First Regular Session Seventy-fifth General Assembly STATE OF COLORADO

ENGROSSED

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

LLS NO. 25-0361.02 Brita Darling x2241

SENATE BILL 25-071

SENATE SPONSORSHIP

Michaelson Jenet and Rich, Hinrichsen

HOUSE SPONSORSHIP

Martinez and Taggart,

Senate Committees Health & Human Services

House Committees

	A BILL FOR AN ACT
101	CONCERNING CERTAIN PRACTICES BY PERSONS PARTICIPATING IN THE
102	SUPPLY CHAIN OF DRUGS PURCHASED UNDER THE FEDERAL 340B
103	DRUG PRICING PROGRAM.

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.)

Under the federal 340B drug pricing program (340B program), a covered entity, including certain hospitals, programs, and federally qualified health centers (covered entity), that serves patients with low income receives discounted outpatient drugs (340B drugs) from manufacturers that participate in the federal medicaid and medicare

programs.

Unless the receipt of 340B drugs is prohibited by the federal department of health and human services, the bill prohibits a manufacturer, wholesaler, third-party logistics provider, or repackager in this state, or an agent, contractor, or affiliate of those entities, including an entity that collects or processes health information, from directly or indirectly denying, restricting, prohibiting, discriminating against, or otherwise limiting the acquisition of a 340B drug by, or delivery of a 340B drug to, a covered entity, a pharmacy contracted with a covered entity, or a location otherwise authorized by a covered entity to receive and dispense 340B drugs.

The bill also prohibits a manufacturer from directly or indirectly requiring a covered entity, a pharmacy contracted with a covered entity, or any other location authorized to receive 340B drugs by a covered entity to submit any health information, claims or utilization data, or other specified data that does not relate to a claim submitted to certain federal health care programs, unless the data is voluntarily furnished or required to be furnished under federal law.

A violation of the prohibitions in the bill is an unfair or deceptive trade practice under the "Colorado Consumer Protection Act" (act), and the violator is subject to the enforcement provisions and penalties contained in that act. The attorney general may investigate and enforce the provisions of the bill, as well as a business harmed by a violation of the provisions of the bill. In addition, a person regulated by the state board of pharmacy (pharmacy board) that violates the provisions of the bill may be subject to discipline by the pharmacy board against the person's license, certification, or registration, as well as other penalties.

The bill requires a covered entity that is a hospital to annually post on its public-facing website information concerning the annual, estimated, aggregate financial benefit to the hospital covered entity resulting from its ability to acquire pharmaceuticals at a discount through the 340B program and a description of how the hospital covered entity uses savings from participation in the 340B program.

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

2 **SECTION 1.** In Colorado Revised Statutes, 6-1-105, **add** (1)(iiii)

3 as follows:

1

4 6-1-105. Unfair or deceptive trade practices - definitions.

5 (1) A person engages in a deceptive trade practice when, in the course of

6 the person's business, vocation, or occupation, the person:

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1	(IIII) VIOLATES ARTICLE 29 OF THIS TITLE 6.
2	SECTION 2. In Colorado Revised Statutes, add article 29 to title
3	6 as follows:
4	ARTICLE 29
5	Colorado 340B Contract Pharmacy Protection Act
6	6-29-101. Short title. The short title of this article 29 is the
7	"COLORADO 340B CONTRACT PHARMACY PROTECTION ACT".
8	6-29-102. Legislative declaration. (1) The General Assembly
9	FINDS AND DETERMINES THAT:
10	(a) The 340B drug pricing program requires drug
11	MANUFACTURERS TO PROVIDE DRUG DISCOUNTS ON IDENTIFIED
12	OUTPATIENT DRUGS TO 340B COVERED ENTITIES AS A CONDITION OF
13	MEDICAID AND MEDICARE PART B COVERING THOSE DRUGS;
14	(b) Congress created the 340B program in 1992, stating
15	THAT THE PROGRAM'S BENEFITS "ENABLE [COVERED] ENTITIES TO STRETCH
16	SCARCE FEDERAL RESOURCES AS FAR AS POSSIBLE, REACHING MORE
17	ELIGIBLE PATIENTS AND PROVIDING MORE COMPREHENSIVE SERVICES."
18	(H.R. Rep. No.102-384 (II), at 12 (1992)).
19	(c) The 340B program supports Colorado's medically
20	VULNERABLE AND UNDERSERVED POPULATIONS BY PROVIDING
21	ADDITIONAL RESOURCES TO 340B COVERED ENTITIES AND ALLOWING
22	THESE ENTITIES TO DETERMINE THE MOST EFFECTIVE USE OF THESE
23	RESOURCES;
24	(d) The 340B program is a critical component of
25	COLORADO'S SAFETY NET INFRASTRUCTURE;
26	(e) Colorado has sixty-eight hospitals statewide that
2.7	PARTICIPATE IN THE 340B PROGRAM. WITH NEARLY NINETY PERCENT OF

