

Union Calendar No. 627

118TH CONGRESS
2^D SESSION

H. R. 4529

[Report No. 118-756]

To amend the Public Health Service Act regarding guidance documents of the Centers for Disease Control and Prevention, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 11, 2023

Mrs. RODGERS of Washington introduced the following bill; which was referred to the Committee on Energy and Commerce

NOVEMBER 19, 2024

Additional sponsor: Mr. CRENSHAW

NOVEMBER 19, 2024

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italie*]

[For text of introduced bill, see copy of bill as introduced on July 11, 2023]

A BILL

To amend the Public Health Service Act regarding guidance documents of the Centers for Disease Control and Prevention, 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 “Public Health Guidance*
5 *Transparency and Accountability Act of 2023”.*

6 **SEC. 2. CDC GUIDANCE DOCUMENTS.**

7 *The Public Health Service Act (42 U.S.C. 201 et seq.)*
8 *is amended by inserting after section 317V of such Act (42*
9 *U.S.C. 247b–24) the following:*

10 **“SEC. 317W. CDC GUIDANCE DOCUMENTS.**

11 *“(a) GOOD GUIDANCE PRACTICES.—*

12 *“(1) IN GENERAL.—The Secretary, acting*
13 *through the Director of the Centers for Disease Con-*
14 *trol and Prevention (in this section referred to as the*
15 *‘Secretary’), shall, by regulation, develop, establish,*
16 *and maintain good guidance practices setting forth*
17 *the policies and procedures of the Centers for the de-*
18 *velopment, issuance, dissemination, and use of guid-*
19 *ance documents of the Centers for Disease Control and*
20 *Prevention.*

21 *“(2) CONTENTS.—The regulation required by*
22 *paragraph (1) shall—*

23 *“(A) incorporate each requirement of sub-*
24 *sections (b) through (j); and*

1 “(B) require guidance documents of the
2 Centers for Disease Control and Prevention to be
3 developed with public participation.

4 “(3) INITIAL REGULATION.—The Secretary
5 shall—

6 “(A) not later than 30 days after the date
7 of enactment of the Public Health Guidance
8 Transparency and Accountability Act of 2023,
9 initiate the rulemaking process for the initial
10 regulation under paragraph (1); and

11 “(B) not later than 2 years after the date
12 of enactment of the Public Health Guidance
13 Transparency and Accountability Act of 2023,
14 finalize such regulation.

15 “(b) NO CREATION, CONFERRING, RESTRICTING, OR
16 REVOKING OF RIGHTS, RESPONSIBILITIES, OR LIABIL-
17 ITIES.—Guidance documents of the Centers for Disease
18 Control and Prevention may present views on matters
19 under the jurisdiction of the Centers, but shall not—

20 “(1) create, confer, restrict, or revoke any rights,
21 responsibilities, or liabilities for or on any person;

22 “(2) be treated (including in any civil or crimi-
23 nal proceeding) as having the force and effect of law;
24 or

25 “(3) include any provision that—

1 “(A) is binding on the public or a State,
2 local, Tribal, or Territorial government; or

3 “(B) requires an individual to take or re-
4 frain from an action.

5 “(c) TRAINING.—The Secretary shall—

6 “(1) provide training to employees of the Centers
7 for Disease Control and Prevention in how to develop,
8 issue, disseminate, and use guidance documents of the
9 Centers in accordance with the regulation under sub-
10 section (a)(1); and

11 “(2) monitor the development, issuance, dissemi-
12 nation, and use of such documents to ensure compli-
13 ance with the regulation under subsection (a)(1).

14 “(d) PUBLIC PARTICIPATION IN PROCESS.—

15 “(1) IN GENERAL.—Subject to paragraph (2), the
16 Secretary shall ensure that public participation re-
17 quired by subsection (a)(2)(B) occurs prior to final-
18 ization and implementation of any guidance docu-
19 ment of the Centers for Disease Control and Preven-
20 tion, including any guidance document that sets
21 forth—

22 “(A) initial interpretations of a statute, a
23 regulation, or an emerging public health situa-
24 tion;

1 “(B) changes or updates in interpretation
2 or policy that are of more than a minor nature;

3 “(C) complex scientific issues; or

4 “(D) highly controversial issues.

5 “(2) *EXCEPTIONS.*—*The Secretary may provide*
6 *for public participation required by subsection*
7 *(a)(2)(B) with respect to a guidance document of the*
8 *Centers for Disease Control and Prevention to occur*
9 *after the guidance document has been finalized and*
10 *after implementation of the guidance document has*
11 *begun if—*

12 “(A) the Secretary determines that com-
13 mencing public participation sooner is not fea-
14 sible or appropriate; or

15 “(B) the guidance document sets forth only
16 existing practices or minor changes in policy.

17 “(3) *CONSIDERATION.*—*In finalizing, imple-*
18 *menting, and revising a guidance document of the*
19 *Centers for Disease Control and Prevention, the Sec-*
20 *retary shall take into account public comments re-*
21 *ceived during public participation on the guidance*
22 *document.*

23 “(e) *UNIFORM NOMENCLATURE.*—*In developing guid-*
24 *ance documents of the Centers for Disease Control and Pre-*
25 *vention, the Secretary shall ensure uniform nomenclature*

1 *for such documents and uniform internal procedures for ap-*
2 *proval of such documents.*

3 “(f) *INDICATION OF NONBINDING NATURE.*—*The Sec-*
4 *retary shall ensure that guidance documents of the Centers*
5 *for Disease Control and Prevention and revisions of such*
6 *documents are properly dated and indicate the nonbinding*
7 *nature of the documents.*

8 “(g) *PERIODIC REVIEW.*—*The Secretary shall periodi-*
9 *cally review all guidance documents of the Centers for Dis-*
10 *ease Control and Prevention and, where appropriate, revise*
11 *such documents.*

12 “(h) *LIST OF DOCUMENTS.*—*The Secretary shall*
13 *maintain electronically, and update and publish periodi-*
14 *cally in the Federal Register, a list of all guidance docu-*
15 *ments of the Centers for Disease Control and Prevention.*

16 “(i) *PUBLIC AVAILABILITY.*—*The Secretary shall make*
17 *available to the public the list under subsection (h) and all*
18 *guidance documents of the Centers for Disease Control and*
19 *Prevention, including by posting on the public website of*
20 *the Centers.*

21 “(j) *APPEALS MECHANISM.*—*The Secretary shall en-*
22 *sure that an effective appeals mechanism is in place to ad-*
23 *dress complaints that guidance documents of the Centers for*
24 *Disease Control and Prevention are not being developed,*

1 *issued, disseminated, or used in accordance with this sec-*
2 *tion.”.*

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