

115TH CONGRESS
2^D SESSION

H. R. 5605

IN THE SENATE OF THE UNITED STATES

JUNE 20, 2018

Received; read twice and referred to the Committee on Finance

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 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-

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)), \$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:

KAREN L. HAAS,

Clerk.