

117TH CONGRESS
2D SESSION

H. R. 9321

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

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 16, 2022

Ms. SPEIER (for herself, Mr. NADLER, and Ms. PORTER) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Independent Drug
5 Value Assessment Act”.

6 **SEC. 2. INDEPENDENT VALUE ASSESSMENTS FOR DRUGS.**

7 Part D of title III of the Public Health Service Act
8 (21 U.S.C. 254b et seq.) is amended by adding at the end
9 the following:

1 **“Subpart XIII—Independent Value Assessments for**
2 **Drugs**

3 **“SEC. 340J. INDEPENDENT VALUE ASSESSMENTS.**

4 “(a) IN GENERAL.—The Secretary, acting through
5 the Assistant Secretary for Planning and Evaluation, shall
6 complete, by contract under subsection (e), an inde-
7 pendent value assessment for any drug—

8 “(1) that is approved under section 505(c) of
9 the Federal Food, Drug, and Cosmetic Act, or li-
10 censed under section 351(a) of the Public Health
11 Service Act, on or after the day that is 1 year after
12 the date of enactment of this section; or

13 “(2) for which a new indication or use is ap-
14 proved or licensed under such section 505(c) or
15 351(a) on or after such day.

16 “(b) TIMELINE.—The Secretary shall ensure that an
17 independent value assessment required by subsection (a)
18 is completed not later than 90 days after the effective date
19 of the approval or licensure involved.

20 “(c) PREVIOUSLY APPROVED DRUGS.—The Sec-
21 retary shall—

22 “(1) not later than 5 years after the date of en-
23 actment of this section, complete, by contract under
24 subsection (e), an independent value assessment for
25 no fewer than 25 drugs not described in subsection
26 (a); and

1 “(2) in selecting drugs for assessment under
2 paragraph (1), prioritize—

3 “(A) drugs in the top 35 percent of ex-
4 penditures for particular drugs under part B or
5 D of title XVIII of the Social Security Act; and

6 “(B) drugs approved as a breakthrough
7 therapy pursuant to section 506(a), as a fast
8 track product pursuant to section 506(b), or
9 pursuant to accelerated approval under section
10 506(c).

11 “(d) PUBLICATION.—The Secretary shall publish
12 each independent value assessment prepared under sub-
13 section (a) or (c) on the public website of the Department
14 of Health and Human Services without modification, ex-
15 cept that the Secretary may redact any confidential or
16 proprietary information in accordance with applicable law.

17 “(e) CONTRACTS.—

18 “(1) IN GENERAL.—To the extent and in the
19 amounts made available in advance in appropriations
20 Acts, the Secretary shall enter into a contract with
21 an eligible entity to develop an independent value as-
22 sessment under this section.

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

1 “(A) shall be a nonprofit organization, a
2 university, a federally funded research and de-
3 velopment center, or another type of organiza-
4 tion that is determined by the Secretary to be
5 capable of developing such an independent value
6 assessment;

7 “(B) shall not be an entity that—

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

10 “(ii) operates fully insured and self-in-
11 sured health plans, pharmaceutical benefit
12 managers, or other entities that pay for
13 drugs; and

14 “(C) shall be, as determined by the Sec-
15 retary, independent of any other entity de-
16 scribed in subparagraph (B).

17 “(3) INFORMATION.—

18 “(A) INFORMATION IN POSSESSION OF
19 HHS.—The Secretary shall ensure that any or-
20 ganization under contract to develop an inde-
21 pendent value assessment under this section has
22 access to all of the information in the posses-
23 sion of the Department of Health and Human
24 Services that is necessary to complete the as-
25 sessment.

1 “(B) INFORMATION IN POSSESSION OF
2 MANUFACTURER.—The manufacturer of any
3 drug for which an independent value assess-
4 ment is being developed under this section shall,
5 at the request of the Secretary or the entity
6 under contract to develop the independent value
7 assessment, provide to the Secretary or entity,
8 as applicable, information in the possession of
9 the manufacturer that is necessary to complete
10 the assessment.

11 “(C) ADDITIONAL INFORMATION.—An en-
12 tity under contract to develop an independent
13 value assessment under this section for a drug
14 shall offer manufacturers, patient advocates,
15 clinical experts, and members of the public an
16 opportunity to submit additional information
17 and analyses for consideration before the inde-
18 pendent value assessment is complete.

19 “(f) PROHIBITIONS.—The Secretary shall prohibit
20 the use in any independent value assessment under this
21 section of—

22 “(1) any analysis based on the quality-adjusted
23 life year; and

24 “(2) any research findings that do not weigh
25 the value of each year of life gained from treatment

1 equally for all patients no matter their severity of ill-
2 ness, age, or pre-existing disability.

3 “(g) DEFINITIONS.—In this section:

4 “(1) The term ‘independent value assessment’
5 means an economic analysis that—

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

12 “(i) an economic analysis of direct
13 benefits to the patient, including to the
14 quality and duration of life of the patient;
15 and

16 “(ii) an economic analysis of indirect
17 benefits, including—

18 “(I) benefits to the earnings ca-
19 pacity of the patient;

20 “(II) benefits to family members,
21 employers, and caregivers of the pa-
22 tient; and

23 “(III) benefits to the health care
24 system, including savings to public-
25 and private-sector payers resulting

1 from potential use of health services
2 that is avoided due to the benefits of
3 the particular drug; and

4 “(B) includes an estimate of a price, price
5 range, or a proposed value-based payment ar-
6 rangement for the particular drug that is com-
7 mensurate with the economic benefits of the
8 particular drug, including a list and explanation
9 of the factors that support the estimated price,
10 price range, or proposed value-based payment
11 arrangement.

12 “(2) The term ‘value-based payment arrange-
13 ment’—

14 “(A) means a form of payment for a drug,
15 other than a fixed payment per dose or other
16 standard administration of the drug, that takes
17 into consideration the effectiveness of the drug;
18 and

19 “(B) may include an overall payment for a
20 course of treatment with the drug, an overall
21 payment to cover all indicated uses of the drug
22 for a particular population, or another approach
23 to payment, any of which may include a provi-
24 sion to vary the amount of the payment based

1 on the effectiveness of the drug for an indi-
2 vidual or a population, as the case may be.”.

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