118TH CONGRESS
2D SESSION

S. 4845

To lower the cost of drugs for all Americans.

IN THE SENATE OF THE UNITED STATES

JULY 30, 2024

Mr. BOOKER (for himself and Mr. SANDERS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To lower the cost of drugs for all Americans.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Prescription Drug Affordability and Access Act''.

SEC. 2. ESTABLISHMENT OF THE BUREAU OF PRESCRIPTION DRUG AFFORDABILITY AND ACCESS.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—There is established within the Department of Health and Human Services a bureau, to be known as the Bureau of Prescription

Drug Affordability and Access (in this Act referred to as the ''Bureau'') to carry out the duties described in this section. The purposes of the Bureau are to—

(A) attain lower prescription drug costs for patients;

(B) decrease unnecessary government expenditures on prescription drugs; and

(C) ensure access to clinically beneficial prescription drugs.

(2) EXECUTIVE AGENCY.—The Bureau shall be considered an Executive agency, as defined in section 105 of title 5, United States Code.

(3) DIRECTOR.—

(A) APPOINTMENT.—The Bureau shall be headed by a Director (in this Act referred to as the ''Director'') who shall be appointed by the President, by and with the advice and consent of the Senate.

(B) QUALIFICATION.—The President shall nominate the Director from among individuals who are citizens of the United States.

(C) TERM.—The Director shall serve for a term of 5 years. The term of the first Director to be appointed shall begin on the date that is

180 days after the date of enactment of this Act.

(4) CONSULTATION.—

(A) CONSULTATIONS AND PUBLIC MEETINGS.—

(i) IN GENERAL.—In carrying out the duties under this section, the Bureau shall—

(I) regularly consult with relevant stakeholders, including patients, representatives of relevant Federal agencies, and medical and health care finance experts; and

(II) hold regular public meetings, not less frequently than quarterly, to solicit input from relevant stakeholders.

(ii) PUBLIC DISCLOSURES.—The Bureau shall make publicly available a list of individuals it consults or meets with pursuant to clause (i), and the organizations with which such individuals are affiliated.

(B) PATIENT ENGAGEMENT.—

(i) IN GENERAL.—The Director shall ensure that patients or organizations rep-

resenting patients have opportunities to meaningfully engage with the Bureau as it conducts its work, including while the Bureau makes appropriate price determinations under section 3(d). Such opportunities may include holding regular panels, forums, and other meetings for patient engagement.

(ii) PETITION.—The Director shall establish a process by which patients can petition the entity and raise concerns about the price of their prescription drugs.

(C) CONSUMER ADVISORY COUNCIL.—

(i) ESTABLISHMENT.—The Director shall establish a Consumer Advisory Council to advise and consult with the Bureau as it conducts its work.

(ii) MEMBERSHIP.—The Council established under this subparagraph shall be composed of not fewer than 6 members appointed by the Director. In appointing members to the Council, the Director shall ensure that at least half of the members of the Council are patients or organizations representing patients, particularly those

who have been significantly impacted by high priced medications. The Director shall also seek to appoint members to the Council who are experts in relevant areas, including medicine and health care finance.

(iii) MEETINGS.—The Consumer Advisory Council shall meet from time to time at the call of the Director but shall meet at least twice a year.

(5) EMPLOYMENT CONDITION.—

(A) IN GENERAL.—An individual who has a conflict of interest shall not be appointed to be a member of, or employed by, the Bureau, including the Consumer Advisory Council established under paragraph (4)(C).

(B) DISCLOSURE.—Individuals under consideration for employment by, or appointment to, the Bureau, including the Consumer Advisory Council, shall—

(i) disclose any potential conflict of interest, including the type, nature, and magnitude of the interests involved; and

(ii) consent to an investigation into potential conflicts of interest, which may

be initiated at the discretion of the Secretary.

(b) DUTIES.—The Bureau shall carry out the following duties:

(1) Carry out the provisions of section 3.

(2) Submit the annual reports under subsection (c).

(3) Any other duty that the Director determines appropriate.

(c) ANNUAL REPORTING.—

(1) IN GENERAL.—Not later than January 1 of the first year that is not less than 2 years after the date of enactment of this Act, and annually thereafter, the Director shall submit to Congress a report on the activities of the Bureau.

(2) CONTENTS.—Each report under paragraph (1) shall contain the following:

(A) A description of the activities of the Bureau, including—

(i) the total estimated savings achieved by the Bureau since the most recent report;

(ii) the disaggregated estimated savings achieved since the most recent report,

including by each therapeutic class of prescription drugs;

(iii) a summary of the information submitted by prescription drug manufacturers as required under section 3; and

(iv) the impact of the Bureau's work on patient affordability and access to essential prescription drugs.

