

115TH CONGRESS
2D SESSION

H. R. 6

To provide for opioid use disorder prevention, recovery, and treatment, and
for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 13, 2018

Mr. WALDEN (for himself, Mr. PALLONE, Mr. BRADY of Texas, Mr. NEAL, Mr. ROE of Tennessee, Mr. SHUSTER, Ms. FOXX, Mr. GOODLATTE, Mr. WALZ, Mr. DEFazio, and Mr. BURGESS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and the Judiciary, 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 provide for opioid use disorder prevention, recovery, and
treatment, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Substance Use-Disorder Prevention that Promotes
6 Opioid Recovery and Treatment for Patients and Commu-

1 nities Act” or the “SUPPORT for Patients and Commu-
 2 nities Act”.

3 (b) TABLE OF CONTENTS.—The table of contents for
 4 the Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—MEDICAID PROVISIONS TO ADDRESS THE OPIOID CRISIS

Sec. 101. At-risk youth Medicaid protection.

Sec. 102. Health Insurance for Former Foster Youth.

Sec. 103. Demonstration project to increase substance use provider capacity
under the Medicaid program.

Sec. 104. Drug management program for at-risk beneficiaries.

Sec. 105. Medicaid drug review and utilization.

Sec. 106. Guidance to improve care for infants with neonatal abstinence syn-
drome and their mothers; GAO study on gaps in Medicaid cov-
erage for pregnant and postpartum women with substance use
disorder.

Sec. 107. Medicaid health homes for opioid-use-disorder Medicaid enrollees.

TITLE II—MEDICARE PROVISIONS TO ADDRESS THE OPIOID CRISIS

Sec. 201. Authority not to apply certain Medicare telehealth requirements in
the case of certain treatment of a substance use disorder or co-
occurring mental health disorder.

Sec. 202. Encouraging the use of non-opioid analgesics for the management of
post-surgical pain.

Sec. 203. Requiring a review of current opioid prescriptions for chronic pain
and screening for opioid use disorder to be included in the Wel-
come to Medicare initial preventive physical examination.

Sec. 204. Modification of payment for certain outpatient surgical services.

Sec. 205. Requiring e-prescribing for coverage of covered part D controlled sub-
stances.

Sec. 206. Requiring prescription drug plan sponsors under Medicare to estab-
lish drug management programs for at-risk beneficiaries.

Sec. 207. Medicare coverage of certain services furnished by opioid treatment
programs.

TITLE III—OTHER HEALTH PROVISIONS TO ADDRESS THE OPIOID CRISIS

Sec. 301. Clarifying FDA regulation of non-addictive pain and addiction thera-
pies.

Sec. 302. Surveillance and Testing of Opioids to Prevent Fentanyl Deaths.

Sec. 303. Allowing for more flexibility with respect to medication-assisted treat-
ment for opioid use disorders.

TITLE IV—OFFSETS

Sec. 401. Promoting value in Medicaid managed care.

Sec. 402. Extending period of application of Medicare secondary payer rules for individuals with end stage renal disease.

Sec. 403. Requiring reporting by group health plans of prescription drug coverage information for purposes of identifying primary payer situations under the Medicare program.

1 **TITLE I—MEDICAID PROVISIONS** 2 **TO ADDRESS THE OPIOID CRISIS**

3 **SEC. 101. AT-RISK YOUTH MEDICAID PROTECTION.**

4 (a) IN GENERAL.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended—

6 (1) in subsection (a)—

7 (A) by striking “and” at the end of paragraph (82);

9 (B) by striking the period at the end of paragraph (83) and inserting “; and”; and

11 (C) by inserting after paragraph (83) the following new paragraph:

13 “(84) provide that—

14 “(A) the State shall not terminate eligibility for medical assistance under the State plan for an individual who is an eligible juvenile (as defined in subsection (nn)(2)) because the juvenile is an inmate of a public institution (as defined in subsection (nn)(3)), but may suspend coverage during the period the juvenile is such an inmate;

22 “(B) in the case of an individual who is an eligible juvenile described in paragraph (2)(A)

1 of subsection (nn), the State shall, prior to the
2 individual's release from such a public institu-
3 tion, conduct a redetermination of eligibility for
4 such individual with respect to such medical as-
5 sistance (without requiring a new application
6 from the individual) and, if the State deter-
7 mines pursuant to such redetermination that
8 the individual continues to meet the eligibility
9 requirements for such medical assistance, the
10 State shall restore coverage for such medical
11 assistance to such an individual upon the indi-
12 vidual's release from such public institution;
13 and

14 “(C) in the case of an individual who is an
15 eligible juvenile described in paragraph (2)(B)
16 of subsection (nn), the State shall process any
17 application for medical assistance submitted by,
18 or on behalf of, such individual such that the
19 State makes a determination of eligibility for
20 such individual with respect to such medical as-
21 sistance upon release of such individual from
22 such public institution.”; and

23 (2) by adding at the end the following new sub-
24 section:

1 “(nn) JUVENILE; ELIGIBLE JUVENILE; PUBLIC IN-
 2 STITUTION.—For purposes of subsection (a)(84) and this
 3 subsection:

4 “(1) JUVENILE.—The term ‘juvenile’ means an
 5 individual who is—

6 “(A) under 21 years of age; or

7 “(B) described in subsection
 8 (a)(10)(A)(i)(IX).

9 “(2) ELIGIBLE JUVENILE.—The term ‘eligible
 10 juvenile’ means a juvenile who is an inmate of a
 11 public institution and who—

12 “(A) was determined eligible for medical
 13 assistance under the State plan immediately be-
 14 fore becoming an inmate of such a public insti-
 15 tution; or

16 “(B) is determined eligible for such med-
 17 ical assistance while an inmate of a public insti-
 18 tution.

19 “(3) INMATE OF A PUBLIC INSTITUTION.—The
 20 term ‘inmate of a public institution’ has the meaning
 21 given such term for purposes of applying the sub-
 22 division (A) following paragraph (29) of section
 23 1905(a), taking into account the exception in such
 24 subdivision for a patient of a medical institution.”.

1 (b) NO CHANGE IN EXCLUSION FROM MEDICAL AS-
2 SISTANCE FOR INMATES OF PUBLIC INSTITUTIONS.—
3 Nothing in this section shall be construed as changing the
4 exclusion from medical assistance under the subdivision
5 (A) following paragraph (29) of section 1905(a) of the So-
6 cial Security Act (42 U.S.C. 1396d(a)), including any ap-
7 plicable restrictions on a State submitting claims for Fed-
8 eral financial participation under title XIX of such Act
9 for such assistance.

10 (c) NO CHANGE IN CONTINUITY OF ELIGIBILITY BE-
11 FORE ADJUDICATION OR SENTENCING.—Nothing in this
12 section shall be construed to mandate, encourage, or sug-
13 gest that a State suspend or terminate coverage for indi-
14 viduals before they have been adjudicated or sentenced.

15 (d) EFFECTIVE DATE.—

16 (1) IN GENERAL.—Except as provided in para-
17 graph (2), the amendments made by subsection (a)
18 shall apply to eligibility of juveniles who become in-
19 mates of public institutions on or after the date that
20 is 1 year after the date of the enactment of this Act.

