

115TH CONGRESS  
2D SESSION

# H. R. 4938

To address the opioid epidemic, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 6, 2018

Ms. KUSTER of New Hampshire introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, Ways and Means, Education and the Workforce, and the Budget, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To address the opioid epidemic, 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 “Respond to the Needs  
5 in the Opioid War Act” or the “Respond NOW Act”.

6 **TITLE I—OPIOID EPIDEMIC**  
7 **RESPONSE FUND**

8 **SEC. 101. OPIOID EPIDEMIC RESPONSE FUND.**

9 (a) IN GENERAL.—The Secretary of Health and  
10 Human Services (referred to in this section as the “Sec-

1   retary”) shall use any funds appropriated pursuant to the  
2   authorization of appropriations under subsection (c) to  
3   carry out the programs and activities described in sub-  
4   section (d) to address the opioid and substance use epi-  
5   demic. Such funds shall be in addition to any funds which  
6   are otherwise available to carry out such programs and  
7   activities.

8       (b) OPIOID EPIDEMIC RESPONSE FUND.—

9           (1) ESTABLISHMENT OF ACCOUNT.—There is  
10       established in the Treasury an account, to be known  
11       as the Opioid Epidemic Response Fund (referred to  
12       in this subsection as the “Funds”), for purposes of  
13       funding the programs and activities described in  
14       subsection (d).

15          (2) TRANSFER.—For each of fiscal years 2018  
16       through 2022, \$5,000,000,000 shall be transferred  
17       to the Fund from the general fund of the Treasury.

18          (3) AMOUNTS DEPOSITED.—Any amounts  
19       transferred under paragraph (2) shall remain un-  
20       available in the Fund until such amounts are appro-  
21       priated pursuant to subsection (c).

22       (c) APPROPRIATIONS.—

23          (1) AUTHORIZATION OF APPROPRIATIONS.—For  
24       the period of fiscal years 2018 through 2022, there  
25       is authorized to be appropriated from the Fund to

1 the Department of Health and Human Services, for  
2 the purpose of carrying out the programs and activi-  
3 ties described in subsection (d), an amount not to  
4 exceed the total amount transferred to the Fund  
5 under subsection (b)(2), to remain available until ex-  
6 pended.

7 (2) OFFSETTING FUTURE APPROPRIATIONS.—  
8 For any of fiscal years 2018 through 2022, for any  
9 discretionary appropriation to the Department of  
10 Health and Human Services (or any agency therein)  
11 pursuant to the authorization of appropriations  
12 under paragraph (1) for the purpose of carrying out  
13 the programs and activities described in subsection  
14 (d), the total amount of such appropriations for the  
15 applicable fiscal year (not to exceed the total amount  
16 remaining in the Account) shall be subtracted from  
17 the estimate of discretionary budget authority and  
18 the resulting outlays for any estimate under the  
19 Congressional Budget and Impoundment Control  
20 Act of 1974 or the Balanced Budget and Emergency  
21 Deficit Control Act of 1985, and the amount trans-  
22 ferred to the Fund shall be reduced by the same  
23 amount.

24 (d) PROGRAMS AND ACTIVITIES.—Of the total  
25 amount authorized to be appropriated from the Fund to

1 the Department of Health and Human Services by sub-  
2 section (c)(1), such amount shall be allocated as follows:

3 (1) SAMHSA.—For the Substance Abuse and  
4 Mental Health Services Administration to carry out  
5 programs and activities pursuant to section 102,  
6 \$3,650,000,000 for each of fiscal years 2018  
7 through 2022.

8 (2) CDC.—For the Centers for Disease Control  
9 and Prevention to carry out programs and activities  
10 pursuant to section 103, \$500,000,000 for each of  
11 fiscal years 2018 through 2022.

12 (3) FDA.—For the Food and Drug Adminis-  
13 tration to carry out programs and activities pursu-  
14 ant to section 104, \$65,000,000 for each of fiscal  
15 years 2018 through 2022.

16 (4) NIH.—For the National Institutes of  
17 Health to carry out programs and activities pursu-  
18 ant to section 105, \$500,000,000 for each of fiscal  
19 years 2018 through 2022.

20 (5) HRSA.—For the Health Resources and  
21 Services Administration to carry out programs and  
22 activities pursuant to section 106, \$235,000,000 for  
23 each of fiscal years 2018 through 2022.