(B) Recommendations for such legislation and administrative action as the Bureau determines appropriate.

(C) A copy of each report submitted by drug manufacturers as required under section 3.

(D) Other items, as the Bureau determines appropriate.

(d) FUNDING.—There are appropriated, from amounts in the Treasury not otherwise appropriated, $50,000,000 for fiscal year 2025 and each subsequent fiscal year to carry out the activities of the Bureau. Amounts appropriated under the preceding sentence shall remain available until expended.

SEC. 3. PRESCRIPTION DRUG CONSUMER PRICE PROTECTIONS.

(a) REVIEW OF PRICES.—

(1) IN GENERAL.—

(A) AUTHORITY.—The Bureau shall conduct annual reviews of the prices of prescription drugs to ensure that the wholesale acquisition cost of, and the net cost after application of any rebates for, each such drug is appropriate.

(B) MANDATORY REVIEWS.—Pursuant to subparagraph (A), the Bureau shall conduct reviews of the prices of any prescription drug—

(i)(I) for which a price increase described in subsection (b)(2) has been imposed in the previous year; and

(II) which surpass the revenue benchmark under subsection (c); or

(ii) for which there is an increase in demand for the drug that is significant, as determined by the Secretary.

(C) DISCRETIONARY REVIEWS.—The Bureau may conduct reviews of the prices of prescription drugs other than the drugs described in subparagraph (B). In conducting reviews under this subparagraph, the Bureau shall prioritize any such prescription drug—

(i) that is in the top fiftieth percentile of net spending on prescription drugs

under any Federal program, including the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or the Medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.);

(ii) that is in the top fiftieth percentile of utilization under any Federal program, including such Medicare program or such Medicaid program;

(iii) that has experienced an increase in the wholesale acquisition cost or net price of 25 percent or more over the preceding 3 years;

(iv) for which such review is expected to support a great patient need, such as on the basis of the therapeutic impacts and high costs of the drug; or

(v) that has been identified in a patient petition pursuant to section 2(a)(4)(B)(ii).

(2) INFORMATION ON PRESCRIPTION DRUGS APPROVED AS OF ENACTMENT.—With respect to any prescription drug that, as of the date of enactment of this Act, has in effect an application approved under section 505 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262), each manufacturer, not later than 180 days after such date of enactment, shall provide to the Bureau the following information:

(A) The name of the prescription drug.

(B) A description of the prescription drug and its approved indications.

(C) The number of individuals in the United States and globally for which such prescription drug is clinically indicated, disaggregated by indication, if applicable.

(D) A list of patents and patent applications that claim the prescription drug; a use of the prescription drug; any formulation, metabolite, or component of the prescription drug; a method of use of the prescription drug; or a method of manufacture of the prescription drug.

(E) Data on any patents and government-granted exclusivities that affect the date on which drug applications sponsored by other manufacturers may be submitted and approved by the Food and Drug Administration.

(F) The date on which the prescription drug was approved under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.

(G) International price data with respect to the drug.

(H) The total expenditures of the manufacturer and other persons on—

(i) domestic and foreign research and development of the drug, including an itemized description of—

(I) clinical research, including the cost of each clinical trial associated with the prescription drug, reported separately for each clinical trial;

(II) the development of alternative dosage forms and strengths for the prescription drug molecule or combinations, including the molecule;

(III) other prescription drug development activities, such as nonclinical laboratory studies and record and report maintenance;

(IV) pursuing new or expanded indications for such prescription drug

through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;

(V) carrying out postmarket requirements related to such prescription drug, including under subsection (o) of such section 505 or such section 351;

(VI) carrying out risk evaluation and mitigation strategies in accordance with section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) or such section 351; and

(VII) marketing research;

(ii) the acquisition of prescription drug components and packaging, in total and per unit sold, broken out by source and cost and identifying specific costs that reflect internal transfers within the manufacturer's company;

(iii) other acquisitions relating to the prescription drug, including for the pur-

chase of patents and licensing or acquisition of any corporate entity owning any rights to the drug during or after development of the prescription drug;

(iv) current unit costs of production and distribution of the prescription drug;

(v) marketing, advertising, and educating for the promotion of a prescription drug, including a breakdown of amounts aimed at consumers, prescribers, managed care organizations, and others, irrespective of whether a prescription drug is mentioned in marketing, advertising, or educating;

(vi) any patient assistance and co-pay programs to which the manufacturer sponsors or contributes;

