[~117H9321]

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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend the Public Health Service Act to provide for a demonstration project for the development and publication of independent value assessments for drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. NADLER introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to provide for a demonstration project for the development and publication of independent value assessments for drugs, and for other purposes.

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 ''Independent Drug Value Assessment Act of 2023''.

SEC. 2. DEMONSTRATION PROJECT FOR INDEPENDENT VALUE ASSESSMENTS FOR DRUGS.

Part D of title III of the Public Health Service Act (21 U.S.C. 254b et seq.) is amended by adding at the end the following:

"Subpart XIII—Demonstration Project for Independent Value Assessments for Drugs

"SEC. 340J. INDEPENDENT VALUE ASSESSMENTS.

''(a) NEWLY APPROVED DRUGS.—

''(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Planning and Evaluation, shall complete, by contract under subsection (d), an independent value assessment for every drug—

''(A) that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, or licensed under section 351(a) of the Public Health Service Act; or

''(B) for which a new indication or use is approved or licensed under such section 505(c) or 351(a).

''(2) TIMELINE.—The Secretary shall ensure that an independent value assessment required by paragraph (1) is completed not later than 90 days after the effective date of the approval or licensure involved.

''(b) PREVIOUSLY APPROVED DRUGS.—The Secretary shall—

''(1) not later than the end of fiscal year 2028, complete, by contract under subsection (d), for each of fiscal years 2024, 2025, 2026, 2027, and 2028, an independent value assessment for no fewer than 5 drugs not described in subsection (a); and

''(2) in selecting drugs for assessment under paragraph (1)—

''(A) prioritize—

''(i) drugs in the top 35 percent of expenditures for particular drugs under part B or D of title XVIII of the Social Security Act; and

''(ii) drugs approved as a breakthrough therapy pursuant to section 506(a), as a fast track product pursuant to section 506(b), or pursuant to accelerated approval under section 506(c); and

''(B) exclude any drug (including any biological product) that is a selected drug (as referred to in section 1192(c) of the Social Security Act), with respect to a price applicability period (as defined in section 1191(b)(2) of such Act).

''(c) PUBLICATION.—The Secretary shall publish each independent value assessment prepared under subsection (a) or (b) on the public website of the Department of Health and Human Services without modification, except that the Secretary may redact any confidential or proprietary information in accordance with applicable law.

''(d) CONTRACTS.—

''(1) IN GENERAL.—To the extent and in the amounts made available in advance in appropriations Acts, the Secretary shall enter into a contract with an eligible entity to develop independent value assessments under this section.

''(2) ELIGIBLE ENTITIES.—To be eligible to prepare an independent value assessment under this section, an entity—

''(A) shall be a nonprofit organization, a university, a federally funded research and development center, or another type of organization that is determined by the Secretary to be capable of developing such an independent value assessment;

''(B) shall not be an entity that—

''(i) is involved in the manufacturing, research, and development of drugs; or

''(ii) operates fully insured or self-insured health plans, pharmaceutical benefit managers, or other entities that pay for drugs; and

''(C) shall be, as determined by the Secretary, independent of any other entity described in subparagraph (B).

''(3) INFORMATION.—

''(A) INFORMATION IN POSSESSION OF HHS.—The Secretary shall ensure that the entity under contract to develop an independent value assessment under this section has access to all of the information in the possession of the Department of Health and Human Services that is necessary to complete the assessment.

''(B) INFORMATION IN POSSESSION OF MANUFACTURER.—The manufacturer of any drug for which an independent value assessment is being developed under this section shall, at the request of the Secretary or the entity under contract to develop the independent value assessment, provide to the Secretary or entity, as applicable, information in the possession of the manufacturer that is necessary to complete the assessment.

''(C) PATIENT INPUT.—The Secretary shall ensure that any organization under contract to develop an independent value assessment under this section for a drug solicits from and takes into consideration the impact on patients who use the drug.

''(D) ADDITIONAL INFORMATION.—An entity under contract to develop an independent value assessment under this section for a drug shall offer manufacturers, patients, patient advocates, clinical experts, and members of the public an opportunity to submit additional information and analyses for consideration before the independent value assessment is complete.

''(e) PROHIBITIONS.—The Secretary shall prohibit the use in any independent value assessment under this section of—

''(1) any analysis based on the quality-adjusted life year; and

''(2) any research findings that do not weigh the value of each year of life gained from treatment equally for all patients no matter their severity of illness, age, or pre-existing disability.

''(f) DEFINITIONS.—In this section:

''(1) The term 'independent value assessment' means an economic analysis that—

''(A) analyzes the benefits of a particular drug for the average patient and for various subgroups of patients, as determined by the Secretary, and the benefits of the drug on a standalone basis and in comparison with other approved treatments, including—

''(i) an economic analysis of direct benefits to the patient, including to the quality and duration of life of the patient; and

''(ii) an economic analysis of indirect benefits, including—

''(I) benefits to family members, employers, and caregivers of the patient; and

''(II) benefits to the health care system, including savings to public- and private-sector payers resulting from potential use of health services that is avoided due to the benefits of the particular drug; and

''(B) includes, for the current year and each of the next 4 years, an estimate of a price,

price range, or a proposed value-based payment arrangement for the particular drug that is commensurate with the economic benefits of the particular drug, including a list and explanation of the factors that support the estimated price, price range, or proposed value-based payment arrangement.

''(C) includes—

''(i) an estimate of a price, price range, or a proposed value-based payment arrangement for the particular drug that—

''(I) is tied to the Consumer Price Index for medical services starting with the year the drug was approved or licensed; and

''(II) is commensurate with the economic benefits of the particular drug; and

''(ii) a list and explanation of the factors that support the estimated price, price range, or proposed value-based payment arrangement

''(2) The term 'value-based payment arrangement'—

''(A) means a form of payment for a drug, other than a fixed payment per dose or other standard administration of the drug, that takes into consideration the effectiveness of the drug; and

''(B) may include an overall payment for a course of treatment with the drug, an overall payment to cover all indicated uses of the drug for a particular population, or another approach to payment, any of which may include a provision to vary the amount of the payment based on the effectiveness of the drug for an individual or a population, as the case may be.''.