24 (6) ACF.—For the Administration for Children  
25 and Families to carry out programs and activities

pursuant to section 107, \$50,000,000 for each of fiscal years 2018 through 2022.

(e) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a work plan including the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (c) for each of fiscal years 2018 through 2022 and the contents described in subparagraph (B).

(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—

(i) the amount of money to be obligated or expended out of the Fund in each fiscal year for each program and activity described in subsection (d); and

1 (ii) a description and justification of  
2 each such program and activity.

3 (2) REPORTS.—

4 (A) ANNUAL REPORTS.—Not later than  
5 October 1 of each of fiscal years 2019 through  
6 2023, the Secretary of Health and Human  
7 Services shall submit to the Committee on  
8 Health, Education, Labor, and Pensions and  
9 the Committee on Appropriations of the Senate  
10 and the Committee on Energy and Commerce  
11 and the Committee on Appropriations of the  
12 House of Representatives, a report including—

13 (i) the amount of money obligated or  
14 expended out of the Fund in the prior fis-  
15 cal year for each program and activity de-  
16 scribed in subsection (d);

17 (ii) a description of all programs and  
18 activities using funds provided pursuant to  
19 the authorization of appropriations under  
20 subsection (c); and

21 (iii) how the programs and activities  
22 are responding to the opioid epidemic.

23 (B) ADDITIONAL REPORTS.—At the re-  
24 quest of the Committee on Health, Education,  
25 Labor, and Pensions or the Committee on Ap-

1           appropriations of the Senate, or the Committee on  
2           Energy and Commerce or the Committee on  
3           Appropriations of the House of Representatives,  
4           the Commissioner shall provide an update in  
5           the form of testimony and any additional re-  
6           ports to the respective congressional committee  
7           regarding the allocation of funding under this  
8           section or the description of the programs and  
9           activities undertaken with such funding.

10       (f) LIMITATIONS.—Notwithstanding any transfer au-  
11       thority authorized by this Act or any appropriations Act,  
12       any funds made available pursuant to the authorization  
13       of appropriations under subsection (c) may not be used  
14       for any purpose other than the programs and activities  
15       described in subsection (d) to address the opioid and sub-  
16       stance use epidemic.

17       (g) SUNSET.—This section shall expire at the end of  
18       fiscal year 2027.

19       **SEC. 102. SUBSTANCE ABUSE AND MENTAL HEALTH SERV-**  
20                               **ICES ADMINISTRATION.**

21       The entirety of the funds made available pursuant to  
22       section 101(d)(1) shall be for carrying out subsections (c)  
23       and (d) of section 1003 of the 21st Century Cures Act,  
24       as amended by section 203.

1 **SEC. 103. CENTERS FOR DISEASE CONTROL AND PREVEN-**  
2 **TION.**

3 (a) ADDRESSING OPIOID USE DISORDER.—The en-  
4 tirety of the funds made available pursuant to section  
5 101(d)(2) shall be for the Director of the Centers for Dis-  
6 ease Control and Prevention, pursuant to applicable au-  
7 thorities in the Public Health Service Act (42 U.S.C. 201  
8 et seq.), to continue and expand programs of the Centers  
9 for Disease Control and Prevention to address opioid use  
10 disorder, including by—

11 (1) improving the timeliness and quality of data  
12 on the opioid epidemic, including improvement of—

13 (A) data on fatal and nonfatal overdoses;

14 (B) syndromic surveillance;

15 (C) data on long-term sequelae (including  
16 neonatal abstinence syndrome); and

17 (D) cause of death reporting related to  
18 substance abuse or opioid overdose;

19 (2) expanding and strengthening evidence-based  
20 prevention and education strategies;

21 (3) supporting responsible prescribing practices,  
22 including through development and dissemination of  
23 prescriber guidelines;

24 (4) improving access to and use of effective pre-  
25 vention, treatment, and recovery support, including

1 through grants and the provision of technical assist-  
2 ance to States and localities;

3 (5) strengthening partnerships with first re-  
4 sponders, including to protect their safety;

5 (6) considering the needs of vulnerable popu-  
6 lations;

7 (7) addressing infectious diseases linked to the  
8 opioid crisis; and

9 (8) strengthening prescription drug monitoring  
10 programs.

