

**Suspend the Rules And Pass the Bill, H.R. 5605, with Amendments**

**(The amendments strike all after the enacting clause and insert a new text and a new title)**

115<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 5605

To amend title XVIII of the Social Security Act to provide for an opioid use disorder treatment demonstration program.

---

## IN THE HOUSE OF REPRESENTATIVES

APRIL 24, 2018

Mr. RUIZ introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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

---

## A BILL

To amend title XVIII of the Social Security Act to provide for an opioid use disorder treatment demonstration program.

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 “Advancing High Qual-  
5 ity Treatment for Opioid Use Disorders in Medicare Act”.

1 **SEC. 2. OPIOID USE DISORDER TREATMENT DEMONSTRATION PROGRAM.**  
2

3 Title XVIII of the Social Security Act (42 U.S.C.  
4 1395 et seq.) is amended by inserting after section 1866E  
5 (42 U.S.C. 1395cc-5) the following new section:

6 **“SEC. 1866F. OPIOID USE DISORDER TREATMENT DEMONSTRATION PROGRAM.**  
7

8 “(a) IMPLEMENTATION OF 4-YEAR DEMONSTRATION  
9 PROGRAM.—

10 “(1) IN GENERAL.—Not later than January 1,  
11 2021, the Secretary shall implement a 4-year dem-  
12 onstration program under this title (in this section  
13 referred to as the ‘Program’) to increase access of  
14 applicable beneficiaries to opioid use disorder treat-  
15 ment services, improve physical and mental health  
16 outcomes for such beneficiaries, and to the extent  
17 possible, reduce expenditures under this title. Under  
18 the Program, the Secretary shall make payments  
19 under subsection (e) to participants (as defined in  
20 subsection (c)(1)(A)) for furnishing opioid use dis-  
21 order treatment services delivered through opioid use  
22 disorder care teams, or arranging for such service to  
23 be furnished, to applicable beneficiaries participating  
24 in the Program.

1           “(2) OPIOID USE DISORDER TREATMENT SERV-  
2           ICES.—For purposes of this section, the term ‘opioid  
3           use disorder treatment services’—

4                   “(A) means, with respect to an applicable  
5                   beneficiary, services that are furnished for the  
6                   treatment of opioid use disorders and that uti-  
7                   lize drugs approved under section 505 of the  
8                   Federal Food, Drug, and Cosmetic Act for the  
9                   treatment of opioid use disorders in an out-  
10                  patient setting; and

11                  “(B) includes—

12                          “(i) medication assisted treatment;

13                          “(ii) treatment planning;

14                          “(iii) psychiatric, psychological, or  
15                          counseling services (or any combination of  
16                          such services), as appropriate;

17                          “(iv) social support services, as appro-  
18                          priate; and

19                          “(v) care management and care co-  
20                          ordination services, including coordination  
21                          with other providers of services and sup-  
22                          pliers not on an opioid use disorder care  
23                          team.

24                  “(b) PROGRAM DESIGN.—

1           “(1) IN GENERAL.—The Secretary shall design  
2           the Program in such a manner to allow for the eval-  
3           uation of the extent to which the Program accom-  
4           plishes the following purposes:

5                   “(A) Reduces hospitalizations and emer-  
6                   gency department visits.

7                   “(B) Increases use of medication-assisted  
8                   treatment for opioid use disorders.

9                   “(C) Improves health outcomes of individ-  
10                  uals with opioid use disorders, including by re-  
11                  ducing the incidence of infectious diseases (such  
12                  as hepatitis C and HIV).

13                  “(D) Does not increase the total spending  
14                  on items and services under this title.

15                  “(E) Reduces deaths from opioid overdose.

16                  “(F) Reduces the utilization of inpatient  
17                  residential treatment.

18           “(2) CONSULTATION.—In designing the Pro-  
19           gram, including the criteria under subsection  
20           (e)(2)(A), the Secretary shall, not later than 3  
21           months after the date of the enactment of this sec-  
22           tion, consult with specialists in the field of addiction,  
23           clinicians in the primary care community, and bene-  
24           ficiary groups.

