

PUBLIC HEALTH GUIDANCE TRANSPARENCY AND  
ACCOUNTABILITY ACT OF 2023

NOVEMBER 19, 2024.—Committed to the Committee of the Whole House on the  
State of the Union and ordered to be printed

Mrs. RODGERS of Washington, from the Committee on Energy and  
Commerce, submitted the following

R E P O R T

together with

MINORITY VIEWS

[To accompany H.R. 4529]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4529) to amend the Public Health Service Act regarding guidance documents of the Centers for Disease Control and Prevention, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:  
Strike all after the enacting clause and insert the following:

**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 of the Centers for Disease Control and Prevention.

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

**“(A) incorporate each requirement of subsections (b) through (j); and**

**“(B) require guidance documents of the Centers for Disease Control and Prevention 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) 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 of the Centers 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).**

**“(d) 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 of the Centers for Disease Control and Prevention, 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) with respect to a guidance document of the Centers for Disease Control and Prevention 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 of the Centers for Disease Control and Prevention, the Secretary shall take into account public comments received during public participation on the guidance document.

“(e) 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.

“(f) 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.

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

“(h) 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.

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

“(j) 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.”.

#### PURPOSE AND SUMMARY

H.R. 4529, the “Public Health Guidance Transparency and Accountability Act of 2023,” would direct the Director of the Centers for Disease Control and Prevention (CDC) to, through regulation, develop and maintain good guidance practices for the issuance and use of guidance documents. The bill would establish requirements for public participation in the development of any CDC guidance document and direct the Secretary to maintain public availability of guidance documents and conduct periodic review of such documents.

#### BACKGROUND AND NEED FOR LEGISLATION

Federal agencies may issue guidance documents to provide the public and regulated industry with an agency’s interpretation of existing statute and regulations, or to communicate administrative priorities and policy initiatives. These documents are non-binding and do not carry the force of law; however, guidance documents are typically subject to fewer procedural requirements, such as public notice-and-comment, and guidance is not necessarily subject to judicial review after issuance. Efforts to set forth best practices in the development and implementation of guidance and other interpretative agency documents have been advanced in past congresses, as authorized by the Administrative Procedure Act (APA).

The COVID–19 public health emergency highlighted procedural limitations in the CDC guidance development process in providing opportunities for public participation and preventing undue coercion of regulated parties. Guidance documents issued throughout the COVID–19 pandemic related to the use of masks, considerations of school closures, and distance recommendations to prevent transmission of COVID–19, were issued without public notice-and-comment and seemingly understood by the public as enforceable law rather than agency guidance.

H.R. 4529 would establish good guidance practices for the development and dissemination of guidance documents issued by the CDC, which would include processes for public participation and periodic review, and appropriate revision, of issued guidance by the CDC Director.

#### COMMITTEE ACTION

On June 13, 2023, the Subcommittee on Health held a hearing on H.R. 4529. The title of the hearing was “Legislative Solutions to Bolster Preparedness and Response for All Hazards and Public Health Security Threats.” The Subcommittee received testimony from:

- Gerald Parker, DVM, PhD, Associate Dean for Global One Health and Director for the Pandemic and Biosecurity Policy Program, Texas A&M University;
- Raynard Washington, PhD, MPH, Director, Public Health Department, Mecklenburg County Health and Human Services Agency Mecklenburg County, North Carolina;
- Phyllis Arthur, MBA, Senior Vice President, Infectious Disease and Emerging Science Policy, Biotechnology Innovation Organization (BIO);
- Julie R. Galow, MD, FACP, FASCO, Chief Medical Officer and Executive Vice President, American Society of Clinical Oncology; and
- Ted Okon, MBA, Executive Director, Community Oncology Alliance.

On July 13, 2023, the Subcommittee on Health met in open markup session and forwarded H.R. 4529, without amendment, to the full Committee by a record vote of 14 yeas and 11 nays.

On July 19, 2023, the Committee on Energy and Commerce met in open markup session and ordered H.R. 4529, as amended, favorably reported to the House by a record vote of 25 yeas and 21 nays.

#### COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

**COMMITTEE ON ENERGY AND COMMERCE  
118TH CONGRESS  
ROLL CALL VOTE # 10**

**BILL:** H.R. 4529, the Public Health Guidance Transparency and Accountability Act of 2023

**AMENDMENT:** A motion by Mrs. Rodgers to order H.R. 4529 favorably reported to the House, as amended (Final Passage).

**DISPOSITION:** **AGREED TO**, by a roll call vote of 25 yeas to 21 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Rodgers	X			Rep. Pallone		X	
Rep. Burgess	X			Rep. Eshoo		X	
Rep. Latta	X			Rep. DeGette		X	
Rep. Guthrie	X			Rep. Schakowsky		X	
Rep. Griffith				Rep. Matsui		X	
Rep. Bilirakis	X			Rep. Castor		X	
Rep. Johnson	X			Rep. Sarbanes		X	
Rep. Bucshon	X			Rep. Tonko		X	
Rep. Hudson	X			Rep. Clarke		X	
Rep. Walberg	X			Rep. Cárdenas		X	
Rep. Carter	X			Rep. Ruiz		X	
Rep. Duncan	X			Rep. Peters		X	
Rep. Palmer				Rep. Dingell		X	
Rep. Dunn				Rep. Veasey		X	
Rep. Curtis				Rep. Kuster		X	
Rep. Lesko	X			Rep. Kelly		X	
Rep. Pence	X			Rep. Barragán		X	
Rep. Crenshaw	X			Rep. Blunt Rochester			
Rep. Joyce	X			Rep. Soto		X	
Rep. Armstrong	X			Rep. Craig			
Rep. Weber	X			Rep. Schrier		X	
Rep. Allen	X			Rep. Trahan		X	
Rep. Balderson	X			Rep. Fletcher		X	
Rep. Fulcher	X						
Rep. Pfluger	X						
Rep. Harshbarger	X						
Rep. Miller-Meecks	X						
Rep. Cammack	X						
Rep. Obernolte	X						

07/19/2023

#### OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held hearings and made findings that are reflected in this report.

#### NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 4529 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

#### CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, at the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

#### FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

#### STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to establish public participation requirements prior to finalization or implementation of guidance developed and disseminated by the CDC.

#### DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 4529 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

#### RELATED COMMITTEE AND SUBCOMMITTEE HEARINGS

Pursuant to clause 3(c)(6) of rule XIII, the following hearing was used to develop or consider H.R. 4529:

- On June 13, 2023, the Subcommittee on Health held a hearing on H.R. 4529. The title of the hearing was “Legislative Solutions to Bolster Preparedness and Response for All Hazards and Public Health Security Threats.” The Subcommittee received testimony from:
  - Gerald Parker, DVM, PhD, Associate Dean for Global One Health and Director for the Pandemic and Biosecurity Policy Program, Texas A&M University;
  - Raynard Washington, PhD, MPH, Director, Public Health Department, Mecklenburg, County Health and Human Services Agency Mecklenburg County, North Carolina;

- Phyllis Arthur, MBA, Senior Vice President, Infectious Disease and Emerging Science Policy, Biotechnology Innovation Organization (BIO);
- Julie R. Gralow, MD, FACP, FASCO, Chief Medical Officer and Executive Vice President, American Society of Clinical Oncology; and
- Ted Okon, MBA, Executive Director, Community Oncology Alliance.

#### COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

#### EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 4529 contains no earmarks, limited tax benefits, or limited tariff benefits.

#### ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

#### APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

#### SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

##### *Section 1. Short title*

Section 1 provides a short title of “Public Health Guidance Transparency and Accountability Act of 2023”.

##### *Section 2. CDC guidance documents*

Section 2 amends the Public Health Service Act to establish public participation requirements prior to finalization or implementation of guidance developed, issued, and disseminated by the CDC. It also states that CDC guidance documents should not restrict or revoke any person’s rights, responsibilities, or liabilities. Additionally, this section establishes requirements for uniform nomenclature for CDC guidance documents and uniform internal procedures for approval of such documents. Lastly, section 2 clarifies that CDC guidance does not have the force or effect of the law.

#### CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italics)

and existing law in which no change is proposed is shown in roman):

**PUBLIC HEALTH SERVICE ACT**

\* \* \* \* \*

**TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE**

\* \* \* \* \*

**PART B—FEDERAL-STATE COOPERATION**

\* \* \* \* \*

**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 of the Centers for Disease Control and Prevention.*

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

*(A) incorporate each requirement of subsections (b) through (j); and*

*(B) require guidance documents of the Centers for Disease Control and Prevention 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) 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 of the Centers 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).

(d) **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 of the Centers for Disease Control and Prevention, 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) with respect to a guidance document of the Centers for Disease Control and Prevention 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 of the Centers for Disease Control and Prevention, the Secretary shall take into account public comments received during public participation on the guidance document.

(e) **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.

(f) **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.

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

(h) **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.

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

(j) **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 Preven-

*tion are not being developed, issued, disseminated, or used in accordance with this section.*

\* \* \* \* \*

## MINORITY VIEWS

H.R. 4529, the Public Health Guidance Transparency and Accountability Act, would limit the flexibility of the Centers for Disease Control and Prevention (CDC) in drafting guidance that adequately disseminates critical health information according to the best science of the agency's public health experts. CDC routinely issues public health awareness guidance that is geared toward both public health professionals as well as members of the general public. Adding hurdles to the agency's process for publishing this guidance could stunt public health response efforts at the federal, state, and local levels.

Throughout the COVID-19 pandemic, we learned how important it is for CDC and other public health agencies to be nimble and to adapt their processes and their guidance to address quickly changing data and emerging science. We also learned the critical importance of strong two-way communication between federal public health agencies and their state, local, and community partners.

Rather than building on these lessons, H.R. 4529 would undercut them. According to technical assistance received by the committee, this legislation could be interpreted to limit the CDC's ability to provide infection prevention and control guidance that is designed to improve the safety of patients, nursing home residents, and health care workers. This kind of limitation would endanger patients and providers, and result in increased confusion around public health risks.

Rather than undermining our public health institutions, we should be working to enhance the nimbleness of CDC and other public health agencies so that they are able to respond to emergency quickly and effectively. This includes meaningfully improving the ability of CDC to collect, analyze, and share data as well as provide guidance on the public health response to such data to our state and local partners and the public.

H.R. 4529 would hamper CDC's ability to disseminate vitally important guidance to the public on how to best respond to crises and impede public health response efforts at every level.

FRANK PALLONE, Jr.  
*Ranking Member.*

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