21 (2) RULE FOR CHANGES REQUIRING STATE
22 LEGISLATION.—In the case of a State plan for med-
23 ical assistance under title XIX of the Social Security
24 Act which the Secretary of Health and Human Serv-
25 ices determines requires State legislation (other than

1 legislation appropriating funds) in order for the plan
 2 to meet the additional requirements imposed by the
 3 amendments made by subsection (a), the State plan
 4 shall not be regarded as failing to comply with the
 5 requirements of such title solely on the basis of its
 6 failure to meet these additional requirements before
 7 the first day of the first calendar quarter beginning
 8 after the close of the first regular session of the
 9 State legislature that begins after the date of the en-
 10 actment of this Act. For purposes of the previous
 11 sentence, in the case of a State that has a 2-year
 12 legislative session, each year of such session shall be
 13 deemed to be a separate regular session of the State
 14 legislature.

15 **SEC. 102. HEALTH INSURANCE FOR FORMER FOSTER**
 16 **YOUTH.**

17 (a) COVERAGE CONTINUITY FOR FORMER FOSTER
 18 CARE CHILDREN UP TO AGE 26.—

19 (1) IN GENERAL.—Section
 20 1902(a)(10)(A)(i)(IX) of the Social Security Act (42
 21 U.S.C. 1396a(a)(10)(A)(i)(IX)) is amended—

22 (A) in item (bb), by striking “are not de-
 23 scribed in or enrolled under” and inserting “are
 24 not described in and are not enrolled under”;

1 (B) in item (cc), by striking “responsibility
2 of the State” and inserting “responsibility of a
3 State”; and

4 (C) in item (dd), by striking “the State
5 plan under this title or under a waiver of the”
6 and inserting “a State plan under this title or
7 under a waiver of such a”.

8 (2) EFFECTIVE DATE.—The amendments made
9 by this subsection shall take effect with respect to
10 foster youth who attain 18 years of age on or after
11 January 1, 2023.

12 (b) GUIDANCE.—Not later than one year after the
13 date of the enactment of this Act, the Secretary of Health
14 and Human Services shall issue guidance to States, with
15 respect to the State Medicaid programs of such States—

16 (1) on best practices for—

17 (A) removing barriers and ensuring
18 streamlined, timely access to Medicaid coverage
19 for former foster youth up to age 26; and

20 (B) conducting outreach and raising
21 awareness among such youth regarding Med-
22 icaid coverage options for such youth; and

23 (2) which shall include examples of States that
24 have successfully extended Medicaid coverage to
25 former foster youth up to age 26.

1 **SEC. 103. DEMONSTRATION PROJECT TO INCREASE SUB-**
2 **STANCE USE PROVIDER CAPACITY UNDER**
3 **THE MEDICAID PROGRAM.**

4 Section 1903 of the Social Security Act (42 U.S.C.
5 1396b) is amended by adding at the end the following new
6 subsection:

7 “(aa) DEMONSTRATION PROJECT TO INCREASE SUB-
8 STANCE USE PROVIDER CAPACITY.—

9 “(1) IN GENERAL.—Not later than the date
10 that is 180 days after the date of the enactment of
11 this section, the Secretary shall, in consultation, as
12 appropriate, with the Director of the Agency for
13 Healthcare Research and Quality and the Assistant
14 Secretary for Mental Health and Substance Use,
15 conduct a 54-month demonstration project for the
16 purpose described in paragraph (2) under which the
17 Secretary shall—

18 “(A) for the first 18-month period of such
19 project, award planning grants described in
20 paragraph (3); and

21 “(B) for the remaining 36-month period of
22 such project, provide to each State selected
23 under paragraph (4) payments in accordance
24 with paragraph (5).

25 “(2) PURPOSE.—The purpose described in this
26 paragraph is for each State selected under para-

1 graph (4) to increase the treatment capacity of pro-
2 viders participating under the State plan (or a waiv-
3 er of such plan) to provide substance use disorder
4 treatment or recovery services under such plan (or
5 waiver) through the following activities:

6 “(A) For the purpose described in para-
7 graph (3)(C)(i), activities that support an ongo-
8 ing assessment of the behavioral health treat-
9 ment needs of the State, taking into account
10 the matters described in subclauses (I) through
11 (IV) of such paragraph.

12 “(B) Activities that, taking into account
13 the results of the assessment described in sub-
14 paragraph (A), support the recruitment, train-
15 ing, and provision of technical assistance for
16 providers participating under the State plan (or
17 a waiver of such plan) that offer substance use
18 disorder treatment or recovery services.

19 “(C) Improved reimbursement for and ex-
20 pansion of, through the provision of education,
21 training, and technical assistance, the number
22 or treatment capacity of providers participating
23 under the State plan (or waiver) that—

24 “(i) are authorized to dispense drugs
25 approved by the Food and Drug Adminis-

1 tration for individuals with a substance use
2 disorder who need withdrawal management
3 or maintenance treatment for such dis-
4 order;

5 “(ii) have in effect a registration or
6 waiver under section 303(g) of the Con-
7 trolled Substances Act for purposes of dis-
8 pensing narcotic drugs to individuals for
9 maintenance treatment or detoxification
10 treatment and are in compliance with any
11 regulation promulgated by the Assistant
12 Secretary for Mental Health and Sub-
13 stance Use for purposes of carrying out
14 the requirements of such section 303(g);
15 and

16 “(iii) are qualified under applicable
17 State law to provide substance use disorder
18 treatment or recovery services.

19 “(D) Improved reimbursement for and ex-
20 pansion of, through the provision of education,
21 training, and technical assistance, the number
22 or treatment capacity of providers participating
23 under the State plan (or waiver) that have the
24 qualifications to address the treatment or recov-
25 ery needs of—

1 “(i) individuals enrolled under the
2 State plan (or a waiver of such plan) who
3 have neonatal abstinence syndrome, in ac-
4 cordance with guidelines issued by the
5 American Academy of Pediatrics and
6 American College of Obstetricians and
7 Gynecologists relating to maternal care
8 and infant care with respect to neonatal
9 abstinence syndrome;

10 “(ii) pregnant women, postpartum
11 women, and infants, particularly the con-
12 current treatment, as appropriate, and
13 comprehensive case management of preg-
14 nant women, postpartum women and in-
15 fants, enrolled under the State plan (or a
16 waiver of such plan);

17 “(iii) adolescents and young adults be-
18 tween the ages of 12 and 21 enrolled
19 under the State plan (or a waiver of such
20 plan); or

21 “(iv) American Indian and Alaska Na-
22 tive individuals enrolled under the State
23 plan (or a waiver of such plan).

24 “(3) PLANNING GRANTS.—

1 “(A) IN GENERAL.—The Secretary shall,
2 with respect to the first 18-month period of the
3 demonstration project conducted under para-
4 graph (1), award planning grants to at least 10
5 States selected in accordance with subpara-
6 graph (B) for purposes of preparing an applica-
7 tion described in paragraph (4)(C) and carrying
8 out the activities described in subparagraph
9 (C).