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1	THESE HOSPITALS OPERATING UNDER UNSUSTAINABLE LONG-TERM
2	MARGINS;
3	(f) Additionally, Colorado has twenty federally
4	QUALIFIED HEALTH CENTERS, OR FQHCS, ALL OF WHICH PARTICIPATE IN
5	THE 340B PROGRAM AND SIXTY-FIVE PERCENT OF WHICH CURRENTLY
6	OPERATE WITH NEGATIVE MARGINS;
7	(g) Colorado hospitals participating in the $340B\text{program}$
8	UTILIZE PROGRAM BENEFITS TO ADDRESS THEIR COMMUNITIES' UNIQUE
9	NEEDS, WHICH INCLUDE PROVIDING DIRECT PRESCRIPTION DRUG
10	DISCOUNTS, SUBSIDIZING UNCOMPENSATED CHARITY CARE AND MEDICAID
11	UNDERPAYMENTS TO REMAIN FINANCIALLY OPERATIONAL, SUPPORTING
12	OPIOID USE DISORDER TREATMENT, FUNDING MOBILE HEALTH-CARE AND
13	IMMUNIZATION CLINICS, AND PAYING FOR CHEMOTHERAPY AND INFUSION
14	CENTERS;
15	(h) COLORADO'S FQHCS ARE THE PRIMARY CARE MEDICAL HOME
16	FOR ONE IN SEVEN COLORADANS, WITH EIGHTY-NINE PERCENT OF FQHCS'
17	PATIENTS IN 2023 LIVING WITH FAMILY INCOMES BELOW TWO HUNDRED
18	PERCENT OF THE FEDERAL POVERTY GUIDELINE AND TWENTY-THREE
19	PERCENT WERE UNINSURED;
20	(i) Colorado's FQHCs utilize 340B program benefits to
21	ADDRESS THEIR COMMUNITIES' UNIQUE NEEDS, WHICH INCLUDE REDUCED
22	DRUG PRICES FOR PATIENTS, PROVIDER RECRUITMENT AND RETENTION,
23	AND EXPANSION OF ORAL HEALTH AND BEHAVIORAL HEALTH SERVICES
24	THAT THE FQHCs WOULD OTHERWISE NOT BE ABLE TO OFFER;
25	(j) FURTHER, COLORADO'S FQHCS EXPERIENCED AN ESTIMATED
26	LOSS OF FOUR MILLION THREE HUNDRED DOLLARS IN 340B PROGRAM
27	SAVINGS IN THE LAST TWO YEARS;

