

[DISCUSSION DRAFT]

118TH CONGRESS
1ST SESSION

H. R. _____

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

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

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 Guid-
5 ance Transparency and Accountability Act of 2023”.

1 **SEC. 2. CDC GUIDANCE DOCUMENTS.**

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

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

6 **“(a) GOOD GUIDANCE PRACTICES.—**

7 **“(1) IN GENERAL.—**The Secretary acting
8 through the Director of the Centers for Disease
9 Control and Prevention (in this section referred to
10 as the ‘Secretary’) shall, by regulation, develop, es-
11 tablish, and maintain good guidance practices set-
12 ting forth the policies and procedures of the Centers
13 for the development, issuance, dissemination, and
14 use of guidance documents.

15 **“(2) CONTENTS.—**The regulation required by
16 paragraph (1) shall—

17 **“(A) incorporate each requirement of sub-**
18 **sections (b) through (k); and**

19 **“(B) require guidance documents to be de-**
20 **veloped with public participation.**

21 **“(3) INITIAL REGULATION.—**The Secretary
22 shall—

23 **“(A) not later than 30 days after the date**
24 **of enactment of the Public Health Guidance**
25 **Transparency and Accountability Act of 2023,**

1 initiate the rulemaking process for the initial
2 regulation under paragraph (1); and

3 “(B) not later than 2 years after the date
4 of enactment of the Public Health Guidance
5 Transparency and Accountability Act of 2023,
6 finalize such regulation.

7 “(b) NO CREATION, CONFERRING, RESTRICTING, OR
8 REVOKING OF RIGHTS, RESPONSIBILITIES, OR LIABIL-
9 ITIES.—Guidance documents of the Centers for Disease
10 Control and Prevention may present views on matters
11 under the jurisdiction of the Centers, but shall not—

12 “(1) create, confer, restrict, or revoke any
13 rights, responsibilities, or liabilities for or on any
14 person;

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

18 “(3) include any provision that—

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

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

23 “(c) EFFECT ON CDC EMPLOYEES AND CONTRAC-
24 TORS.—Although guidance documents of the Centers for
25 Disease Control and Prevention shall not be binding on

1 the Secretary or the Director of the Centers, the Secretary
2 shall ensure that employees and contractors of the Centers
3 do not deviate from such guidance documents without ap-
4 propriate justification and supervisory concurrence.

5 “(d) TRAINING.—The Secretary shall—

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

11 “(2) monitor the development, issuance, dis-
12 semination, and use of such documents to ensure
13 compliance with the regulation under subsection
14 (a)(1).

15 “(e) PUBLIC PARTICIPATION IN PROCESS.—

16 “(1) IN GENERAL.—Subject to paragraph (2),
17 the Secretary shall ensure that public participation
18 required by subsection (a)(2)(B) occurs prior to fi-
19 nalization and implementation of any guidance docu-
20 ment, 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) to occur after the guidance document has
8 been finalized and after implementation of the guid-
9 ance document has begun if—

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

13 “(B) the guidance document sets forth
14 only existing practices or minor changes in pol-
15 icy.

16 “(3) CONSIDERATION.—In finalizing, imple-
17 menting, and revising a guidance document, the Sec-
18 retary shall take into account public comments re-
19 ceived during public participation on the guidance
20 document.

21 “(f) UNIFORM NOMENCLATURE.— In developing
22 guidance documents of the Centers for Disease Control
23 and Prevention, the Secretary shall ensure uniform no-
24 menclature for such documents and uniform internal pro-
25 cedures for approval of such documents.

1 “(g) INDICATION OF NONBINDING NATURE.—The
2 Secretary shall ensure that guidance documents of the
3 Centers for Disease Control and Prevention and revisions
4 of such documents are properly dated and indicate the
5 nonbinding nature of the documents.

6 “(h) PERIODIC REVIEW.—The Secretary shall peri-
7 odically review all guidance documents of the Centers for
8 Disease Control and Prevention and, where appropriate,
9 revise such documents.

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

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

19 “(k) APPEALS MECHANISM.—The Secretary shall en-
20 sure that an effective appeals mechanism is in place to
21 address complaints that guidance documents of the Cen-
22 ters for Disease Control and Prevention are not being de-
23 veloped, issued, disseminated, or used in accordance with
24 this section.”.