10 “(B) SELECTION.—In selecting States for
11 purposes of this paragraph, the Secretary
12 shall—

13 “(i) select States that have a State
14 plan (or waiver of the State plan) approved
15 under this title;

16 “(ii) select States in a manner that
17 ensures geographic diversity; and

18 “(iii) give preference to States with a
19 prevalence of substance use disorders (in
20 particular opioid use disorders) that is
21 comparable to or higher than the national
22 average prevalence, as measured by aggre-
23 gate per capita drug overdoses, or any
24 other measure that the Secretary deems
25 appropriate.

1 “(C) ACTIVITIES DESCRIBED.—Activities
2 described in this subparagraph are, with respect
3 to a State, each of the following:

4 “(i) Activities that support the devel-
5 opment of an initial assessment of the be-
6 havioral health treatment needs of the
7 State to determine the extent to which pro-
8 viders are needed (including the types of
9 such providers and geographic area of
10 need) to improve the network of providers
11 that treat substance use disorders under
12 the State plan (or waiver), including the
13 following:

14 “(I) An estimate of the number
15 of individuals enrolled under the State
16 plan (or a waiver of such plan) who
17 have a substance use disorder.

18 “(II) Information on the capacity
19 of providers to provide substance use
20 disorder treatment or recovery serv-
21 ices to individuals enrolled under the
22 State plan (or waiver), including in-
23 formation on providers who provide
24 such services and their participation
25 under the State plan (or waiver).

1 “(III) Information on the gap in
2 substance use disorder treatment or
3 recovery services under the State plan
4 (or waiver) based on the information
5 described in subclauses (I) and (II).

6 “(IV) Projections regarding the
7 extent to which the State partici-
8 pating under the demonstration
9 project would increase the number of
10 providers offering substance use dis-
11 order treatment or recovery services
12 under the State plan (or waiver) dur-
13 ing the period of the demonstration
14 project.

15 “(ii) Activities that, taking into ac-
16 count the results of the assessment de-
17 scribed in clause (i), support the develop-
18 ment of State infrastructure to, with re-
19 spect to the provision of substance use dis-
20 order treatment or recovery services under
21 the State plan (or a waiver of such plan),
22 recruit prospective providers and provide
23 training and technical assistance to such
24 providers.

1 “(D) FUNDING.—For purposes of subpara-
2 graph (A), there is appropriated, out of any
3 funds in the Treasury not otherwise appro-
4 priated, \$50,000,000, to remain available until
5 expended.

6 “(4) POST-PLANNING STATES.—

7 “(A) IN GENERAL.—The Secretary shall,
8 with respect to the remaining 36-month period
9 of the demonstration project conducted under
10 paragraph (1), select not more than 5 States in
11 accordance with subparagraph (B) for purposes
12 of carrying out the activities described in para-
13 graph (2) and receiving payments in accordance
14 with paragraph (5).

15 “(B) SELECTION.—In selecting States for
16 purposes of this paragraph, the Secretary
17 shall—

18 “(i) select States that received a plan-
19 ning grant under paragraph (3);

20 “(ii) select States that submit to the
21 Secretary an application in accordance
22 with the requirements in subparagraph
23 (C), taking into consideration the quality
24 of each such application;

1 “(iii) select States in a manner that
2 ensures geographic diversity; and

3 “(iv) give preference to States with a
4 prevalence of substance use disorders (in
5 particular opioid use disorders) that is
6 comparable to or higher than the national
7 average prevalence, as measured by aggregate
8 per capita drug overdoses, or any
9 other measure that the Secretary deems
10 appropriate.

11 “(C) APPLICATIONS.—

12 “(i) IN GENERAL.—A State seeking to
13 be selected for purposes of this paragraph
14 shall submit to the Secretary, at such time
15 and in such form and manner as the Secretary
16 requires, an application that includes
17 such information, provisions, and
18 assurances, as the Secretary may require,
19 in addition to the following:

20 “(I) A proposed process for carrying
21 out the ongoing assessment described
22 in paragraph (2)(A), taking
23 into account the results of the initial
24 assessment described in paragraph
25 (3)(C)(i).

1 “(II) A review of reimbursement
2 methodologies and other policies re-
3 lated to substance use disorder treat-
4 ment or recovery services under the
5 State plan (or waiver) that may create
6 barriers to increasing the number of
7 providers delivering such services.

8 “(III) The development of a plan,
9 taking into account activities carried
10 out under paragraph (3)(C)(ii), that
11 will result in long-term and sustain-
12 able provider networks under the
13 State plan (or waiver) that will offer
14 a continuum of care for substance use
15 disorders. Such plan shall include the
16 following:

17 “(aa) Specific activities to
18 increase the number of providers
19 (including providers that spe-
20 cialize in providing substance use
21 disorder treatment or recovery
22 services, hospitals, health care
23 systems, Federally qualified
24 health centers, and, as applicable,
25 certified community behavioral

1 health clinics) that offer sub-
2 stance use disorder treatment, re-
3 covery, or support services, in-
4 cluding short-term detoxification
5 services, outpatient substance use
6 disorder services, and evidence-
7 based peer recovery services.

8 “(bb) Strategies that will
9 incentivize providers described in
10 subparagraphs (C) and (D) of
11 paragraph (2) to obtain the nec-
12 essary training, education, and
13 support to deliver substance use
14 disorder treatment or recovery
15 services in the State.

16 “(cc) Milestones and timeli-
17 ness for implementing activities
18 set forth in the plan.

19 “(dd) Specific measurable
20 targets for increasing the sub-
21 stance use disorder treatment
22 and recovery provider network
23 under the State plan (or a waiver
24 of such plan).

1 “(IV) A proposed process for re-
2 porting the information required
3 under paragraph (6)(A), including in-
4 formation to assess the effectiveness
5 of the efforts of the State to expand
6 the capacity of providers to deliver
7 substance use disorder treatment or
8 recovery services during the period of
9 the demonstration project under this
10 subsection.

11 “(V) The expected financial im-
12 pact of the demonstration project
13 under this subsection on the State.

14 “(VI) A description of all funding
15 sources available to the State to pro-
16 vide substance use disorder treatment
17 or recovery services in the State.

18 “(VII) A preliminary plan for
19 how the State will sustain any in-
20 crease in the capacity of providers to
21 deliver substance use disorder treat-
22 ment or recovery services resulting
23 from the demonstration project under
24 this subsection after the termination
25 of such demonstration project.

1 “(VIII) A description of how the
2 State will coordinate the goals of the
3 demonstration project with any waiver
4 granted (or submitted by the State
5 and pending) pursuant to section
6 1115 for the delivery of substance use
7 services under the State plan, as ap-
8 plicable.

9 “(ii) CONSULTATION.—In completing
10 an application under clause (i), a State
11 shall consult with relevant stakeholders, in-
12 cluding Medicaid managed care plans,
13 health care providers, and Medicaid bene-
14 ficiary advocates, and include in such ap-
15 plication a description of such consultation.

16 “(5) PAYMENT.—

17 “(A) IN GENERAL.—For each quarter oc-
18 ccurring during the period for which the dem-
19 onstration project is conducted (after the first
20 18 months of such period), the Secretary shall
21 pay under this subsection, subject to subpara-
22 graph (C), to each State selected under para-
23 graph (4) an amount equal to 80 percent of so
24 much of the qualified sums expended during
25 such quarter.