1           “(c) PARTICIPANTS; OPIOID USE DISORDER CARE  
2 TEAMS.—

3           “(1) PARTICIPANTS.—

4           “(A) DEFINITION.—In this section, the  
5 term ‘participant’ means an entity or indi-  
6 vidual—

7           “(i) that is otherwise enrolled under  
8 this title and that is—

9           “(I) a physician (as defined in  
10 section 1861(r)(1));

11           “(II) a group practice comprised  
12 of at least one physician described in  
13 subclause (I);

14           “(III) a hospital outpatient de-  
15 partment;

16           “(IV) a federally qualified health  
17 center (as defined in section  
18 1861(aa)(4));

19           “(V) a rural health clinic (as de-  
20 fined in section 1861(aa)(2));

21           “(VI) a community mental health  
22 center (as defined in section  
23 1861(ff)(3)(B));

24           “(VII) a clinic certified as a cer-  
25 tified community behavioral health

1 clinic pursuant to section 223 of the  
2 Protecting Access to Medicare Act of  
3 2014; or

4 “(VIII) any other individual or  
5 entity specified by the Secretary;

6 “(ii) that applied for and was selected  
7 to participate in the Program pursuant to  
8 an application and selection process estab-  
9 lished by the Secretary; and

10 “(iii) that establishes an opioid use  
11 disorder care team (as defined in para-  
12 graph (2)) through employing or con-  
13 tracting with health care practitioners de-  
14 scribed in paragraph (2)(A), and uses such  
15 team to furnish or arrange for opioid use  
16 disorder treatment services in the out-  
17 patient setting under the Program

18 “(B) PREFERENCE.—In selecting partici-  
19 pants for the Program, the Secretary shall give  
20 preference to individuals and entities that are  
21 located in areas with a prevalence of opioid use  
22 disorders that is higher than the national aver-  
23 age prevalence.

24 “(2) OPIOID USE DISORDER CARE TEAMS.—

1           “(A) IN GENERAL.—For purposes of this  
2 section, the term ‘opioid use disorder care team’  
3 means a team of health care practitioners es-  
4 tablished by a participant described in para-  
5 graph (1)(A) that—

6           “(i) shall include—

7                   “(I) at least one physician (as  
8 defined in section 1861(r)(1)) fur-  
9 nishing primary care services or ad-  
10 diction treatment services to an appli-  
11 cable beneficiary; and

12                   “(II) at least one eligible practi-  
13 tioner (as defined in paragraph  
14 (3)(A)), who may be a physician who  
15 meets the criterion in subclause (I);  
16 and

17           “(ii) may include other practitioners  
18 licensed under State law to furnish psy-  
19 chiatric, psychological, counseling, and so-  
20 cial services to applicable beneficiaries.

21           “(B) REQUIREMENTS FOR RECEIPT OF  
22 PAYMENT UNDER PROGRAM.—In order to re-  
23 ceive payments under subsection (e), each par-  
24 ticipant in the Program shall—

1 “(i) furnish opioid use disorder treat-  
2 ment services through opioid use disorder  
3 care teams to applicable beneficiaries who  
4 agree to receive the services;

5 “(ii) meet minimum criteria, as estab-  
6 lished by the Secretary; and

7 “(iii) submit to the Secretary, in such  
8 form, manner, and frequency as specified  
9 by the Secretary, with respect to each ap-  
10 plicable beneficiary for whom opioid use  
11 disorder treatment services are furnished  
12 by the opioid use disorder care team, data  
13 and such other information as the Sec-  
14 retary determines appropriate to—

15 “(I) monitor and evaluate the  
16 Program;

17 “(II) determine if minimum cri-  
18 teria are met under clause (ii); and

19 “(III) determine the incentive  
20 payment under subsection (e).

21 “(3) ELIGIBLE PRACTITIONERS; OTHER PRO-  
22 VIDER-RELATED DEFINITIONS AND APPLICATION  
23 PROVISIONS.—

24 “(A) ELIGIBLE PRACTITIONERS.—For pur-  
25 poses of this section, the term ‘eligible practi-



1           tioner’ means a physician or other health care  
2           practitioner, such as a nurse practitioner,  
3           that—

4                   “(i) is enrolled under section  
5                   1866(j)(1);

6                   “(ii) is authorized to prescribe or dis-  
7                   pense narcotic drugs to individuals for  
8                   maintenance treatment or detoxification  
9                   treatment; and

10                   “(iii) has in effect a waiver in accord-  
11                   ance with section 303(g) of the Controlled  
12                   Substances Act for such purpose and is  
13                   otherwise in compliance with regulations  
14                   promulgated by the Substance Abuse and  
15                   Mental Health Services Administration to  
16                   carry out such section.

17                   “(B) ADDICTION SPECIALISTS.—For pur-  
18                   poses of subsection (e)(1)(B)(iv), the term ‘ad-  
19                   diction specialist’ means a physician that pos-  
20                   sesses expert knowledge and skills in addiction  
21                   medicine, as evidenced by appropriate certifi-  
22                   cation from a specialty body, a certificate of ad-  
23                   vanced qualification in addiction medicine, or  
24                   completion of an accredited residency or fellow-

1           ship in addiction medicine or addiction psychi-  
2           atry, as determined by the Secretary.