(vii) the gross revenue, net revenue, gross profit, and net profit of the manufacturer with respect to such prescription drug;

(viii) the total number of units of such prescription drug that were sold in the United States; and

(ix) pricing information with respect to the sale of such prescription drug, including—

(I) the current wholesale acquisition cost;

(II) the introductory wholesale acquisition cost;

(III) the net average price realized by pharmacy benefit managers for such prescription drug provided to individuals in the United States, after accounting for any rebates or other payments from the manufacturer to the pharmacy benefit manager and from the pharmacy benefit manager to the manufacturer;

(IV) the list price of such prescription drug charged to purchasers in each applicable prescription drug reference country;

(V) the net price of such prescription drug, after accounting for discounts, rebates, or other financial considerations, charged to purchasers

in each applicable prescription drug reference country;

(VI) a description of the timing and magnitude of all price changes of the prescription drug since the introductory wholesale acquisition cost; and

(VII) the average net price of such prescription drug for each year since first being sold in the United States.

(I) Any Federal benefits and amounts and periods of impact for each such benefit received by the manufacturer with respect to the prescription drug, including tax credits, Federal grants, patent applications that benefitted from such grants, patent extensions, government-granted exclusivities, and waivers of fees.

(J) Prior outside financial support for clinical trials or basic and translational scientific inputs to the disclovery and development with respect to the drug, including the percentage of research and development expenditures described in this section that were derived from Federal funds.

(K) Executive compensation for the chief executive officer, chief financial officer, and the three other most highly compensated executive officers, including bonuses, paid by such manufacturer, and stock options affiliated with the manufacturer that were offered to or accrued by such officers.

(L) Other information as the Director may require.

(3) INFORMATION ON PRESCRIPTION DRUGS APPROVED AFTER ENACTMENT.—With respect to any prescription drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) after the date of enactment of this Act, each manufacturer, not later than 45 days prior to introducing such prescription drug into interstate commerce in the United States, shall provide to the Bureau the following information:

(A) The information described in the following provisions of paragraph (2), except for the information required under subparagraphs (G)(v) and (H) of such paragraph.

(B) Pricing information with respect to the sale of such prescription drug, including—

(i) the planned introductory wholesale acquisition cost;

(ii) the list price of such prescription drug charged or planned to be charged to purchasers in each applicable prescription drug reference country; and

(iii) the net price of such prescription drug, after accounting for discounts, rebates, or other financial considerations, charged or planned to be charged to purchasers in each applicable prescription drug reference country.

(C) The estimated annual profit and revenue that is expected to be generated by the prescription drug, both domestically and globally.

(D) Other information as the Director may require.

(b) REVIEW OF CERTAIN PRICE INCREASES.—

(1) IN GENERAL.—The Bureau shall conduct a review of the price of a prescription drug for which a submission is required under paragraph (2).

(2) NOTIFICATION OF INTENTION TO INCREASE PRICE.—If a manufacturer intends to increase the wholesale acquisition cost of a prescription drug by

more than the percentage by which the Consumer Price Index for all urban consumers for that year exceeds such index for the preceding calendar year, such manufacturer, not later than 60 days before the price increase takes effect, shall submit to the Bureau the following information:

(A) The information described in subsection (a)(2)(A).

(B) The planned increase in the wholesale acquisition cost and the planned date the increase will go into effect.

(C) A justification of the planned increase in wholesale acquisition cost.

(D) Any other information as the Secretary may require.

(c) REVENUE BENCHMARK REVIEW.—

(1) IN GENERAL.—The Bureau shall conduct a review of a prescription drug when revenue for such prescription drug surpasses the revenue benchmark to ensure that the wholesale acquisition cost of the prescription drug remains appropriate.

(2) REQUIRED SUBMISSION.—Not later than 60 days before the manufacturer of a prescription drug anticipates the global revenue for such drug will surpass the revenue benchmark, the manufacturer shall

submit to the Bureau the information outlined in subsection (a)(2)(A).

(3) REVENUE BENCHMARK.—

(A) IN GENERAL.—Subject to subparagraph (B), for purposes of this subsection, the revenue benchmark is $5,000,000,000 in global revenue.

(B) UPDATE.—The Bureau may update the amount of the global benchmark over time.

(d) GENERAL AUTHORITY TO REVIEW.—

(1) IN GENERAL.—The Bureau may at any time review the wholesale acquisition cost of a prescription drug to determine if such price is appropriate, including in response to a patient petition under section 2(a)(3)(B)(ii).