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1	(k) Conversely, in 2023, sixteen of the largest
2	PHARMACEUTICAL COMPANIES REPORTED SIX HUNDRED EIGHTY-FOUR
3	BILLION DOLLARS IN EARNINGS IN THEIR ANNUAL FINANCIAL REPORTS, A
4	FIGURE THAT WAS HIGHER THAN THE GROSS DOMESTIC PRODUCT OF
5	EIGHTY-EIGHT PERCENT OF THE COUNTRIES IN THE WORLD;
6	(1) IN ADDITION, THE EIGHT LARGEST PHARMACEUTICAL
7	COMPANIES PAID A COMBINED TWO BILLION DOLLARS IN FEDERAL TAXES
8	ON TWO HUNDRED FOURTEEN BILLION DOLLARS OF DOMESTIC REVENUE IN
9	2022, ACCORDING TO THEIR 10-K ANNUAL FINANCIAL REPORTS;
10	(m) IN 2022, COLORADO HOSPITALS PROVIDED TWO BILLION ONE
11	HUNDRED MILLION DOLLARS OF COMMUNITY BENEFIT;
12	$(n) \ Starting in 2020, pharmaceutical manufacturers began$
13	to unlawfully place restrictions on $340B\text{covered}$ entities using
14	CONTRACT PHARMACIES TO DISPENSE DRUGS TO PATIENTS, UNILATERALLY
15	LIMITING THE 340B PROGRAM'S BENEFITS; AND
16	(o) In a letter dated July 28, 2023, from William Tong,
17	ATTORNEY GENERAL OF CONNECTICUT, TO THE UNITED STATES SENATE
18	340B WORKING GROUP, AND SIGNED BY TWENTY-TWO OTHER BIPARTISAN
19	ATTORNEYS GENERAL, THE ATTORNEYS GENERAL DECLARED THAT
20	"OUTPATIENT PHARMACIES ARE A KEY MECHANISM FOR THE DELIVERY OF
21	LIFE-SAVING DRUGS TO ELIGIBLE PATIENTS, INCLUDING THOSE WHO HAVE
22	LIMITED ACCESS TO TRANSPORTATION, LIVE IN REMOTE OR RURAL AREAS,
23	OR ARE CONFINED TO THEIR HOMES AND RELY ON MAIL-ORDER
24	PHARMACIES."
25	(2) Therefore, the general assembly declares that this
26	ARTICLE 29 PROHIBITING PHARMACEUTICAL MANUFACTURERS FROM
2.7	IMPOSING LIMITATIONS OR PLACING RESTRICTIVE CONDITIONS ON 340B

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1	COVERED ENTITIES IS NECESSARY TO PROTECT COLORADO'S VULNERABLE
2	PATIENTS AND SAFETY NET PROVIDERS AND TO ENSURE THAT
3	$\hbox{\it MUCH-NEEDED FINANCIAL RESOURCES GENERATED BY THE 340B PROGRAM}$
4	REMAIN IN COLORADO FOR THE BENEFIT OF THE PUBLIC.
5	6-29-103. Definitions. As used in this article 29, unless the
6	CONTEXT OTHERWISE REQUIRES:
7	(1) "340B COVERED ENTITY" OR "COVERED ENTITY" HAS THE
8	Meaning set forth in section $340B$ (a)(4) of the federal "Public
9	HEALTH SERVICE ACT", 42 U.S.C. SEC. 256b (a)(4).
10	(2) "340B DRUG" MEANS A DRUG THAT:
11	(a) Is a covered outpatient drug within the meaning set
12	FORTH IN 42 U.S.C. SEC. 256b;
13	(b) HAS BEEN SUBJECT TO ANY OFFER FOR REDUCED PRICES BY A
14	MANUFACTURER PURSUANT TO 42 U.S.C. SEC. 256b (a)(1); AND
15	(c) Is purchased by a covered entity. As used in this
16	SUBSECTION (2)(c), A DRUG IS CONSIDERED "PURCHASED" IF IT WOULD
17	HAVE BEEN PURCHASED BUT FOR THE RESTRICTION OR LIMITATION
18	DESCRIBED IN SECTION 6-29-105.
19	(3) "340B DRUG PRICING PROGRAM" OR "340B PROGRAM" MEANS
20	THE PROGRAM DESCRIBED IN 42 U.S.C. SEC. 256b (a)(1).
21	(4) "340B SAVINGS" MEANS THE DIFFERENCE BETWEEN THE
22	AGGREGATED MARKET RATE COSTS AND THE AGGREGATED ACQUISITION
23	COSTS FOR 340B DRUGS.
24	(5) "Board" means the state board of Pharmacy created in
25	SECTION 12-280-104.
26	(6) "FEDERAL HEALTH CARE PROGRAM" HAS THE MEANING SET
27	FORTH IN SECTION 42 U.S.C. SEC. 1320a-7b (f).

