGH THE PROGRAM, THE PHARMACY MAY
27	SUBMIT TO THE MANUFACTURER OF THE DISPENSED INSULIN, DIRECTLY OR

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1	THROUGH THE MANUFACTURER'S DELEGATED REPRESENTATIVE,
2	SUBCONTRACTOR, OR OTHER VENDOR, AN ELECTRONIC CLAIM FOR
3	PAYMENT THAT IS MADE IN ACCORDANCE WITH THE NATIONAL COUNCIL
4	FOR PRESCRIPTION DRUG PROGRAMS' STANDARDS FOR ELECTRONIC
5	CLAIMS PROCESSING.
6	(b) By January 1, 2022, Each Manufacturer shall develop
7	A PROCESS FOR A PHARMACY TO SUBMIT AN ELECTRONIC CLAIM FOR
8	REIMBURSEMENT AS PROVIDED IN SUBSECTION (8)(a) OF THIS SECTION.
9	(c) IF THE PHARMACY SUBMITS AN ELECTRONIC CLAIM TO THE
10	MANUFACTURER PURSUANT TO SUBSECTION (8)(a) OF THIS SECTION, THE
11	MANUFACTURER OR THE MANUFACTURER'S DELEGATED REPRESENTATIVE,
12	SUBCONTRACTOR, OR OTHER VENDOR SHALL, WITHIN THIRTY DAYS AFTER
13	RECEIPT OF THE CLAIM, EITHER:
14	(I) REIMBURSE THE PHARMACY IN AN AMOUNT THAT COVERS THE
15	DIFFERENCE BETWEEN THE PHARMACY'S WHOLESALE ACQUISITION COST
16	FOR THE INSULIN DISPENSED THROUGH THE PROGRAM AND THE AMOUNT
17	THE INDIVIDUAL PAID FOR THE INSULIN PURSUANT TO SUBSECTION (7) OF
18	THIS SECTION; OR
19	(II) SEND THE PHARMACY A REPLACEMENT SUPPLY OF THE SAME
20	INSULIN IN AN AMOUNT EQUAL TO OR GREATER THAN THE AMOUNT THAT
21	COVERS THE DIFFERENCE BETWEEN THE PHARMACY'S WHOLESALE
22	ACQUISITION COST FOR THE INSULIN DISPENSED THROUGH THE PROGRAM
23	AND THE AMOUNT THE INDIVIDUAL PAID FOR THE INSULIN PURSUANT TO
24	SUBSECTION (7) OF THIS SECTION.
25	(d) A PHARMACY SHALL NOT SUBMIT A CLAIM FOR PAYMENT FOR
26	INSULIN WITH A WHOLESALE ACQUISITION COST OF EIGHT DOLLARS OR
27	LESS PER MILLILITER, ADJUSTED ANNUALLY BASED ON THE ANNUAL