1 “(B) QUALIFIED SUMS DEFINED.—For
2 purposes of subparagraph (A), the term ‘quali-
3 fied sums’ means, with respect to a State and
4 a quarter, the amount equal to the amount (if
5 any) by which the sums expended by the State
6 during such quarter attributable to substance
7 use treatment or recovery services furnished by
8 providers participating under the State plan (or
9 a waiver of such plan) exceeds $\frac{1}{4}$ of such sums
10 expended by the State during fiscal year 2018
11 attributable to substance use treatment or re-
12 covery services.

13 “(C) NON-DUPLICATION OF PAYMENT.—In
14 the case that payment is made under subpara-
15 graph (A) with respect to expenditures for sub-
16 stance use treatment or recovery services fur-
17 nished by providers participating under the
18 State plan (or a waiver of such plan), payment
19 may not also be made under subsection (a) with
20 respect to expenditures for the same services so
21 furnished.

22 “(6) REPORTS.—

23 “(A) STATE REPORTS.—A State receiving
24 payments under paragraph (5) shall, for the pe-
25 riod of the demonstration project under this

1 subsection, submit to the Secretary a quarterly
2 report, with respect to expenditures for sub-
3 stance use treatment or recovery services for
4 which payment is made to the State under this
5 subsection, on the following:

6 “(i) The specific activities with re-
7 spect to which payment under this sub-
8 section was provided.

9 “(ii) The number of providers that de-
10 livered substance use disorder treatment or
11 recovery services in the State under the
12 demonstration project compared to the es-
13 timated number of providers that would
14 have otherwise delivered such services in
15 the absence of such demonstration project.

16 “(iii) The number of individuals en-
17 rolled under the State plan (or a waiver of
18 such plan) who received substance use dis-
19 order treatment or recovery services under
20 the demonstration project compared to the
21 estimated number of such individuals who
22 would have otherwise received such services
23 in the absence of such demonstration
24 project.

1 “(iv) Other matters as determined by
2 the Secretary.

3 “(B) CMS REPORTS.—

4 “(i) INITIAL REPORT.—Not later than
5 October 1, 2020, the Administrator of the
6 Centers for Medicare & Medicaid Services
7 shall, in consultation with the Director of
8 the Agency for Healthcare Research and
9 Quality and the Assistant Secretary for
10 Mental Health and Substance Use, submit
11 to Congress an initial report on—

12 “(I) the States awarded planning
13 grants under paragraph (3);

14 “(II) the criteria used in such se-
15 lection; and

16 “(III) the activities carried out
17 by such States under such planning
18 grants.

19 “(ii) INTERIM REPORT.—Not later
20 than October 1, 2022, the Administrator
21 of the Centers for Medicare & Medicaid
22 Services shall, in consultation with the Di-
23 rector of the Agency for Healthcare Re-
24 search and Quality and the Assistant Sec-
25 retary for Mental Health and Substance

1 Use, submit to Congress an interim re-
2 port—

3 “(I) on activities carried out
4 under the demonstration project
5 under this subsection;

6 “(II) on the extent to which
7 States selected under paragraph (4)
8 have achieved the stated goals sub-
9 mitted in their applications under sub-
10 paragraph (C) of such paragraph;

11 “(III) with a description of the
12 strengths and limitations of such dem-
13 onstration project; and

14 “(IV) with a plan for the sustain-
15 ability of such project.

16 “(iii) FINAL REPORT.—Not later than
17 October 1, 2024, the Administrator of the
18 Centers for Medicare & Medicaid Services
19 shall, in consultation with the Director of
20 the Agency for Healthcare Research and
21 Quality and the Assistant Secretary for
22 Mental Health and Substance Use, submit
23 to Congress a final report—

1 “(I) providing updates on the
2 matters reported in the interim report
3 under clause (ii);

4 “(II) including a description of
5 any changes made with respect to the
6 demonstration project under this sub-
7 section after the submission of such
8 interim report; and

9 “(III) evaluating such dem-
10 onstration project.

11 “(C) AHRQ REPORT.—Not later than
12 three years after the date of the enactment of
13 this subsection, the Director of the Agency for
14 Healthcare Research and Quality, on consulta-
15 tion with the Administrator of the Centers for
16 Medicare & Medicaid Services, shall submit to
17 Congress a summary on the experiences of
18 States awarded planning grants under para-
19 graph (3) and States selected under paragraph
20 (4).

21 “(7) DATA SHARING AND BEST PRACTICES.—
22 During the period of the demonstration project
23 under this subsection, the Secretary shall, in collabo-
24 ration with States selected under paragraph (4), fa-
25 cilitate data sharing and the development of best

1 practices between such States and States that were
2 not so selected.

3 “(8) CMS FUNDING.—There is appropriated,
4 out of any funds in the Treasury not otherwise ap-
5 propriated, \$5,000,000 to the Centers for Medicare
6 & Medicaid Services for purposes of implementing
7 this subsection. Such amount shall remain available
8 until expended.”.

9 **SEC. 104. DRUG MANAGEMENT PROGRAM FOR AT-RISK**
10 **BENEFICIARIES.**

11 (a) IN GENERAL.—Title XIX of the Social Security
12 Act is amended by inserting after section 1927 (42 U.S.C.
13 1396r–8) the following new section:

14 **“SEC. 1927A. DRUG MANAGEMENT PROGRAM FOR AT-RISK**
15 **BENEFICIARIES.**

16 “(a) IN GENERAL.—Beginning January 1, 2020, a
17 State shall operate a qualified drug management program
18 under which a State may enroll certain at-risk bene-
19 ficiaries identified by the State under the program.

20 “(b) QUALIFIED DRUG MANAGEMENT PROGRAM.—
21 For purposes of this section, the term ‘qualified drug man-
22 agement program’ means, with respect to a State, a pro-
23 gram carried out by the State (including through a con-
24 tract with a pharmacy benefit manager) that provides at
25 least for the following:

1 “(1) IDENTIFICATION OF AT-RISK INDIVID-
2 UALS.—Under the program, the State identifies, in
3 accordance with subsection (c), individuals enrolled
4 under the State plan (or waiver of the State plan)
5 who are at-risk beneficiaries.

6 “(2) ELEMENTS OF PROGRAM.—

7 “(A) IN GENERAL.—Under the program,
8 the State, with respect to each individual identi-
9 fied under paragraph (1) and enrolled under
10 the program under paragraph (5)—

11 “(i) subject to subparagraphs (B) and
12 (C), selects at least one, but not more than
13 three, health care providers and at least
14 one, but not more than three, pharmacies
15 for each such individual for purposes of
16 clause (ii), in accordance with a selection
17 process that takes into account reasonable
18 factors such as the individual’s previous
19 utilization of items and services from
20 health care providers and pharmacies, geo-
21 graphic proximity of the individual to such
22 health care providers and pharmacies, ac-
23 cess of the individual to health care, rea-
24 sonable travel time, information regarding
25 housing status, and any known preference

1 of the individual for a certain health care
2 provider or pharmacy; and

3 “(ii) requires that any controlled sub-
4 stance furnished to such individual during
5 the period for which such individual is en-
6 rolled under the program be prescribed by
7 a health care provider selected under
8 clause (i) for such individual and dispensed
9 by a pharmacy selected under clause (i) for
10 such individual in order for such controlled
11 substance to be covered under the State
12 plan (or waiver).