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1	(7) "HEALTH INFORMATION" MEANS INFORMATION, INCLUDING
2	DEMOGRAPHIC INFORMATION COLLECTED FROM AN INDIVIDUAL OR A
3	GROUP OF INDIVIDUALS THAT:
4	(a) IS CREATED OR RECEIVED BY A HEALTH-CARE PROVIDER,
5	PHARMACY, HEALTH BENEFIT PLAN, EMPLOYER, OR HEALTH-CARE
6	CLEARINGHOUSE; AND
7	(b) Relates to the past, present, or future physical or
8	MENTAL HEALTH OR CONDITION OF AN INDIVIDUAL, THE PROVISION OF
9	HEALTH CARE TO AN INDIVIDUAL, OR THE PAST, PRESENT, OR FUTURE
10	PAYMENT FOR THE PROVISION OF HEALTH CARE TO AN INDIVIDUAL.
11	(8) "Manufacturer" has the meaning set forth in section
12	12-280-103 (27).
13	(9) "Package" has the meaning set forth in 21 U.S.C. sec.
14	360eee (11)(A).
15	(10) "Pharmacy" has the meaning set forth in section
16	12-280-103 (43).
17	(11) "Repackager" has the meaning set forth in section
18	12-280-103 (46).
19	(12) "Third-party logistics provider" has the meaning set
20	FORTH IN SECTION 12-280-103 (52.5).
21	
22	6-29-104. Applicability. This article 29 applies to a
23	${\tt MANUFACTURER}, \phantom{MMMMMMMmmmmmmmmmmmmmmmmmmmmmmmmmmmmm$
24	OF A MANUFACTURER'S DRUGS DOING BUSINESS IN THIS STATE AND
25	ENGAGED IN THE PRODUCTION, MANUFACTURE, DISTRIBUTION, OR SALE OF
26	A 340B DRUG IN THIS STATE.
27	6-29-105. Acquisition of 340B drugs - prohibited acts - use of

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1	<u>savings - enforcement - penarties - nonpreemption - data exclusions.</u>
2	(1) Prohibited acts. On and after the effective date of this
3	ARTICLE 29:
4	(a) Unless the receipt of the 340B drugs is prohibited by
5	THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES, A
6	MANUFACTURER,THIRD-PARTY LOGISTICS PROVIDER, OR REPACKAGER,
7	OR AN AGENT, CONTRACTOR, OR AFFILIATE OF A MANUFACTURER,
8	THIRD-PARTY LOGISTICS PROVIDER, OR REPACKAGER, INCLUDING AN
9	ENTITY THAT COLLECTS OR PROCESSES HEALTH INFORMATION, SHALL NOT,
10	DIRECTLY OR INDIRECTLY, DENY, RESTRICT, PROHIBIT, DISCRIMINATE
11	against, or otherwise limit the acquisition of a $340B\text{drug}\text{by}$, or
12	DELIVERY OF A 340B DRUG TO, A 340B COVERED ENTITY, A PHARMACY
13	CONTRACTED WITH A 340B COVERED ENTITY, OR A LOCATION OTHERWISE
14	${\tt AUTHORIZEDBYA340BCOVEREDENTITYTORECEIVEANDDISPENSE340B}$
15	DRUGS; AND
16	(b) A MANUFACTURER SHALL NOT DIRECTLY OR INDIRECTLY
17	REQUIRE, INCLUDING AS A CONDITION, A 340B COVERED ENTITY, A
18	PHARMACY CONTRACTED WITH A 340B COVERED ENTITY, OR ANY OTHER
19	LOCATION AUTHORIZED TO RECEIVE 340B DRUGS BY A 340B COVERED
20	ENTITY TO SUBMIT ANY HEALTH INFORMATION, CLAIMS OR UTILIZATION
21	DATA, PURCHASING DATA, PAYMENT DATA, OR OTHER DATA THAT DOES
22	NOT RELATE TO A CLAIM SUBMITTED TO A FEDERAL HEALTH CARE
23	PROGRAM, UNLESS SUCH DATA IS VOLUNTARILY FURNISHED BY SUCH
24	COVERED ENTITY OR OTHERWISE REQUIRED TO BE FURNISHED UNDER
25	APPLICABLE FEDERAL LAW.
26	(2) A COVERED ENTITY THAT IS A REPORTING HOSPITAL, AS
27	DEFINED IN SECTION 25.5-1-701, SHALL NOT USE 340B SAVINGS FOR THE