3           “(d) PARTICIPATION OF APPLICABLE BENE-  
4 FICIARIES.—

5           “(1) APPLICABLE BENEFICIARY DEFINED.—In  
6 this section, the term ‘applicable beneficiary’ means  
7 an individual who—

8                   “(A) is entitled to, or enrolled for, benefits  
9                   under part A and enrolled for benefits under  
10                   part B;

11                   “(B) is not enrolled in a Medicare Advan-  
12                   tage plan under part C;

13                   “(C) has a current diagnosis for an opioid  
14                   use disorder; and

15                   “(D) meets such other criteria as the Sec-  
16                   retary determines appropriate.

17           Such term shall include an individual who is dually  
18           eligible for benefits under this title and title XIX if  
19           such individual satisfies the criteria described in  
20           subparagraphs (A) through (D).

21           “(2) VOLUNTARY PARTICIPATION; LIMITATION  
22           ON NUMBER OF PARTICIPANTS.—An applicable bene-  
23           ficiary may participate in the Program on a vol-  
24           untary basis and may terminate participation in the  
25           Program at any time. Not more than 20,000 appli-

1 cable beneficiaries may participate in the Program  
2 at any time.

3 “(3) SERVICES.—In order to participate in the  
4 Program, an applicable beneficiary shall agree to re-  
5 ceive opioid use disorder treatment services from a  
6 participant. Participation under the Program shall  
7 not affect coverage of or payment for any other item  
8 or service under this title for the applicable bene-  
9 ficiary.

10 “(4) BENEFICIARY ACCESS TO SERVICES.—  
11 Nothing in this section shall be construed as encour-  
12 aging providers to limit applicable beneficiary access  
13 to services covered under this title and applicable  
14 beneficiaries shall not be required to relinquish ac-  
15 cess to any benefit under this title as a condition of  
16 receiving services from a participant in the Program.

17 “(e) PAYMENTS.—

18 “(1) PER APPLICABLE BENEFICIARY PER  
19 MONTH CARE MANAGEMENT FEE.—

20 “(A) IN GENERAL.—The Secretary shall  
21 establish a schedule of per applicable bene-  
22 ficiary per month care management fees. Such  
23 a per applicable beneficiary per month care  
24 management fee shall be paid to a participant  
25 in addition to any other amount otherwise pay-

1           able under this title to the health care practi-  
2           tioners in the participant’s opioid use disorder  
3           care team or, if applicable, to the participant.  
4           A participant may use such per applicable bene-  
5           ficiary per month care management fee to de-  
6           liver additional services to applicable bene-  
7           ficiaries, including services not otherwise eligi-  
8           ble for payment under this title.

9           “(B) PAYMENT AMOUNTS.—In carrying  
10          out subparagraph (A), the Secretary shall—

11           “(i) consider payments otherwise pay-  
12          able under this title for opioid use disorder  
13          treatment services and the needs of appli-  
14          cable beneficiaries;

15           “(ii) pay a higher per applicable bene-  
16          ficiary per month care management fee for  
17          an applicable beneficiary who receives more  
18          intensive treatment services from a partici-  
19          pant and for whom those services are ap-  
20          propriate based on clinical guidelines for  
21          opioid use disorder care;

22           “(iii) pay a higher per applicable ben-  
23          eficiary per month care management fee  
24          for the month in which the applicable ben-  
25          eficiary begins treatment with a partici-

1           pant than in subsequent months, to reflect  
2           the greater time and costs required for the  
3           planning and initiation of treatment, as  
4           compared to maintenance of treatment;

5           “(iv) pay higher per applicable bene-  
6           ficiary per month care management fees  
7           for participants that have established  
8           opioid use disorder care teams that include  
9           an addiction specialist (as defined in sub-  
10          section (c)(3)(B)); and

11          “(v) take into account whether a par-  
12          ticipant’s opioid use disorder care team re-  
13          fers applicable beneficiaries to other sup-  
14          pliers or providers for any opioid use dis-  
15          order treatment services.

16          “(C) NO DUPLICATE PAYMENT.—The Sec-  
17          retary shall make payments under this para-  
18          graph to only one participant for services fur-  
19          nished to an applicable beneficiary during a cal-  
20          endar month.