13 “(B) BENEFICIARY PREFERENCE.—In the
14 case of an individual receiving a notice under
15 paragraph (3)(A) of being identified as poten-
16 tially being an at-risk beneficiary described in
17 such paragraph, such individual may submit,
18 during the 30-day period following receipt of
19 such notice, preferences for which health care
20 providers and pharmacies the individual would
21 prefer the State to select under subparagraph
22 (A). The State shall select or change the selec-
23 tion of health care providers and pharmacies
24 under subparagraph (A) for the individuals
25 based on such preferences, except that in the

1 case that State determines that such selection
2 (or change of selection) of a health care pro-
3 vider or pharmacy under subparagraph (A) is
4 contributing or would contribute to prescription
5 drug abuse or drug diversion by the individual,
6 the State may select or change the selection of
7 health care provider or pharmacy for the indi-
8 vidual without regard to the preferences of the
9 individual described in this subparagraph. If the
10 State selects or changes the selection pursuant
11 to the preceding sentence without regard to the
12 preferences of the individual, the State shall
13 provide the individual with at least 30 days
14 written notice of the selection or change of se-
15 lection and a rationale for the selection or
16 change.

17 “(C) TREATMENT OF PHARMACY WITH
18 MULTIPLE LOCATIONS.—For purposes of sub-
19 paragraph (A)(i), in the case of a pharmacy
20 that has multiple locations that share real-time
21 electronic prescription data, all such locations
22 of the pharmacy shall collectively be treated as
23 one pharmacy.

24 “(D) TREATMENT OF EXISTING FFS DRUG
25 MANAGEMENT PROGRAMS.—In the case of a pa-

1 tient review and restriction program (as identi-
2 fied in the annual report submitted to the Sec-
3 retary under section 1927(g)(3)(D)) operated
4 by a State pursuant to section 1915(a)(2) be-
5 fore the date of the enactment of this section,
6 such program shall be treated as a qualified
7 drug management program.

8 “(E) REASONABLE ACCESS.—The program
9 shall ensure, including through waiver of ele-
10 ments of the program (including under sub-
11 paragraph (A)(ii)), reasonable access to health
12 care (including access to health care providers
13 and pharmacies with respect to prescription
14 drugs described in subparagraph (A)) in the
15 case of individuals with multiple residences, in
16 the case of natural disasters and similar situa-
17 tions, and in the case of the provision of emer-
18 gency services (as defined for purposes of sec-
19 tion 1860D–4(c)(5)(D)(ii)(II)).

20 “(3) NOTIFICATION TO IDENTIFIED INDIVID-
21 UALS.—Under the program, the State provides each
22 individual who is identified under paragraph (1),
23 prior to enrolling such individual under the program,
24 at least one notification of each of the following:

1 “(A) Notice that the State has identified
2 the individual as potentially being an at-risk
3 beneficiary for abuse or misuse of a controlled
4 substance.

5 “(B) The name, address, and contact in-
6 formation of each health care provider and
7 pharmacy that may be selected for the indi-
8 vidual under paragraph (2)(A).

9 “(C) Information describing all State and
10 Federal public health resources that are de-
11 signed to address such abuse or misuse to
12 which the individual has access, including men-
13 tal health services, substance use disorder and
14 recovery services, and other counseling services.

15 “(D) Notice of, and information about, the
16 right of the individual to—

17 “(i) submit preferences of the indi-
18 vidual for health care providers and phar-
19 macies to be selected under paragraph
20 (2)(A), including as described in paragraph
21 (2)(B);

22 “(ii) appeal under paragraph (4)—

23 “(I) such identification described
24 in subparagraph (A); and

1 “(II) the selection of health care
2 providers and pharmacies under para-
3 graph (2)(A).

4 “(E) An explanation of the meaning and
5 consequences of the identification of the indi-
6 vidual as potentially being an at-risk beneficiary
7 for abuse or misuse of a controlled substance,
8 including an explanation of the program.

9 “(F) Information, including a contact list
10 and clear instructions, that explain how the in-
11 dividual can contact the appropriate entities ad-
12 ministering the program in order to submit
13 preferences described in paragraph (2)(B) and
14 any other communications relating to the pro-
15 gram.

16 “(4) APPEALS PROCESS.—Under the program,
17 the State provides for an appeals process under
18 which, with respect to an individual identified under
19 paragraph (1)—

20 “(A) such individual may appeal—

21 “(i) such identification; and

22 “(ii) the selection of a health care pro-
23 vider or pharmacy under paragraph (2)(A);

24 “(B) in the case of an appeal described in
25 subparagraph (A)(ii), the State shall accommo-

1 date the health care provider or pharmacy pre-
2 ferred by the individual for selection for pur-
3 poses of paragraph (2)(A), unless the State de-
4 termines that a change to the selection of
5 health care provider or pharmacy under such
6 paragraph is contributing or would contribute
7 to prescription drug abuse or drug diversion by
8 the individual;

9 “(C) such individual is provided a period of
10 not less than 30 days following the date of re-
11 ceipt of the notice described in paragraph (3) to
12 submit such appeal; and

13 “(D) the State must make a determination
14 with respect to an appeal described in subpara-
15 graph (A), and notify the individual of such de-
16 termination, prior to enrollment of such indi-
17 vidual in the program.

18 “(5) ENROLLMENT.—Under the program, the
19 State initially enrolls individuals who are identified
20 under paragraph (1) in the program for a 12-month
21 period—

22 “(A) in the case of such an individual who
23 does not submit an appeal under paragraph (4)
24 within the period applied by the State pursuant
25 to subparagraph (C) of such paragraph, begin-

1 ning on the day after the last day of such pe-
2 riod; and

3 “(B) in the case of such an individual who
4 does submit an appeal under paragraph (4)
5 within the period applied by the State pursuant
6 to subparagraph (C) of such paragraph but
7 such appeal is denied, beginning not later than
8 30 days after the date of such denial.

9 “(6) NOTIFICATION OF HEALTH CARE PRO-
10 VIDERS AND PHARMACIES.—Under the program, the
11 State provides to each health care provider and
12 pharmacy selected for an individual under paragraph
13 (2)—

14 “(A) notification that the individual is an
15 at-risk beneficiary enrolled under the program
16 and that the provider or pharmacy has been se-
17 lected for the individual under paragraph (2);

18 “(B) information on such program and the
19 role of being so selected; and

20 “(C) a process through which the provider
21 or pharmacy can submit a concern or complaint
22 with respect to being so selected.

23 “(7) CONTINUATION OF ENROLLMENT.—Under
24 the program, the State, with respect to an individual

1 enrolled under the program, provides for a process
2 to—

3 “(A) not later than 30 days before the end
4 of the 12-month period for which the individual
5 is so enrolled pursuant to paragraph (5)—

6 “(i) assess, in accordance with pub-
7 licly available evidence-based guidelines,
8 whether or not such individual should con-
9 tinue to be enrolled under the program;
10 and

11 “(ii) notify such individual of the re-
12 sults of the assessment under clause (i);

13 “(B) continue, subject to subparagraph
14 (C), enrollment of such individual if such as-
15 sessment recommends such continuation; and

16 “(C) appeal the continuation of enrollment
17 in accordance with the appeals process de-
18 scribed in paragraph (4).