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1	FOLLOWING PURPOSES:
2	(a) More than thirty-five percent of total annual
3	COMPENSATION OR EXPENSE REIMBURSEMENT FOR THE HOSPITAL'S BOARD
4	OF DIRECTORS;
5	(b) TAX PENALTIES OR FINES ISSUED AGAINST THE HOSPITAL;
6	(c) EXPENSES RELATED TO ADVERTISING AND PUBLIC RELATIONS
7	THAT PROMOTE THE HOSPITAL'S IMAGE, SERVICES, OR PROPOSALS, NOT
8	INCLUDING COMMUNICATIONS REQUIRED BY LAW OR THAT ARE ESSENTIAL
9	FOR PATIENT SAFETY AND PATIENT INFORMATION;
10	(d) Lobbying expenses and other costs intended to
11	INFLUENCE LEGISLATION OR BALLOT MEASURES AT THE LOCAL, STATE, OR
12	FEDERAL LEVEL;
13	(e) Travel, lodging, food, or beverage expenses for the
14	HOSPITAL'S BOARD OF DIRECTORS AND OFFICERS; AND
15	(f) GIFTS OR ENTERTAINMENT EXPENSES.
16	(3) Enforcement - penalties. (a) THE ATTORNEY GENERAL MAY
17	INVESTIGATE A COMPLAINT CONCERNING A VIOLATION OF THIS ARTICLE
18	29. A PERSON THAT VIOLATES THIS ARTICLE 29 RISKS THE PUBLIC'S
19	HEALTH AND ENGAGES IN AN UNFAIR OR DECEPTIVE TRADE PRACTICE
20	PURSUANT TO SECTION 6-1-105 (1)(iiii) AND IS SUBJECT TO THE
21	ENFORCEMENT PROVISIONS, CIVIL PENALTIES, AND DAMAGES SET FORTH
22	IN ARTICLE 1 OF THIS TITLE 6.
23	(b) EACH PACKAGE OF A 340B DRUG THAT CONSTITUTES A
24	PROHIBITED ACT UNDER THIS ARTICLE 29 CONSTITUTES A SEPARATE
25	VIOLATION OF SUBSECTION (1) OF THIS SECTION.
26	(c) Limited distribution of a drug required under 21 U.S.C.
27	SEC. 355-1 DOES NOT CONSTITUTE A VIOLATION OF THIS ARTICLE 29.