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1	PERCENTAGE CHANGE IN THE CONSUMER PRICE INDEX.
2	(9) THE DIVISION OF INSURANCE AND THE DEPARTMENT OF HEALTH
3	CARE POLICY AND FINANCING SHALL PROMOTE THE AVAILABILITY OF THE
4	$PROGRAM\ TO\ COLORADANS. \underline{THE\ PROMOTIONAL\ MATERIAL\ MUST\ INCLUDE}$
5	INFORMATION ABOUT EACH MANUFACTURER'S CONSUMER INSULIN
6	PROGRAMS. EACH AGENCY MAY SEEK AND ACCEPT GIFTS, GRANTS, AND
7	DONATIONS TO FULFILL THE REQUIREMENTS OF THIS SUBSECTION (9).
8	(10) A MANUFACTURER'S REIMBURSEMENT PURSUANT TO
9	SUBSECTION (8)(b) OF THIS SECTION IS NOT A KICKBACK.
10	(11) A MANUFACTURER THAT FAILS TO COMPLY WITH THE
11	REQUIREMENTS OF THIS SECTION IS SUBJECT TO A FINE OF TEN THOUSAND
12	DOLLARS FOR EACH MONTH OF NONCOMPLIANCE.
13	12-280-138. Emergency prescription insulin supply - eligibility
14	- record keeping - definition. (1) (a) EFFECTIVE JANUARY 1, 2022, AN
15	INDIVIDUAL WHO MEETS THE REQUIREMENTS OF SUBSECTION (2) OF THIS
16	SECTION MAY RECEIVE ONE EMERGENCY THIRTY-DAY SUPPLY OF
17	PRESCRIPTION INSULIN WITHIN A TWELVE-MONTH PERIOD. THE PHARMACY
18	MAY CHARGE THE INDIVIDUAL AN AMOUNT NOT TO EXCEED THIRTY-FIVE
19	DOLLARS FOR THE THIRTY-DAY SUPPLY.
20	(b) By January 1, 2022, Each Manufacturer shall establish
21	PROCEDURES TO MAKE INSULIN AVAILABLE IN ACCORDANCE WITH THIS
22	SECTION TO ELIGIBLE INDIVIDUALS WHO NEED ACCESS TO AN EMERGENCY
23	PRESCRIPTION INSULIN SUPPLY.
24	(2) TO BE ELIGIBLE FOR AN EMERGENCY PRESCRIPTION INSULIN
25	SUPPLY, AN INDIVIDUAL MUST:
26	(a) HAVE A VALID PRESCRIPTION FOR INSULIN OR BE ELIGIBLE FOR
27	AN EMERGENCY SUPPLY AS PROVIDED IN SECTION 12-280-125.5;

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1	(b) HAVE LESS THAN A SEVEN-DAY SUPPLY OF INSULIN AVAILABLE;
2	(c) BE REQUIRED TO PAY MORE THAN ONE HUNDRED DOLLARS OUT
3	OF POCKET EACH MONTH FOR THE INDIVIDUAL'S INSULIN; AND
4	(d) BE A RESIDENT OF COLORADO.
5	(3) (a) THE DIVISION OF INSURANCE SHALL CREATE AND MAKE
6	AVAILABLE TO THE PUBLIC AN APPLICATION FORM FOR INDIVIDUALS
7	SEEKING AN EMERGENCY PRESCRIPTION INSULIN SUPPLY PURSUANT TO
8	THIS SECTION.
9	(b) AT A MINIMUM, THE APPLICATION FORM MUST REQUIRE THE
10	INDIVIDUAL TO SHOW PROOF THAT THE INDIVIDUAL MEETS THE
11	REQUIREMENTS OF SUBSECTION (2) OF THIS SECTION.
12	(c) EACH PHARMACY IN THE STATE SHALL MAKE THE APPLICATION
13	FORM AVAILABLE AT THE PHARMACY.
14	(4) (a) Upon receipt of an individual's completed
15	APPLICATION FORM DEMONSTRATING THAT THE INDIVIDUAL IS ELIGIBLE
16	PURSUANT TO SUBSECTION (2) OF THIS SECTION AND THE INDIVIDUAL'S
17	PROOF OF RESIDENCY, A PHARMACIST SHALL DISPENSE THE PRESCRIBED
18	INSULIN IN AN AMOUNT THAT WILL PROVIDE THE INDIVIDUAL WITH A
19	THIRTY-DAY SUPPLY.
20	(b) If the individual is under eighteen years of age, the
21	INDIVIDUAL'S PARENT OR LEGAL GUARDIAN MAY PROVIDE THE
22	PHARMACIST WITH PROOF OF RESIDENCY.
23	(5) EACH PHARMACY SHALL KEEP THE APPLICATION FORM FOR
24	EACH INDIVIDUAL WHO RECEIVES AN EMERGENCY PRESCRIPTION INSULIN
25	SUPPLY PURSUANT TO THIS SECTION FOR TWO YEARS FOLLOWING THE DATE
26	ON WHICH THE INSULIN WAS DISPENSED.
27	(6) (a) EXCEPT AS PROVIDED IN SUBSECTION (6)(d) OF THIS