19 “(c) AT-RISK BENEFICIARY.—

20 “(1) IDENTIFICATION.—For purposes of this
21 section, a State shall identify an individual enrolled
22 under the State plan (or waiver of the State plan)
23 as an at-risk beneficiary if the individual is not an
24 exempted individual described in paragraph (2)
25 and—

1 “(A) is identified as such an at-risk bene-
2 ficiary through the use of publicly available evi-
3 dence-based guidelines that indicate misuse or
4 abuse of a controlled substance; or

5 “(B) the State received notification from a
6 PDP sponsor or Medicare Advantage organiza-
7 tion that such individual was identified as being
8 an at-risk beneficiary for prescription drug
9 abuse for enrollment in a drug management
10 program established by the sponsor or organiza-
11 tion pursuant to section 1860D–4(c)(5) and
12 such identification has not been terminated
13 under subparagraph (F) of such section.

14 “(2) EXEMPTED INDIVIDUAL DESCRIBED.—For
15 purposes of paragraph (1), an exempted individual
16 described in this paragraph is an individual who—

17 “(A) is receiving—

18 “(i) hospice or palliative care; or

19 “(ii) treatment for cancer;

20 “(B) is a resident of a long-term care facil-
21 ity, of a facility described in section 1905(d), or
22 of another facility for which frequently abused
23 drugs are dispensed for residents through a
24 contract with a single pharmacy; or

1 “(C) the State elects to treat as an ex-
2 empted individual for purposes of paragraph
3 (1).

4 “(d) APPLICATION OF PRIVACY RULES CLARIFICA-
5 TION.—The Secretary shall clarify privacy requirements,
6 including requirements under the regulations promulgated
7 pursuant to section 264(c) of the Health Insurance Port-
8 ability and Accountability Act of 1996 (42 U.S.C. 1320d–
9 2 note), related to the sharing of data under subsection
10 (b)(6) in the same manner as the Secretary is required
11 under subparagraph (J) of section 1860D–4(c)(5) to clar-
12 ify privacy requirements related to the sharing of data de-
13 scribed in such subparagraph.

14 “(e) REPORTS.—

15 “(1) ANNUAL REPORTS.—A State operating a
16 qualified drug management program shall include in
17 the annual report submitted to the Secretary under
18 section 1927(g)(3)(D), beginning with such reports
19 submitted for 2021, the following information:

20 “(A) The number of individuals enrolled
21 under the State plan (or waiver of the State
22 plan) who are enrolled under the program and
23 the percentage of individuals enrolled under the
24 State plan (or waiver) who are enrolled under
25 such program.

1 “(B) The number of prescriptions for con-
2 trolled substances that were dispensed per
3 month during each such year per individual en-
4 rolled under the program, including the daily
5 morphine milligram equivalents and the quan-
6 tity prescribed for each such prescription.

7 “(C) The number of pharmacies filling pre-
8 scriptions for controlled substances for individ-
9 uals enrolled under such program.

10 “(D) The number of health care providers
11 writing prescriptions for controlled substances
12 (other than prescriptions for a refill) for indi-
13 viduals enrolled under such program.

14 “(E) Any other data that the Secretary
15 may require.

16 “(F) Any report submitted by a managed
17 care entity under subsection (f)(1)(B) with re-
18 spect to the year involved.

19 For each such report for a year after 2021, the in-
20 formation described in this paragraph shall be pro-
21 vided in a manner that compares such information
22 with respect to the prior calendar year to such infor-
23 mation with respect to the second prior calendar
24 year.

1 “(2) MACPAC REPORTS AND REVIEW.—Not
2 later than two years after the date of the enactment
3 of this section, the Medicaid and CHIP Payment
4 and Access Commission (in this section referred to
5 as ‘MACPAC’), in consultation with the National
6 Association of Medicaid Directors, pharmacy benefit
7 managers, managed care organizations, health care
8 providers (including pharmacists), beneficiary advo-
9 cates, and other stakeholders, shall publish a report
10 that includes—

11 “(A) best practices for operating drug
12 management programs, based on a review of a
13 representative sample of States administering
14 such a program;

15 “(B) a summary of the experience of the
16 appeals process under drug management pro-
17 grams operated by several States, such as the
18 frequency at which individuals appealed the
19 identification of being an at-risk individual, the
20 frequency at which individuals appealed the se-
21 lection of a health care provider or pharmacy
22 under such a program, the timeframes for such
23 appeals, a summary of the reasons for such ap-
24 peals, and the design of such appeals processes;

1 “(C) a summary of trends and the effec-
2 tiveness of qualified drug management pro-
3 grams operated under this section; and

4 “(D) recommendations to States on how
5 improvements can be made with respect to the
6 operation of such programs.

7 In reporting on State practices, the MACPAC shall
8 consider how such programs have been implemented
9 in rural areas, under fee-for-service as well as man-
10 aged care arrangements, and the extent to which
11 such programs have resulted in increased efficiencies
12 to such States or to the Federal Government under
13 this title.

14 “(3) REPORT ON PLAN FOR COORDINATED
15 CARE.—Not later than January 1, 2021, each State
16 operating a qualified drug management program
17 shall submit to the Administrator of the Centers for
18 Medicare & Medicaid Services a report on how such
19 State plans to provide coordinated care for individ-
20 uals enrolled under the State plan (or waiver of the
21 State plan) and—

22 “(A) who are enrolled under the program;
23 or

1 “(B) who are enrolled with a managed care
2 entity and enrolled under such a qualified drug
3 management program operated by such entity.

4 “(f) APPLICABILITY TO MANAGED CARE ENTI-
5 TIES.—

6 “(1) IN GENERAL.—With respect to any con-
7 tract that a State enters into on or after January
8 1, 2020, with a managed care entity (as defined in
9 section 1932(a)(1)(B)) pursuant to section 1903(m),
10 the State shall, as a condition of the contract, re-
11 quire the managed care entity—

12 “(A) to operate a qualified drug manage-
13 ment program (as defined in subsection (b)) for
14 at-risk beneficiaries who are enrolled with such
15 entity and identified by the managed care entity
16 by means of application of paragraph (2);

17 “(B) to submit to the State an annual re-
18 port on the matters described in subparagraphs
19 (A) through (E) of subsection (e)(1); and

20 “(C) to submit to the State a list (and as
21 necessary update such list) of individuals en-
22 rolled with such entity under the qualified drug
23 management program operated by such entity
24 under subparagraph (A) for purposes of allow-
25 ing State plans for which medical assistance is

1 paid on a fee-for-service basis to have access to
2 such information.

3 “(2) APPLICATION.—For purposes of applying,
4 with respect to a managed care entity—

5 “(A) under paragraph (1)(A)—

6 “(i) the definition of the term ‘quali-
7 fied drug management program’ under
8 subsection (b), other than paragraph
9 (2)(D) of such subsection; and

10 “(ii) the provisions of paragraphs (1)
11 and (2) of subsection (c); and

12 “(B) under paragraph (1)(B), the report
13 requirements described in subparagraphs (A)
14 through (E) of subsection (e)(1);

15 each reference in such subsection (b) and para-
16 graphs of subsection (c) to ‘a State’ or ‘the State’
17 (other than to ‘a State plan’ or ‘the State plan’)
18 shall be deemed a reference to the managed care en-
19 tity, each reference under such subsection, para-
20 graphs, or subparagraphs to individuals enrolled
21 under the State plan (or waiver of the State plan)
22 shall be deemed a reference to individuals enrolled
23 with such entity, and each reference under such sub-
24 section, paragraphs, or subparagraphs to individuals
25 enrolled under the qualified drug management pro-

1 gram operated by the State shall be deemed a ref-
 2 erence to individuals enrolled under the qualified
 3 drug management program operated by the man-
 4 aged care entity.