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1	(a) A PERSON REGULATED BY THE STATE BOARD OF PHARMACY
2	CREATED IN SECTION 12-280-104 MAY BE SUBJECT TO DISCIPLINE
3	PURSUANT TO SECTION 12-280-108 (1)(c), (1)(d), OR (1)(i) FOR VIOLATING
4	THIS ARTICLE 29.
5	(4) Nonpreemption. Nothing in this article 29 shall be
6	CONSTRUED OR APPLIED TO BE LESS RESTRICTIVE THAN ANY FEDERAL LAW
7	APPLYING TO PERSONS REGULATED BY THIS SECTION. NOTHING IN THIS
8	SECTION SHALL BE CONSTRUED OR APPLIED TO BE IN CONFLICT WITH ANY
9	OF THE FOLLOWING:
10	(a) APPLICABLE FEDERAL LAW AND RELATED REGULATIONS; OR
11	(b) OTHER LAWS OF THIS STATE, IF THE LAWS ARE COMPATIBLE
12	WITH APPLICABLE FEDERAL LAW.
13	(5) Data exclusions. Subsection (1) of this section does not
14	PROHIBIT A MANUFACTURER FROM REQUIRING HEALTH INFORMATION OR
15	OTHER DATA THAT A COVERED ENTITY IS REQUIRED TO FURNISH TO THE
16	MANUFACTURER UNDER APPLICABLE FEDERAL LAW, INCLUDING DATA
17	RELATING TO AN AUDIT IN ACCORDANCE WITH PROCEDURES ESTABLISHED
18	BY THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES UNDER
19	42 U.S.C. SEC. 256b (a)(5)(C).
20	SECTION 3. In Colorado Revised Statutes, add 25-3-132 as
21	follows:
22	25-3-132. 340B drug pricing program transparency -
23	definitions. (1) AS USED IN THIS SECTION:
24	(a) "340B drug pricing program" or "340B program" means
25	THE PROGRAM DESCRIBED IN 42 U.S.C. SEC. 256b (a)(1).
26	(b) "340B SAVINGS" MEANS THE DIFFERENCE BETWEEN THE
27	AGGREGATED MARKET RATE COSTS AND THE AGGREGATED ACQUISITION

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1	COSTS FOR 340B DRUGS.
2	(c) "Hospital covered entity" means a hospital licensed or
3	CERTIFIED BY THE DEPARTMENT PURSUANT TO THE DEPARTMENT'S
4	AUTHORITY UNDER SECTION 25-1.5-103 (1)(a) AND THAT IS A "COVERED
5	ENTITY" AS DEFINED IN 42 U.S.C. SEC. 256b (a)(4).
6	(2) EXCEPT AS PROVIDED IN SUBSECTION (3) OF THIS SECTION.
7	EACH HOSPITAL COVERED ENTITY THAT IS A REPORTING HOSPITAL, AS
8	DEFINED IN SECTION 25.5-1-701, SHALL INCLUDE THE FOLLOWING
9	INFORMATION IN THE ANNUAL REPORT SUBMITTED PURSUANT TO SECTION
10	<u>25.5-1-703 (3):</u>
11	(a) The annual, reported 340B savings to the hospital
12	COVERED ENTITY RESULTING FROM ITS ABILITY TO ACQUIRE
13	PHARMACEUTICALS AT A DISCOUNT THROUGH THE 340B DRUG PRICING
14	PROGRAM;
15	(b) A DESCRIPTION OF HOW THE HOSPITAL COVERED ENTITY USES
16	SAVINGS FROM PARTICIPATION IN THE $340B \underline{\text{PROGRAM}};$
17	(c) The aggregated market rate costs and the aggregated
18	ACQUISITION COSTS FOR 340B DRUGS USED TO CALCULATE 340B SAVINGS
19	<u>AND</u>
20	(d) The total operating costs of the hospital covered
21	ENTITY AND COSTS RELATING TO PROVIDING CHARITY CARE.
22	(3) NOTHING IN THIS SECTION REQUIRES THE PUBLIC DISCLOSURE
23	OF RECORDS THAT ARE PUBLIC RECORDS UNDER THE "COLORADO OPEN
24	RECORDS ACT", PART 2 OF ARTICLE 72 OF TITLE 24, BUT THAT ARE
25	EXEMPTED FROM DISCLOSURE UNDER THAT ACT.
26	SECTION 4. Severability. If any provision of this act or the
27	application thereof to any person or circumstance is held invalid, such

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invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to this end the provisions of this act are declared to be severable.

SECTION 5. Act subject to petition - effective date. This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly; except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect unless approved by the people at the general election to be held in November 2026 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

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