

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 4529  
OFFERED BY M . \_\_\_\_\_**

Strike all after the enacting clause and insert the following:

**1 SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Public Health Guid-  
3 ance Transparency and Accountability Act of 2023”.

**4 SEC. 2. CDC GUIDANCE DOCUMENTS.**

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

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

9 “(a) GOOD GUIDANCE PRACTICES.—

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

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

3           “(A) incorporate each requirement of sub-  
4 sections (b) through (j); and

5           “(B) require guidance documents of the  
6 Centers for Disease Control and Prevention to  
7 be developed with public participation.

8           “(3) INITIAL REGULATION.—The Secretary  
9 shall—

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

15           “(B) not later than 2 years after the date  
16 of enactment of the Public Health Guidance  
17 Transparency and Accountability Act of 2023,  
18 finalize such regulation.

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

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

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

7           “(3) include any provision that—

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

10               “(B) requires an individual to take or re-  
11 frair from an action.

12           “(c) TRAINING.—The Secretary shall—

13               “(1) provide training to employees of the Cen-  
14 ters for Disease Control and Prevention in how to  
15 develop, issue, disseminate, and use guidance docu-  
16 ments of the Centers in accordance with the regula-  
17 tion under subsection (a)(1); and

18               “(2) monitor the development, issuance, dis-  
19 semination, and use of such documents to ensure  
20 compliance with the regulation under subsection  
21 (a)(1).

22           “(d) PUBLIC PARTICIPATION IN PROCESS.—

23               “(1) IN GENERAL.—Subject to paragraph (2),  
24 the Secretary shall ensure that public participation  
25 required by subsection (a)(2)(B) occurs prior to fi-

1       nalization and implementation of any guidance docu-  
2       ment of the Centers for Disease Control and Preven-  
3       tion, including any guidance document that sets  
4       forth—

5               “(A) initial interpretations of a statute, a  
6       regulation, or an emerging public health situa-  
7       tion;

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

10              “(C) complex scientific issues; or

11              “(D) highly controversial issues.

12              “(2) EXCEPTIONS.—The Secretary may provide  
13       for public participation required by subsection  
14       (a)(2)(B) with respect to a guidance document of  
15       the Centers for Disease Control and Prevention to  
16       occur after the guidance document has been final-  
17       ized and after implementation of the guidance docu-  
18       ment has begun if—

19              “(A) the Secretary determines that com-  
20       mencing public participation sooner is not fea-  
21       sible or appropriate; or

22              “(B) the guidance document sets forth  
23       only existing practices or minor changes in pol-  
24       icy.

1           “(3) CONSIDERATION.—In finalizing, imple-  
2           menting, and revising a guidance document of the  
3           Centers for Disease Control and Prevention, the  
4           Secretary shall take into account public comments  
5           received during public participation on the guidance  
6           document.

7           “(e) UNIFORM NOMENCLATURE.— In developing  
8           guidance documents of the Centers for Disease Control  
9           and Prevention, the Secretary shall ensure uniform no-  
10          menclature for such documents and uniform internal pro-  
11          cedures for approval of such documents.

12          “(f) INDICATION OF NONBINDING NATURE.—The  
13          Secretary shall ensure that guidance documents of the  
14          Centers for Disease Control and Prevention and revisions  
15          of such documents are properly dated and indicate the  
16          nonbinding nature of the documents.

17          “(g) PERIODIC REVIEW.—The Secretary shall peri-  
18          odically review all guidance documents of the Centers for  
19          Disease Control and Prevention and, where appropriate,  
20          revise such documents.

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

1       “(i) PUBLIC AVAILABILITY.—The Secretary shall  
2 make available to the public the list under subsection (h)  
3 and all guidance documents of the Centers for Disease  
4 Control and Prevention, including by posting on the public  
5 website of the Centers.

6       “(j) APPEALS MECHANISM.—The Secretary shall en-  
7 sure that an effective appeals mechanism is in place to  
8 address complaints that guidance documents of the Cen-  
9 ters for Disease Control and Prevention are not being de-  
10 veloped, issued, disseminated, or used in accordance with  
11 this section.”.