5 “(g) CONTROLLED SUBSTANCE DEFINED.—For pur-
 6 poses of this section, the term ‘controlled substance’
 7 means a drug that is included in schedule II, III, or IV
 8 of section 202(c) of the Controlled Substances Act, or any
 9 combination thereof, as specified by the State.”.

10 (b) GUIDANCE ON AT-RISK POPULATION
 11 TRANSITIONING BETWEEN MEDICAID FFS AND MAN-
 12 AGED CARE.—Not later than October 1, 2019, the Sec-
 13 retary of Health and Human Services shall issue guidance
 14 for State Medicaid programs, with respect to individuals
 15 who are enrolled under a State plan (or waiver of such
 16 plan) under title XIX of the Social Security Act and under
 17 a drug management program, for purposes of providing
 18 best practices—

19 (1) for transitioning, as applicable, such indi-
 20 viduals from fee-for-service Medicaid (and such a
 21 program operated by the State) to receiving medical
 22 assistance under such title through a managed care
 23 entity (as defined in section 1932(a)(1)(B) of the
 24 Social Security Act) with a contract that with the

1 State pursuant to section 1903(m) of such Act (and
2 such a program operated by such entity); and

3 (2) for transitioning, as applicable, such indi-
4 viduals from receiving medical assistance under such
5 title through a managed care entity (as defined in
6 section 1932(a)(1)(B) of the Social Security Act)
7 with a contract that with the State pursuant to sec-
8 tion 1903(m) of such Act (and such a program oper-
9 ated by such entity) to fee-for-service Medicaid (and
10 such a program operated by the State).

11 (c) GUIDANCE ON AT-RISK POPULATION
12 TRANSITIONING TO MEDICARE.—

13 (1) IN GENERAL.—Not later than January 1,
14 2020, the Secretary of Health and Human Services,
15 after consultation with the Federal Coordinated
16 Health Care Office established under section 2602
17 of the Patient Protection and Affordable Care Act
18 (42 U.S.C. 1315b), shall issue guidance for State
19 Medicaid programs, with respect to transitioning in-
20 dividuals, providing for—

21 (A) notification to be submitted by the
22 State to the Centers for Medicare & Medicaid
23 Services and such individuals of the status of
24 such individuals as transitioning individuals;

1 (B) notification to such individuals about
2 enrollment under a prescription drug plan
3 under part D of such title or under a MA–PD
4 plan under part C of such title;

5 (C) best practices for transitioning such in-
6 dividuals to such a plan; and

7 (D) best practices for coordination between
8 the qualified drug management program (as de-
9 scribed in section 1927A(b) of the Social Secu-
10 rity Act, as added by subsection (a)) carried out
11 by the State and a drug management program
12 carried out under such a plan pursuant to sec-
13 tion 1860D–4(c)(5) of the Social Security Act
14 (42 U.S.C. 1395w–10(c)(5)).

15 (2) TRANSITIONING INDIVIDUALS.—For pur-
16 poses of paragraph (1), a transitioning individual is
17 an individual who, with respect to a month—

18 (A) is enrolled under the State plan (or
19 waiver of the State plan) and under the quali-
20 fied drug management program (as described in
21 section 1927A(b) of the Social Security Act, as
22 added by subsection (a)) carried out by the
23 State; and

1 (B) is expected to become eligible for the
 2 Medicare program under title XVIII of such
 3 Act during the subsequent 12-month period.

4 **SEC. 105. MEDICAID DRUG REVIEW AND UTILIZATION.**

5 (a) MEDICAID DRUG UTILIZATION REVIEW.—

6 (1) STATE PLAN REQUIREMENT.—Section
 7 1902(a) of the Social Security Act (42 U.S.C.
 8 1396a(a)), as amended by section 101, is further
 9 amended—

10 (A) in paragraph (83), at the end, by
 11 striking “and”;

12 (B) in paragraph (84), at the end, by
 13 striking the period and inserting “; and”; and

14 (C) by inserting after paragraph (84) the
 15 following new paragraph:

16 “(85) provide that the State is in compliance
 17 with the drug review and utilization requirements
 18 under subsection (oo)(1).”.

19 (2) DRUG REVIEW AND UTILIZATION REQUIRE-
 20 MENTS.—Section 1902 of the Social Security Act
 21 (42 U.S.C. 1396a), as amended by section 101, is
 22 further amended by adding at the end the following
 23 new subsection:

24 “(oo) DRUG REVIEW AND UTILIZATION REQUIRE-
 25 MENTS.—

1 “(1) IN GENERAL.—For purposes of subsection
2 (a)(85), the drug review and utilization requirements
3 under this subsection are, subject to paragraph (3)
4 and beginning October 1, 2019, the following:

5 “(A) CLAIMS REVIEW LIMITATIONS.—

6 “(i) IN GENERAL.—The State has in
7 place—

8 “(I) safety edits (as specified by
9 the State) for subsequent fills for
10 opioids and a claims review automated
11 process (as designed and implemented
12 by the State) that indicates when an
13 individual enrolled under the State
14 plan (or under a waiver of the State
15 plan) is prescribed a subsequent fill of
16 opioids in excess of any limitation
17 that may be identified by the State;

18 “(II) safety edits (as specified by
19 the State) on the maximum daily mor-
20 phine equivalent that can be pre-
21 scribed to an individual enrolled under
22 the State plan (or under a waiver of
23 the State plan) for treatment of
24 chronic pain and a claims review auto-
25 mated process (as designed and imple-

1 mented by the State) that indicates
2 when an individual enrolled under the
3 plan (or waiver) is prescribed the mor-
4 phine equivalent for such treatment in
5 excess of any limitation that may be
6 identified by the State; and

7 “(III) a claims review automated
8 process (as designed and implemented
9 by the State) that monitors when an
10 individual enrolled under the State
11 plan (or under a waiver of the State
12 plan) is concurrently prescribed
13 opioids and—

14 “(aa) benzodiazepines; or

15 “(bb) antipsychotics.

16 “(ii) MANAGED CARE ENTITIES.—The
17 State requires each managed care entity
18 (as defined in section 1932(a)(1)(B)) with
19 respect to which the State has a contract
20 under section 1903(m) or under section
21 1905(t)(3) to have in place, subject to
22 paragraph (3), with respect to individuals
23 who are eligible for medical assistance
24 under the State plan (or under a waiver of
25 the State plan) and who are enrolled with

1 the entity, the limitations described in sub-
2 clauses (I) and (II) of clause (i) and a
3 claims review automated process described
4 in subclause (III) of such clause.

