

115TH CONGRESS  
2D SESSION

# H. R. 5605

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## AN ACT

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Advancing High Qual-  
3 ity Treatment for Opioid Use Disorders in Medicare Act”.

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

6 Title XVIII of the Social Security Act (42 U.S.C.  
7 1395 et seq.) is amended by inserting after section 1866E  
8 (42 U.S.C. 1395cc–5) the following new section:

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

11 **“(a) IMPLEMENTATION OF 4-YEAR DEMONSTRATION**  
12 **PROGRAM.—**

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

1 be furnished, to applicable beneficiaries participating  
2 in the Program.

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

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

13 “(B) includes—

14 “(i) medication assisted treatment;

15 “(ii) treatment planning;

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

19 “(iv) social support services, as appro-  
20 priate; and

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

1 “(b) PROGRAM DESIGN.—

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

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

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

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

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

16 “(E) Reduces deaths from opioid overdose.

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

19 “(2) CONSULTATION.—In designing the Pro-  
20 gram, including the criteria under subsection  
21 (e)(2)(A), the Secretary shall, not later than 3  
22 months after the date of the enactment of this sec-  
23 tion, consult with specialists in the field of addiction,  
24 clinicians in the primary care community, and bene-  
25 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-



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

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

“(ii) is authorized to prescribe or dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment; and

“(iii) has in effect a waiver in accordance with section 303(g) of the Controlled Substances Act for such purpose and is otherwise in compliance with regulations promulgated by the Substance Abuse and Mental Health Services Administration to carry out such section.

“(B) ADDICTION SPECIALISTS.—For purposes of subsection (e)(1)(B)(iv), the term ‘addiction specialist’ means a physician that possesses expert knowledge and skills in addiction medicine, as evidenced by appropriate certification from a specialty body, a certificate of advanced qualification in addiction medicine, or 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

determined appropriate by the Secretary) to participants based on the performance of participants with respect to criteria, as determined appropriate by the Secretary, in accordance with subparagraph (B).

“(B) CRITERIA.—

“(i) IN GENERAL.—Criteria described in subparagraph (A) may include consideration of the following:

“(I) Patient engagement and retention in treatment.

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

“(III) Other criteria established by the Secretary.

“(ii) REQUIRED CONSULTATION AND CONSIDERATION.—In determining criteria described in subparagraph (A), the Secretary shall—

“(I) consult with stakeholders, including clinicians in the primary care community and in the field of addiction 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)), \$5 million shall be available from  
13          the Federal Supplementary Medical Insurance Trust  
14          Fund under section 1841.

15          “(2) CARE MANAGEMENT FEES AND INCEN-  
16          TIVES.—For the purposes of making payments  
17          under subsection (e), \$10 million shall be available  
18          from the Federal Supplementary Medical Insurance  
19          Trust Fund under section 1841 for each of fiscal  
20          years 2021 through 2024.

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



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

4 **SEC. 3. REQUIRING E-PRESCRIBING FOR COVERAGE OF**  
 5 **COVERED PART D CONTROLLED SUB-**  
 6 **STANCES.**

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

10 “(7) REQUIREMENT OF E-PRESCRIBING FOR  
 11 CONTROLLED SUBSTANCES.—

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

21 “(B) EXCEPTION FOR CERTAIN CIR-  
 22 CUMSTANCES.—The Secretary shall, pursuant  
 23 to rulemaking, specify circumstances with re-  
 24 spect to which the Secretary may waive the re-  
 25 quirement under subparagraph (A), with re-

1 spect to a covered part D drug, including in the  
2 case of—

3 “(i) a prescription issued when the  
4 practitioner and dispenser are the same  
5 entity;

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

11 “(iii) a prescription issued by a practi-  
12 tioner who has received a waiver or a re-  
13 newal thereof for a specified period deter-  
14 mined by the Secretary, not to exceed 1  
15 year, from the requirement to use elec-  
16 tronic prescribing, pursuant to a process  
17 established by regulation by the Secretary,  
18 due to demonstrated economic hardship,  
19 technological limitations that are not rea-  
20 sonably within the control of the practi-  
21 tioner, or other exceptional circumstance  
22 demonstrated by the practitioner;

23 “(iv) a prescription issued by a practi-  
24 tioner under circumstances in which, not-  
25 withstanding the practitioner’s ability to

1 submit a prescription electronically as re-  
2 quired by this subsection, such practitioner  
3 reasonably determines that it would be im-  
4 practical for the individual involved to ob-  
5 tain substances prescribed by electronic  
6 prescription in a timely manner, and such  
7 delay would adversely impact the individ-  
8 ual's medical condition involved;

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

19 “(vi) a prescription issued by a practi-  
20 tioner prescribing a drug under a research  
21 protocol;

22 “(vii) a prescription issued by a prac-  
23 titioner for a drug for which the Food and  
24 Drug Administration requires a prescrip-  
25 tion to contain elements that are not able

1 to be included in electronic prescribing,  
2 such as a drug with risk evaluation and  
3 mitigation strategies that include elements  
4 to assure safe use; and

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

7 “(I) receives hospice care under  
8 this title; or

9 “(II) is a resident of a skilled  
10 nursing facility (as defined in section  
11 1819(a)), or a medical institution or  
12 nursing facility for which payment is  
13 made for an institutionalized indi-  
14 vidual under section 1902(q)(1)(B),  
15 for which frequently abused drugs are  
16 dispensed for residents through a con-  
17 tract with a single pharmacy, as de-  
18 termined by the Secretary in accord-  
19 ance with this paragraph.

20 “(C) DISPENSING.—Nothing in this para-  
21 graph shall be construed as requiring a sponsor  
22 of a prescription drug plan under this part, MA  
23 organization offering an MA–PD plan under  
24 part C, or a pharmacist to verify that a practi-  
25 tioner, with respect to a prescription for a cov-

1           ered part D drug, has a waiver (or is otherwise  
2           exempt) under subparagraph (B) from the re-  
3           quirement under subparagraph (A). Nothing in  
4           this paragraph shall be construed as affecting  
5           the ability of the plan to cover or the phar-  
6           macists' ability to continue to dispense covered  
7           part D drugs from otherwise valid written, oral  
8           or fax prescriptions that are consistent with  
9           laws and regulations. Nothing in this paragraph  
10          shall be construed as affecting the ability of the  
11          beneficiary involved to designate a particular  
12          pharmacy to dispense a prescribed drug to the  
13          extent consistent with the requirements under  
14          subsection (b)(1) and under this paragraph.

15               “(D)    ENFORCEMENT.—The    Secretary  
16           shall, pursuant to rulemaking, have authority to  
17           enforce and specify appropriate penalties for  
18           non-compliance with the requirement under  
19           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.

Passed the House of Representatives June 19, 2018.

Attest:

*Clerk.*



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

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