(2) PROCEDURE.—The Bureau shall notify the manufacturer of a prescription drug it wishes to review pursuant to this subsection, and, within 45 days of receiving such a notification, the manufacturer shall submit to the Bureau information the Bureau determines necessary for such review.

(e) APPROPRIATE PRICE DETERMINATIONS.—

(1) CONSIDERATIONS.—In determining whether the wholesale acquisition cost or proposed wholesale

acquisition cost of a prescription drug is appropriate, the Bureau shall consider the following:

(A) The size of the affected patient population.

(B) The therapeutic benefits of the prescription drug to patients, including the extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives, and the costs of such existing alternatives, and the extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a serious or life-threatening medical condition for which treatment or diagnosis is not addressed adequately by available therapies.

(C) The impact of the price on access to the prescription drug, including for patients who are uninsured, and the associated financial burden on patients who use such prescription drug.

(D) The total annual expenditures by the Federal Government on the prescription drug and the budgetary impact of Federal health care programs providing coverage of the prescription drug.

(E) The risk-adjusted value of Federal Government subsidies and investments related to the prescription drug.

(F) The costs associated with the development or manufacturing of the prescription drug.

(G) The number of similarly effective prescription drugs or alternative treatment regimens for each approved use of such prescription drug.

(H) Whether the prescription drug provided a clinically meaningful improvement in health outcomes, compared to other therapies available at the time of approval, as determined through comparative clinical effectiveness, including the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.

(I) The current wholesale acquisition cost of comparable prescription drugs in the United States, to the extent that those prices have been deemed appropriate.

(J) The cumulative and expected global revenue generated by the prescription drug.

(K) The price of the drug in other countries, including in the prescription drug reference countries.

(L) The public health benefit of the drug.

(M) The information that the manufacturer submits to the Bureau as required under this section.

(N) Any other information, as the Bureau requires.

(2) SPECIAL RULES.—

(A) INTERIM APPROPRIATE PRICE OF PRESCRIPTION DRUGS.—

(i) IN GENERAL.—For each prescription drug described in clause (ii), the Bureau shall—

(I) establish an interim appropriate price, which shall be the lesser of—

(aa) the median list price of the prescription drug in the prescription drug reference countries; or

(bb) if applicable, the appropriate price determination made by the Bureau; and

(II) direct the manufacturer to set the wholesale acquisition cost at a level that does not exceed the interim appropriate price.

(ii) APPLICABLE DRUGS.—A prescription drug described in this clause is a prescription drug—

(I) that—

(aa) as of the date of the enactment of this Act, has in effect an application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)); and

(bb) is not a listed drug or a reference product for more than 2 prescription drugs or biological products approved and currently marketed under section 505(j) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 355(j)) or under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); or

(II) with respect to which the Secretary has authorized under subsection (g) the use of any patent, clinical trial data, or other government-granted exclusivity related to such drug by another sponsor, until the date that is 1 year after the date on which another application for such drug, for which the sponsor relies upon a such authorization under subsection (g), is approved under such section 505 or such section 351.

(B) SPIKE IN PRICE.—If a manufacturer increases the wholesale acquisition cost of a prescription drug by more than the percentage by which the Consumer Price Index for all urban consumers for that year exceeds such index for the preceding calendar year, such prescription drug shall be deemed to have a wholesale acquisition cost that is not appropriate un-

less the Bureau determines, based on the information submitted under paragraphs (2) and (3) of subsection (a) and under subsection (b)(2) and the considerations described in paragraph (1), that the wholesale acquisition cost is appropriate.

(3) OPPORTUNITY TO COMMENT.—Prior to making a determination on whether the wholesale acquisition cost of a prescription drug is appropriate, the Bureau shall ensure relevant stakeholders, including patients, have an opportunity to comment.

(f) REQUIRED ACTIONS IF PRICE IS NOT APPROPRIATE.—

(1) NOTICE AND REQUIREMENT TO REMIT EXCESS.—If the Bureau determines that the wholesale acquisition cost or proposed wholesale acquisition cost of a prescription drug is not appropriate, the Bureau shall notify and direct the manufacturer to lower the wholesale acquisition cost to a level that would be deemed appropriate. The Bureau shall also require the manufacturer to remit the excess revenue earned as a result of the prescription drug having a price that is not appropriate.

(2) PATIENT REBATE.—The Director of the Bureau shall establish a process to distribute funds remitted under paragraph (1) to patients who were impacted by the prescription drug having a price that is not appropriate.

