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.

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 “Public Health Guidance Transparency and Accountability Act of 2023”.

SEC. 2. CDC GUIDANCE DOCUMENTS.

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

"SEC. 317W. CDC GUIDANCE DOCUMENTS.

"(a) GOOD GUIDANCE PRACTICES.—

"(1) IN GENERAL.—The Secretary acting through the Director of the Centers for Disease Control and Prevention (in this section referred to as the ‘Secretary’) shall, by regulation, develop, establish, and maintain good guidance practices setting forth the policies and procedures of the Centers for the development, issuance, dissemination, and use of guidance documents.

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

"(A) incorporate each requirement of subsections (b) through (k); and

"(B) require guidance documents to be developed with public participation.

"(3) INITIAL REGULATION.—The Secretary shall—

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

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

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

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

“(2) be treated (including in any civil or criminal proceeding) as having the force and effect of law; or

“(3) include any provision that—

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

“(B) requires an individual to take or refrain from an action.

“(c) EFFECT ON CDC EMPLOYEES AND CONTRACTORS.—Although guidance documents of the Centers for Disease Control and Prevention shall not be binding on
the Secretary or the Director of the Centers, the Secretary shall ensure that employees and contractors of the Centers do not deviate from such guidance documents without appropriate justification and supervisory concurrence.

“(d) TRAINING.—The Secretary shall—

“(1) provide training to employees of the Centers for Disease Control and Prevention in how to develop, issue, disseminate, and use guidance documents in accordance with the regulation under subsection (a)(1); and

“(2) monitor the development, issuance, dissemination, and use of such documents to ensure compliance with the regulation under subsection (a)(1).

“(e) PUBLIC PARTICIPATION IN PROCESS.—

“(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall ensure that public participation required by subsection (a)(2)(B) occurs prior to finalization and implementation of any guidance document, including any guidance document that sets forth—

“(A) initial interpretations of a statute, a regulation, or an emerging public health situation;
“(B) changes or updates in interpretation or policy that are of more than a minor nature;
“(C) complex scientific issues; or
“(D) highly controversial issues.
“(2) EXCEPTIONS.—The Secretary may provide for public participation required by subsection (a)(2)(B) to occur after the guidance document has been finalized and after implementation of the guidance document has begun if—
“(A) the Secretary determines that commencing public participation sooner is not feasible or appropriate; or
“(B) the guidance document sets forth only existing practices or minor changes in policy.
“(3) CONSIDERATION.—In finalizing, implementing, and revising a guidance document, the Secretary shall take into account public comments received during public participation on the guidance document.
“(f) UNIFORM NOMENCLATURE.—In developing guidance documents of the Centers for Disease Control and Prevention, the Secretary shall ensure uniform nomenclature for such documents and uniform internal procedures for approval of such documents.
“(g) INDICATION OF NONBINDING NATURE.—The Secretary shall ensure that guidance documents of the Centers for Disease Control and Prevention and revisions of such documents are properly dated and indicate the nonbinding nature of the documents.

“(h) PERIODIC REVIEW.—The Secretary shall periodically review all guidance documents of the Centers for Disease Control and Prevention and, where appropriate, revise such documents.

“(i) LIST OF DOCUMENTS.—The Secretary shall maintain electronically and update and publish periodically in the Federal Register a list of all guidance documents of the Centers for Disease Control and Prevention.

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

“(k) APPEALS MECHANISM.—The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that guidance documents of the Centers for Disease Control and Prevention are not being developed, issued, disseminated, or used in accordance with this section.”.