

AMENDMENT NO. 1 Calendar No. \_\_\_\_\_

Purpose: To amend the Public Health Service Act to provide for waivers of the Paperwork Reduction Act during public health emergencies.

**IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.**

**S. 2700**

To update the authorizing provisions relating to the workforces of the National Institutes of Health and the Food and Drug Administration, and for other purposes.

Referred to the Committee on \_\_\_\_\_ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. Burr and Mr. Casey

Viz:

- 1 At the appropriate place, insert the following:
- 2 **SEC. \_\_\_\_ . PAPERWORK REDUCTION ACT WAIVER DURING A**
- 3 **PUBLIC HEALTH EMERGENCY.**

4 Section 319 of the Public Health Service Act (42  
5 U.S.C. 247d) is amended by adding at the end the fol-  
6 lowing:

7 “(f) DETERMINATION WITH RESPECT TO PAPER-  
8 WORK REDUCTION ACT WAIVER DURING A PUBLIC  
9 HEALTH EMERGENCY.—

1           “(1) DETERMINATION.—If the Secretary deter-  
2           mines, after consultation with such public health of-  
3           ficials as may be necessary, that—

4                   “(A)(i) the criteria set forth for a public  
5                   health emergency under paragraph (1) or (2) of  
6                   subsection (a) has been met; or

7                   “(ii) a disease or disorder, including a  
8                   novel and emerging public health threat, is sig-  
9                   nificantly likely to become a public health emer-  
10                  gency; and

11                  “(B) the circumstances of such public  
12                  health emergency, or potential for such signifi-  
13                  cantly likely public health emergency, including  
14                  the specific preparation for and response to  
15                  such public health emergency or threat, neces-  
16                  sitate a waiver from the requirements of sub-  
17                  chapter I of chapter 35 of title 44, United  
18                  States Code (commonly referred to as the Pa-  
19                  perwork Reduction Act);

20           then the requirements of such subchapter I with re-  
21           spect to voluntary collection of information shall not  
22           be applicable during the immediate investigation of,  
23           and response to, such public health emergency dur-  
24           ing the period of such public health emergency or  
25           the period of time necessary to determine if a dis-

1 case or disorder, including a novel and emerging  
2 public health threat, will become a public health  
3 emergency as provided for in this paragraph. The re-  
4 quirements of such subchapter I with respect to vol-  
5 untary collection of information shall not be applica-  
6 ble during the immediate post-response review re-  
7 garding such public health emergency if such imme-  
8 diate post-response review does not exceed a reason-  
9 able length of time.

10 “(2) TRANSPARENCY.—If the Secretary deter-  
11 mines that a waiver is necessary under paragraph  
12 (1), the Secretary shall promptly post on the Inter-  
13 net website of the Department of Health and  
14 Human Services a brief justification for such waiver,  
15 the anticipated period of time such waiver will be in  
16 effect, and the agencies and offices within the De-  
17 partment of Health and Human Services to which  
18 such waiver shall apply, and update such informa-  
19 tion posted on the Internet website of the Depart-  
20 ment of Health and Human Services, as applicable.

21 “(3) EFFECTIVENESS OF WAIVER.—Any waiver  
22 under this subsection shall take effect on the date on  
23 which the Secretary posts information on the Inter-  
24 net website as provided for in this subsection.

1           “(4) TERMINATION OF WAIVER.—Upon deter-  
2           mining that the circumstances necessitating a waiver  
3           under paragraph (1) no longer exist, the Secretary  
4           shall promptly update the Internet website of the  
5           Department of Health and Human Services to re-  
6           flect the termination of such waiver.

7           “(5) LIMITATIONS.—

8           “(A) PERIOD OF WAIVER.—The period of  
9           a waiver under paragraph (1) shall not exceed  
10          the period of time for the related public health  
11          emergency, including a public health emergency  
12          declared pursuant to subsection (a), and any  
13          immediate post-response review regarding the  
14          public health emergency consistent with the re-  
15          quirements of this subsection.

16          “(B) SUBSEQUENT COMPLIANCE.—An ini-  
17          tiative subject to a waiver under paragraph (1)  
18          that is ongoing after the date on which the  
19          waiver expires, shall be subject to the require-  
20          ments of subchapter I of chapter 35 of title 44,  
21          United States Code, and the Secretary shall en-  
22          sure that compliance with such requirements  
23          occurs in as timely a manner as possible based  
24          on the applicable circumstances, but not to ex-

1           ceed 30 calendar days after the expiration of  
2           the applicable waiver.”.