11 (b) LIMITATION.—Of the funds made available pur-  
12 suant to section 101(d)(2) for carrying out this section,  
13 not more than 20 percent may be used for intramural pur-  
14 poses.

15 **SEC. 104. FOOD AND DRUG ADMINISTRATION.**

16 The entirety of the funds made available pursuant to  
17 section 101(d)(3) shall be for the Commissioner of Food  
18 and Drugs, pursuant to applicable authorities in the Pub-  
19 lic Health Service Act (42 U.S.C. 201 et seq.) or the Fed-  
20 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et  
21 seq.) and other applicable law, to support widespread inno-  
22 vation in non-opioid and non-addictive medical products  
23 for pain treatment, access to opioid addiction treatments,  
24 appropriate use of approved opioids, and efforts to reduce

1 illicit importation of opioids. Such support may include the  
2 following:

3           (1) Facilitating the development of non-opioid  
4           and non-addictive pain treatments.

5           (2) Advancing guidance documents for sponsors  
6           of non-opioid pain products.

7           (3) Developing evidence to inform the potential  
8           for nonprescription overdose therapies.

9           (4) Examining expanded labeling indications for  
10          medication-assisted treatment.

11          (5) Conducting public education and outreach,  
12          including public workshops or public meetings, re-  
13          garding the benefits of medication-assisted treat-  
14          ment, and approved non-opioid drug and device  
15          treatment options.

16          (6) Exploring the expansion and possible man-  
17          datory nature of prescriber education regarding pain  
18          management and appropriate opioid prescribing  
19          through authorities under section 505–1 of the Fed-  
20          eral Food, Drug, and Cosmetic Act (21 U.S.C. 355–  
21          1).

22          (7) Examining options to limit the duration of  
23          opioid prescriptions for acute pain, including  
24          through packaging options.

1           (8) Increasing staff and infrastructure capacity  
2       to inspect and analyze packages at international  
3       mail facilities and pursue criminal investigations.

4   **SEC. 105. NATIONAL INSTITUTES OF HEALTH.**

5       The entirety of the funds made available pursuant to  
6   section 101(d)(4) shall be for the Director of the National  
7   Institutes of Health, pursuant to applicable authorities in  
8   the Public Health Service Act (42 U.S.C. 201 et seq.),  
9   to carry out activities related to—

10           (1) accelerating research for addressing the  
11       opioid epidemic, including developing non-opioid  
12       medications and interventions, including non-addict-  
13       ive medications, to manage pain, as well as to treat  
14       and to prevent substance use disorders;

15           (2) conducting and supporting research on  
16       which treatments (in terms of pain management as  
17       well as treating and preventing substance use dis-  
18       orders) are optimal for which patients; and

19           (3) conducting and supporting research on cre-  
20       ating longer-lasting or faster-acting antidotes for  
21       opioid overdose, particularly in response to the prev-  
22       alence of fentanyl and carfentanyl overdoses.

1 **SEC. 106. HEALTH RESOURCES AND SERVICES ADMINIS-**  
2 **TRATION.**

3       The entirety of the funds made available pursuant to  
4 section 101(d)(5) shall be for the Administrator of the  
5 Health Resources and Services Administration, pursuant  
6 to applicable authorities in titles III, VII, and VIII of the  
7 Public Health Service Act (42 U.S.C. 241 et seq.), to  
8 carry out activities that increase the availability and ca-  
9 pacity of the behavioral health workforce. Such activities  
10 may include providing loan repayment assistance for sub-  
11 stance abuse treatment providers.

12 **SEC. 107. ADMINISTRATION FOR CHILDREN AND FAMILIES.**

13       Of the funds made available pursuant to section  
14 101(d)(6) for each of fiscal years 2018 through 2022—

15           (1) \$25,000,000 for each such fiscal year shall  
16       be for the Secretary of Health and Human Services  
17       to carry out title I of the Child Abuse Prevention  
18       and Treatment Act (42 U.S.C. 5101 et seq.); and

19           (2) \$25,000,000 for each such fiscal year shall  
20       be for the Secretary of Health and Human Services  
21       to carry out title II of such Act (42 U.S.C. 5116 et  
22       seq.).