21          “(2) INCENTIVE PAYMENTS.—

22          “(A) IN GENERAL.—Under the Program,  
23          the Secretary shall establish a performance-  
24          based incentive payment, which shall be paid  
25          (using a methodology established and at a time

1 determined appropriate by the Secretary) to  
2 participants based on the performance of par-  
3 ticipants with respect to criteria, as determined  
4 appropriate by the Secretary, in accordance  
5 with subparagraph (B).

6 “(B) CRITERIA.—

7 “(i) IN GENERAL.—Criteria described  
8 in subparagraph (A) may include consider-  
9 ation of the following:

10 “(I) Patient engagement and re-  
11 tention in treatment.

12 “(II) Evidence-based medication-  
13 assisted treatment.

14 “(III) Other criteria established  
15 by the Secretary.

16 “(ii) REQUIRED CONSULTATION AND  
17 CONSIDERATION.—In determining criteria  
18 described in subparagraph (A), the Sec-  
19 retary shall—

20 “(I) consult with stakeholders,  
21 including clinicians in the primary  
22 care community and in the field of ad-  
23 diction medicine; and

1                   “(II) consider existing clinical  
2                   guidelines for the treatment of opioid  
3                   use disorders.

4                   “(C) NO DUPLICATE PAYMENT.—The Sec-  
5                   retary shall ensure that no duplicate payments  
6                   under this paragraph are made with respect to  
7                   an applicable beneficiary.

8                   “(f) MULTIPAYER STRATEGY.—In carrying out the  
9                   Program, the Secretary shall encourage other payers to  
10                  provide similar payments and to use similar criteria as ap-  
11                  plied under the Program under subsection (e)(2)(C). The  
12                  Secretary may enter into a memorandum of understanding  
13                  with other payers to align the methodology for payment  
14                  provided by such a payer related to opioid use disorder  
15                  treatment services with such methodology for payment  
16                  under the Program.

17                  “(g) EVALUATION.—

18                  “(1) IN GENERAL.—The Secretary shall con-  
19                  duct an intermediate and final evaluation of the pro-  
20                  gram. Each such evaluation shall determine the ex-  
21                  tent to which each of the purposes described in sub-  
22                  section (b) have been accomplished under the Pro-  
23                  gram.

24                  “(2) REPORTS.—The Secretary shall submit to  
25                  the Secretary and Congress—

1           “(A) a report with respect to the inter-  
2           mediate evaluation under paragraph (1) not  
3           later than 3 years after the date of the imple-  
4           mentation of the Program; and

5           “(B) a report with respect to the final  
6           evaluation under paragraph (1) not later than  
7           6 years after such date.

8           “(h) FUNDING.—

9           “(1) ADMINISTRATIVE FUNDING.—For the pur-  
10          poses of implementing, administering, and carrying  
11          out the Program (other than for purposes described  
12          in paragraph (2)), the Secretary shall provide for  
13          the transfer from the Federal Supplementary Med-  
14          ical Insurance Trust Fund under section 1841 of  
15          \$5,000,000 to the Centers for Medicare & Medicaid  
16          Services Program Management Account.

17          “(2) CARE MANAGEMENT FEES AND INCEN-  
18          TIVES.—For the purposes of making payments  
19          under subsection (e), the Secretary shall provide for  
20          the transfer from the Federal Supplementary Med-  
21          ical Insurance Trust Fund under section 1841 of  
22          \$10,000,000 for each of fiscal years 2021 through  
23          2024.



1           “(3) AVAILABILITY.—Amounts transferred  
2           under this subsection for a fiscal year shall be avail-  
3           able until expended.

4           “(i) WAIVERS.—The Secretary may waive any provi-  
5           sion of this title as may be necessary to carry out the Pro-  
6           gram under this section.”.

7   **SEC. 3. REQUIRING E-PRESCRIBING FOR COVERAGE OF**  
8                   **COVERED PART D CONTROLLED SUB-**  
9                   **STANCES.**

10          (a) IN GENERAL.—Section 1860D–4(e) of the Social  
11          Security Act (42 U.S.C. 1395w–104(e)) is amended by  
12          adding at the end the following:

13               “(7) REQUIREMENT OF E-PRESCRIBING FOR  
14               CONTROLLED SUBSTANCES.—

15                   “(A) IN GENERAL.—Subject to subpara-  
16                   graph (B), a prescription for a covered part D  
17                   drug under a prescription drug plan (or under  
18                   an MA–PD plan) for a schedule II, III, IV, or  
19                   V controlled substance shall be transmitted by  
20                   a health care practitioner electronically in ac-  
21                   cordance with an electronic prescription drug  
22                   program that meets the requirements of para-  
23                   graph (2).