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1	SECTION, UNLESS THE MANUFACTURER AGREES TO SEND TO THE
2	PHARMACY A REPLACEMENT SUPPLY OF THE SAME INSULIN DISPENSED IN
3	THE AMOUNT DISPENSED THROUGH THE PROGRAM, THE PHARMACY MAY
4	SUBMIT TO THE MANUFACTURER OF THE DISPENSED INSULIN, DIRECTLY OR
5	THROUGH THE MANUFACTURER'S DELEGATED REPRESENTATIVE,
6	SUBCONTRACTOR, OR OTHER VENDOR, AN ELECTRONIC CLAIM FOR
7	PAYMENT THAT IS MADE IN ACCORDANCE WITH THE NATIONAL COUNCIL
8	FOR PRESCRIPTION DRUG PROGRAMS' STANDARDS FOR ELECTRONIC
9	CLAIMS PROCESSING.
10	(b) By January 1, 2022, Each Manufacturer shall develop
11	A PROCESS FOR A PHARMACY TO SUBMIT AN ELECTRONIC CLAIM FOR
12	REIMBURSEMENT AS PROVIDED IN SUBSECTION (6)(a) OF THIS SECTION.
13	(c) IF THE PHARMACY SUBMITS AN ELECTRONIC CLAIM TO THE
14	MANUFACTURER PURSUANT TO SUBSECTION (6)(a) OF THIS SECTION, THE
15	MANUFACTURER OR THE MANUFACTURER'S DELEGATED REPRESENTATIVE,
16	SUBCONTRACTOR, OR OTHER VENDOR SHALL, WITHIN THIRTY DAYS AFTER
17	RECEIPT OF THE CLAIM, EITHER:
18	(I) REIMBURSE THE PHARMACY IN AN AMOUNT THAT COVERS THE
19	PHARMACY'S WHOLESALE ACQUISITION COST FOR THE INSULIN DISPENSED
20	PURSUANT TO THIS SECTION; OR
21	(II) SEND THE PHARMACY A REPLACEMENT SUPPLY OF THE SAME
22	INSULIN IN AN AMOUNT EQUAL TO OR GREATER THAN THE AMOUNT THAT
23	COVERS THE PHARMACY'S WHOLESALE ACQUISITION COST FOR THE INSULIN
24	DISPENSED PURSUANT TO THIS SECTION.
25	(d) A PHARMACY SHALL NOT SUBMIT A CLAIM FOR PAYMENT FOR
26	INSULIN WITH A WHOLESALE ACQUISITION COST OF EIGHT DOLLARS OR
27	LESS PER MILLILITER, ADJUSTED ANNUALLY BASED ON THE ANNUAL

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1	PERCENTAGE CHANGE IN THE CONSUMER PRICE INDEX.
2	(7) THE DIVISION OF INSURANCE AND THE DEPARTMENT OF HEALTH
3	CARE POLICY AND FINANCING SHALL PROMOTE THE AVAILABILITY OF THE
4	EMERGENCY PRESCRIPTION INSULIN SUPPLY TO COLORADANS. THE
5	PROMOTIONAL MATERIAL MUST INCLUDE INFORMATION ABOUT EACH
6	MANUFACTURER'S CONSUMER INSULIN PROGRAMS. EACH AGENCY MAY
7	SEEK AND ACCEPT GIFTS, GRANTS, AND DONATIONS TO FULFILL THE
8	REQUIREMENTS OF THIS SUBSECTION (7).
9	(8) A MANUFACTURER'S REIMBURSEMENT PURSUANT TO
10	SUBSECTION $(6)(b)$ OF THIS SECTION IS NOT A KICKBACK.
11	(9) A MANUFACTURER THAT FAILS TO COMPLY WITH THE
12	REQUIREMENTS OF THIS SECTION IS SUBJECT TO A FINE OF TEN THOUSAND
13	DOLLARS FOR EACH MONTH OF NONCOMPLIANCE.
14	SECTION 4. Act subject to petition - effective date. This act
15	takes effect at 12:01 a.m. on the day following the expiration of the
16	ninety-day period after final adjournment of the general assembly; except
17	that, if a referendum petition is filed pursuant to section 1 (3) of article V
18	of the state constitution against this act or an item, section, or part of this
19	act within such period, then the act, item, section, or part will not take
20	effect unless approved by the people at the general election to be held in
21	November 2022 and, in such case, will take effect on the date of the
22	official declaration of the vote thereon by the governor.

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