(g) ENFORCEMENT.—

(1) IN GENERAL.—If, within 30 days of receiving a notice that the wholesale acquisition cost of a prescription drug is not appropriate, the manufacturer of such prescription drug fails to lower the wholesale acquisition cost of a prescription drug or fails to remit excessive revenue earned in accordance with subsection (f), or if the manufacturer of a drug described in subsection (a)(3) sets an introductory wholesale acquisition cost of a drug that is not appropriate, the Director shall notify the Secretary and the Secretary shall authorize the use of any patent, clinical trial data, or government-granted exclusivity by an entity for purposes of manufacturing such prescription drug for sale. An entity that wishes to manufacture such prescription drug for sale shall agree to—

(A) set the wholesale acquisition cost of such prescription drug at or below the level that the Bureau determines is appropriate; and

(B) provide the prescription drug manufacturer with reasonable compensation, which shall be determined by the Bureau, based on the information submitted by the manufacturer under this section including—

(i) the risk-adjusted value of any Federal Government subsidies and investments in research and development used to support the development of such drug;

(ii) the risk-adjusted value of any investment made by such manufacturer in the research and development of such drug;

(iii) the impact of the price, including license compensation payments, on meeting the medical need of all patients;

(iv) the relationship between the price of such drug, including compensation payments and the health benefits of such drug; and

(v) other relevant information determined appropriate by the Secretary, in coordination with the Director.

(2) PUBLIC MANUFACTURING.—Nothing in this section shall prevent the Secretary from entering

into arrangements for the public manufacturing of prescription drugs, including through government-owned and contractor-operated manufacturing, production, or distribution facilities.

(3) POST LICENSING.—

(A) IN GENERAL.—Any manufacturer of a prescription drug that fails to comply with the interim appropriate price under subsection (e)(2)(A)(i)(I) shall be subject to a civil monetary penalty of not less than an amount equal to 150 percent of all revenues obtained by the manufacturer that are in excess of the expected revenues at the interim appropriate price.

(B) PROCEDURE.—The provisions of section 1128A, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section, shall apply to civil monetary penalties under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A.

(C) TRANSFER TO NATIONAL INSTITUTES OF HEALTH.—The civil monetary penalties collected under this paragraph shall be transferred to the National Institutes of Health to supple-

ment activities related to pharmaceutical research and development.

SEC. 4. DEFINITIONS.

In this Act:

(1) CONFLICT OF INTEREST.—The term ''conflict of interest'' means an association, including a financial or personal association, or past employment, that has the potential to bias or have the appearance of biasing an individual's decisions.

(2) EXCESS REVENUE.—The term ''excess revenue'' means the difference between a prescription drug's wholesale acquisition cost at the time of the Bureau review under this section and the maximum wholesale acquisition price for the prescription drugs that the Bureau determines to be appropriate.

(3) GOVERNMENT-GRANTED EXCLUSIVITY.—The term ''government-granted exclusivity'' means prohibitions on the submission or effective approval of prescription drug applications granted under any of the following:

(A) Clauses (ii) through (v) of section 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E)).

(B) Section 505(j)(5)(B)(iv) of such Act (21 U.S.C. 355(j)(5)(B)(iv)) or clause (ii), (iii), or (iv) of section 505(j)(5)(F) of such Act.

(C) Section 505A of such Act (21 U.S.C. 355a).

(D) Section 505E of such Act (21 U.S.C. 355f).

(E) Section 527 of such Act (21 U.S.C. 360cc).

(F) Section 351(k)(7) of such Act (42 U.S.C. 262(k)(7)).

(G) Any other provision of law that provides for exclusivity (or extension of exclusivity) with respect to a drug.

(4) LISTED DRUG.—The term ''listed drug'' means a drug listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)).

(5) MANUFACTURER.—The term ''manufacturer'', with respect to a prescription drug, means an entity that—

(A) is the holder of the approved application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or

under section 351 of the Public Health Service Act (42 U.S.C. 262); and

(B) is responsible for setting the price of the prescription drug.

(6) PRESCRIPTION DRUG.—The term ''prescription drug'' means any drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act and to section 503(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(2)).

(7) PRESCRIPTION DRUG REFERENCE COUNTRY.—The term ''prescription drug reference country'' means Japan, Germany, the United Kingdom, France, Italy, Canada, Australia, Spain, the Netherlands, Switzerland, and Sweden.

(8) REFERENCE PRODUCT.—The term ''reference product'' has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(10) WHOLESALE ACQUISITION COST.—The term ''wholesale acquisition cost'' has the meaning given that term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).

SEC. 5. REPEAL OF MEDICARE'S NONINTERFERENCE CLAUSE.

Section 1860D–11 of the Social Security Act (42 U.S.C. 1395w–111) is amended by striking subsection (i).

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