1 **TITLE II—ADDITIONAL INVEST-**  
2 **MENTS IN EXISTING PRO-**  
3 **GRAMS TO RESPOND TO THE**  
4 **OPIOID EPIDEMIC**

5 **SEC. 201. INCREASE IN FUNDING FOR REGIONAL PARTNER-**  
6 **SHIP GRANTS.**

7 Section 436 of the Social Security Act (42 U.S.C.  
8 629f) is amended—

9 (1) in subsection (a), by striking  
10 “\$345,000,000 for each of fiscal years 2012 through  
11 2016” and inserting “\$385,000,000 for each of fis-  
12 cal years 2018 through 2023”; and

13 (2) in subsection (b)—

14 (A) in paragraph (4)(A), by striking “2012  
15 through 2016” and inserting “2018 through  
16 2023”; and

17 (B) in paragraph (5), by striking  
18 “\$20,000,000 for each of fiscal years 2012  
19 through 2016” and inserting “\$60,000,000 for  
20 each of fiscal years 2018 through 2023”.

21 **SEC. 202. ACCOUNT FOR THE STATE AND TRIBAL RE-**  
22 **SPONSE TO THE OPIOID ABUSE CRISIS.**

23 Section 1003 of the 21st Century Cures Act (42  
24 U.S.C. 290ee–3 note) is amended—

1 (1) in subsection (b)(2), by amending subpara-  
2 graph (A) to read as follows:

3 “(A) IN GENERAL.—The following  
4 amounts shall be transferred to the Account  
5 from the general fund of the Treasury:

6 “(i) For fiscal year 2017,  
7 \$500,000,000.

8 “(ii) For each of fiscal years 2018  
9 through 2022, \$3,750,000,000.”;

10 (2) in subsection (b)(2), by adding at the end  
11 the following:

12 “(C) SET ASIDE.—Of the amount trans-  
13 ferred pursuant to subparagraph (A) for each  
14 of fiscal years 2018 through 2022, 3 percent  
15 shall be set aside for Indian tribes, tribal orga-  
16 nizations, and Urban Indian organizations (as  
17 such terms are defined in section 4 of the In-  
18 dian Health Care Improvement Act).”;

19 (3) in subsection (c)(1), by striking the second  
20 sentence and inserting the following: “In awarding  
21 such grants and allocating funds pursuant to such  
22 grants among the States, the Secretary shall account  
23 for the prevalence of opioid use disorders and deaths  
24 from overdose, including taking into account which  
25 States are hardest hit by the opioid epidemic.”;

1           (4) by redesignating subsection (f) as sub-  
2           section (g); and

3           (5) by inserting after subsection (e) the fol-  
4           lowing:

5           “(f) DEFINITION.—In this section, the term ‘State’  
6 includes an Indian tribe, tribal organization, and Urban  
7 Indian organization (as such terms are defined in section  
8 4 of the Indian Health Care Improvement Act).”.

## 9       **TITLE III—EXPANDING ACCESS** 10       **TO TREATMENT SERVICES**

### 11   **SEC. 301. ALLOWING FOR MORE FLEXIBILITY WITH RE-** 12                   **SPECT TO MEDICATION-ASSISTED TREAT-** 13                   **MENT FOR OPIOID USE DISORDERS.**

14       (a) CONFORMING APPLICABLE NUMBER.—Subclause  
15 (II) of section 303(g)(2)(B)(iii) of the Controlled Sub-  
16 stances Act (21 U.S.C. 823(g)(2)(B)(iii)) is amended to  
17 read as follows:

18                               “(II) The applicable number is—  
19                               “(aa) 100 if, not sooner  
20                               than 1 year after the date on  
21                               which the practitioner submitted  
22                               the initial notification, the practi-  
23                               tioner submits a second notifica-  
24                               tion to the Secretary of the need

1 and intent of the practitioner to  
2 treat up to 100 patients;

3 “(bb) 100 if the practitioner  
4 holds additional credentialing, as  
5 defined in section 8.2 of title 42,  
6 Code of Federal Regulations (or  
7 successor regulations);

8 “(cc) 100 if the practitioner  
9 provides medication-assisted  
10 treatment (MAT) using covered  
11 medications (as defined in section  
12 8.2 of title 42, Code of Federal  
13 Regulations (or successor regula-  
14 tions)) in a qualified practice set-  
15 ting (as described in section  
16 8.615 of title 42, Code of Federal  
17 Regulations (or successor regula-  
18 tions)); or

19 “(dd) 275 if the practitioner  
20 meets the requirements specified  
21 in section 8.610 of title 42, Code  
22 of Federal Regulations (or suc-  
23 cessor regulations).”.