24                   “(B) EXCEPTION FOR CERTAIN CIR-  
25                   CUMSTANCES.—The Secretary shall, pursuant

1 to rulemaking, specify circumstances with re-  
2 spect to which the Secretary may waive the re-  
3 quirement under subparagraph (A), with re-  
4 spect to a covered part D drug, including in the  
5 case of—

6 “(i) a prescription issued when the  
7 practitioner and dispenser are the same  
8 entity;

9 “(ii) a prescription issued that cannot  
10 be transmitted electronically under the  
11 most recently implemented version of the  
12 National Council for Prescription Drug  
13 Programs SCRIPT Standard;

14 “(iii) a prescription issued by a practi-  
15 tioner who has received a waiver or a re-  
16 newal thereof for a specified period deter-  
17 mined by the Secretary, not to exceed one  
18 year, from the requirement to use elec-  
19 tronic prescribing, pursuant to a process  
20 established by regulation by the Secretary,  
21 due to demonstrated economic hardship,  
22 technological limitations that are not rea-  
23 sonably within the control of the practi-  
24 tioner, or other exceptional circumstance  
25 demonstrated by the practitioner;

1           “(iv) a prescription issued by a practi-  
2           tioner under circumstances in which, not-  
3           withstanding the practitioner’s ability to  
4           submit a prescription electronically as re-  
5           quired by this subsection, such practitioner  
6           reasonably determines that it would be im-  
7           practical for the individual involved to ob-  
8           tain substances prescribed by electronic  
9           prescription in a timely manner, and such  
10          delay would adversely impact the individ-  
11          ual’s medical condition involved;

12          “(v) a prescription issued by a practi-  
13          tioner allowing for the dispensing of a non-  
14          patient specific prescription pursuant to a  
15          standing order, approved protocol for drug  
16          therapy, collaborative drug management,  
17          or comprehensive medication management,  
18          in response to a public health emergency,  
19          or other circumstances where the practi-  
20          tioner may issue a non-patient specific pre-  
21          scription;

22          “(vi) a prescription issued by a practi-  
23          tioner prescribing a drug under a research  
24          protocol;

1           “(vii) a prescription issued by a prac-  
2           titioner for a drug for which the Food and  
3           Drug Administration requires a prescrip-  
4           tion to contain elements that are not able  
5           to be included in electronic prescribing,  
6           such as a drug with risk evaluation and  
7           mitigation strategies that include elements  
8           to assure safe use; and

9           “(viii) a prescription issued by a prac-  
10          titioner for an individual who—

11           “(I) receives hospice care under  
12          this title; or

13           “(II) is a resident of a skilled  
14          nursing facility (as defined in section  
15          1819(a)), or a medical institution or  
16          nursing facility for which payment is  
17          made for an institutionalized indi-  
18          vidual under section 1902(q)(1)(B),  
19          for which frequently abused drugs are  
20          dispensed for residents through a con-  
21          tract with a single pharmacy, as de-  
22          termined by the Secretary in accord-  
23          ance with this paragraph.

24           “(C) DISPENSING.—Nothing in this para-  
25          graph shall be construed as requiring a sponsor

1 of a prescription drug plan under this part, MA  
2 organization offering an MA–PD plan under  
3 part C, or a pharmacist to verify that a practi-  
4 tioner, with respect to a prescription for a cov-  
5 ered part D drug, has a waiver (or is otherwise  
6 exempt) under subparagraph (B) from the re-  
7 quirement under subparagraph (A). Nothing in  
8 this paragraph shall be construed as affecting  
9 the ability of the plan to cover or the phar-  
10 macists’ ability to continue to dispense covered  
11 part D drugs from otherwise valid written, oral  
12 or fax prescriptions that are consistent with  
13 laws and regulations. Nothing in this paragraph  
14 shall be construed as affecting the ability of the  
15 beneficiary involved to designate a particular  
16 pharmacy to dispense a prescribed drug to the  
17 extent consistent with the requirements under  
18 subsection (b)(1) and under this paragraph.

19 “(D) ENFORCEMENT.—The Secretary  
20 shall, pursuant to rulemaking, have authority to  
21 enforce and specify appropriate penalties for  
22 non-compliance with the requirement under  
23 subparagraph (A).”.

1           (b) EFFECTIVE DATE.—The amendment made by  
2 subsection (a) shall apply to coverage of drugs prescribed  
3 on or after January 1, 2021.

Amend the title so as to read: “A bill to amend title XVIII of the Social Security Act to provide for an opioid use disorder treatment demonstration program, and for other purposes.”.