24 (b) ELIMINATING ANY TIME LIMITATION FOR NURSE  
25 PRACTITIONERS, CLINICAL NURSE SPECIALISTS, CER-

1 TIFIED REGISTERED NURSE ANESTHETISTS, CERTIFIED  
 2 NURSE MIDWIVES, AND PHYSICIAN ASSISTANTS TO BE-  
 3 COME QUALIFYING PRACTITIONERS.—Section  
 4 303(g)(2)(G)(iii)(II) of the Controlled Substances Act (21  
 5 U.S.C. 823(g)(2)(G)(iii)(II)) is amended by striking “dur-  
 6 ing the period beginning on the date of enactment of the  
 7 Comprehensive Addiction and Recovery Act of 2016 and  
 8 ending on October 1, 2021” and inserting “beginning on  
 9 the date of enactment of the Comprehensive Addiction and  
 10 Recovery Act of 2016”.

11 (c) DEFINITION OF QUALIFYING OTHER PRACTI-  
 12 TIONER.—Clause (iv) of section 303(g)(2)(G) of the Con-  
 13 trolled Substances Act (21 U.S.C. 823(g)(2)(G)) is  
 14 amended by striking “nurse practitioner or physician as-  
 15 sistant” each place it appears and inserting “nurse practi-  
 16 tioner, clinical nurse specialist, certified registered nurse  
 17 anesthetist, certified nurse midwife, or physician assist-  
 18 ant”.

19 **SEC. 302. COVERAGE OF METHADONE UNDER MEDICARE**

20 **PART B.**

21 (a) COVERAGE.—Section 1861(s)(2) of the Social Se-  
 22 curity Act (42 U.S.C. 1395x(s)(2)) is amended—

23 (1) by striking “and” at the end of subpara-  
 24 graph (FF);

1           (2) by adding “and” at the end of subpara-  
 2 graph (GG); and

3           (3) by inserting after subparagraph (GG) the  
 4 following new subparagraph:

5           “(HH) methadone, if furnished or dis-  
 6 pensed (including by prescription) in an oral  
 7 form on or after January 1, 2018, to an indi-  
 8 vidual for the purpose of maintenance or detoxi-  
 9 fication treatment by a physician or other prac-  
 10 titioner who has in effect a registration or waiv-  
 11 er under section 303(g) of such Act (21 U.S.C.  
 12 823(g)) to dispense methadone for such pur-  
 13 pose;”.

14       (b) PAYMENT.—

15           (1) IN CONNECTION WITH PHYSICIAN AND SUP-  
 16 PLIER SERVICE.—Section 1842(o)(1) of the Social  
 17 Security Act (42 U.S.C. 1395u(o)(1)) is amended by  
 18 adding at the end the following new subparagraph:

19           “(H) In the case of methadone (as de-  
 20 scribed in section 1861(s)(2)(HH)), the amount  
 21 provided under section 1847A for such drug.”.

22           (2) COVERED OPD SERVICE.—Section  
 23 1833(t)(1)(B)(iii) of the Social Security Act (42  
 24 U.S.C. 1395l(t)(1)(B)(iii)) is amended by inserting

1 “and methadone described in paragraph (2)(HH) of  
2 such section” after “section 1861(s)”.

3 (c) BUDGET NEUTRALITY.—The Secretary of Health  
4 and Human Services shall implement the amendments  
5 made by this section in a manner such that—

6 (1) estimated expenditures under the physician  
7 fee schedule under section 1848 of the Social Secu-  
8 rity Act (42 U.S.C. 1395w-4) with application of  
9 such amendments are equal to estimated expendi-  
10 tures under such schedule without application of  
11 such amendments; and

12 (2) estimated expenditures under the prospec-  
13 tive payment system under section 1833(t) of the  
14 Social Security Act (42 U.S.C. 1395l(t)) with appli-  
15 cation of such amendments made by this section are  
16 equal to estimated expenditures under such system  
17 without application of such amendments.

○