5 “(iii) RULES OF CONSTRUCTION.—
6 Nothing in this subparagraph may be con-
7 strued as prohibiting a State or managed
8 care entity from designing and imple-
9 menting a claims review automated process
10 under this subparagraph that provides for
11 prospective or retrospective reviews of
12 claims. Nothing in this subparagraph shall
13 be understood as prohibiting the exercise
14 of clinical judgment from a provider en-
15 rolled as a participating provider in a
16 State plan (or waiver of the State plan) or
17 contracting with a managed care entity re-
18 garding the best items and services for an
19 individual enrolled under such State plan
20 (or waiver).

21 “(B) PROGRAM TO MONITOR
22 ANTIPSYCHOTIC MEDICATIONS BY CHILDREN.—
23 The State has in place a program (as designed
24 and implemented by the State) to monitor and
25 manage the appropriate use of antipsychotic

1 medications by children enrolled under the
2 State plan (or under a waiver of the State plan)
3 and submits annually to the Secretary such in-
4 formation as the Secretary may require on ac-
5 tivities carried out under such program for indi-
6 viduals not more than the age of 18 years gen-
7 erally and children in foster care specifically.

8 “(C) FRAUD AND ABUSE IDENTIFICA-
9 TION.—The State has in place a process (as de-
10 signed and implemented by the State) that
11 identifies potential fraud or abuse of controlled
12 substances by individuals enrolled under the
13 State plan (or under a waiver of the State
14 plan), health care providers prescribing drugs
15 to individuals so enrolled, and pharmacies dis-
16 pensing drugs to individuals so enrolled.

17 “(D) REPORTS.—The State shall include
18 in the annual report submitted to the Secretary
19 under section 1927(g)(3)(D) information on the
20 limitations, requirement, program, and proc-
21 esses applied by the State under subparagraphs
22 (A) through (C) in accordance with such man-
23 ner and time as specified by the Secretary.

24 “(E) CLARIFICATION.—Nothing shall pre-
25 vent a State from satisfying the requirement—

1 “(i) described in subparagraph (A) by
 2 having safety edits or a claims review auto-
 3 mated process described in such subpara-
 4 graph that was in place before October 1,
 5 2019;

6 “(ii) described in subparagraph (B)
 7 by having a program described in such
 8 subparagraph that was in place before
 9 such date; or

10 “(iii) described in subparagraph (C)
 11 by having a process described in such sub-
 12 paragraph that was in place before such
 13 date.

14 “(2) ANNUAL REPORT BY SECRETARY.—For
 15 each fiscal year beginning with fiscal year 2020, the
 16 Secretary shall submit to Congress a report on the
 17 most recent information submitted by States under
 18 paragraph (1)(D).

19 “(3) EXCEPTIONS.—

20 “(A) CERTAIN INDIVIDUALS EXEMPTED.—
 21 The drug review and utilization requirements
 22 under this subsection shall not apply with re-
 23 spect to an individual who—

24 “(i) is receiving—

25 “(I) hospice or palliative care; or

1 “(II) treatment for cancer;

2 “(ii) is a resident of a long-term care
3 facility, of a facility described in section
4 1905(d), or of another facility for which
5 frequently abused drugs are dispensed for
6 residents through a contract with a single
7 pharmacy; or

8 “(iii) the State elects to treat as ex-
9 empted from such requirements.

10 “(B) EXCEPTION RELATING TO ENSURING
11 ACCESS.—In order to ensure reasonable access
12 to health care, the Secretary shall waive the
13 drug review and utilization requirements under
14 this subsection, with respect to a State, in the
15 case of natural disasters and similar situations,
16 and in the case of the provision of emergency
17 services (as defined for purposes of section
18 1860D–4(c)(5)(D)(ii)(II)).”.

19 (3) MANAGED CARE ENTITIES.—Section 1932
20 of the Social Security Act (42 U.S.C. 1396u–2) is
21 amended by adding at the end the following new
22 subsection:

23 “(i) DRUG UTILIZATION REVIEW ACTIVITIES AND
24 REQUIREMENTS.—Beginning not later than October 1,
25 2019, each contract under a State plan with a managed

1 care entity (other than a primary care case manager)
 2 under section 1903(m) shall provide that the entity is in
 3 compliance with the applicable provisions of section
 4 438.3(s)(2) of title 42 of the Code of Federal Regulations,
 5 section 483.3(s)(4)) of such title, and section 483.3(s)(5)
 6 of such title, as such provisions were in effect on March
 7 31, 2018.”.

8 (b) IDENTIFYING AND ADDRESSING INAPPROPRIATE
 9 PRESCRIBING AND BILLING PRACTICES UNDER MED-
 10 ICAID.—

11 (1) IN GENERAL.—Section 1927(g) of the So-
 12 cial Security Act (42 U.S.C. 1396r–8(g)) is amend-
 13 ed—

14 (A) in paragraph (1)(A)—

15 (i) by striking “of section
 16 1903(i)(10)(B)” and inserting “of section
 17 1902(a)(54)”;

18 (ii) by striking “, by not later than
 19 January 1, 1993,”;

20 (iii) by inserting after “gross over-
 21 use,” the following: “excessive utilization,”;
 22 and

23 (iv) by striking “or inappropriate or
 24 medically unnecessary care” and inserting
 25 “inappropriate or medically unnecessary

1 care, or prescribing or billing practices
 2 that indicate abuse or excessive utiliza-
 3 tion”; and

4 (B) in paragraph (2)(B)—

5 (i) by inserting after “gross overuse,”
 6 the following: “excessive utilization,”; and

7 (ii) by striking “or inappropriate or
 8 medically unnecessary care” and inserting
 9 “inappropriate or medically unnecessary
 10 care, or prescribing or billing practices
 11 that indicate abuse or excessive utiliza-
 12 tion”.

13 (2) EFFECTIVE DATE.—The amendments made
 14 by paragraph (1) shall take effect with respect to
 15 retrospective drug use reviews conducted on or after
 16 October 1, 2020.

17 **SEC. 106. GUIDANCE TO IMPROVE CARE FOR INFANTS WITH**
 18 **NEONATAL ABSTINENCE SYNDROME AND**
 19 **THEIR MOTHERS; GAO STUDY ON GAPS IN**
 20 **MEDICAID COVERAGE FOR PREGNANT AND**
 21 **POSTPARTUM WOMEN WITH SUBSTANCE USE**
 22 **DISORDER.**

23 (a) GUIDANCE.—Not later than one year after the
 24 date of the enactment of this Act, the Secretary of Health
 25 and Human Services shall issue guidance to improve care

1 for infants with neonatal abstinence syndrome and their
2 families. Such guidance shall include—

3 (1) the types of services, including post-dis-
4 charge services and parenting supports, for families
5 of babies with neonatal abstinence syndrome that
6 States may cover under the Medicaid program under
7 title XIX of the Social Security Act;

8 (2) best practices from States with respect to
9 innovative or evidenced-based payment models that
10 focus on prevention, screening, treatment, plans of
11 safe care, and post-discharge services for mothers
12 and fathers with substance use disorders and babies
13 with neonatal abstinence syndrome that improve
14 care and clinical outcomes;

15 (3) recommendations for States on available fi-
16 nancing options under the Medicaid program under
17 title XIX of such Act and under the Children’s
18 Health Insurance Program under title XXI of such
19 Act for Children’s Health Insurance Program
20 Health Services Initiative funds for parents with
21 substance use disorders, infants with neonatal absti-
22 nence syndrome, and home visiting services; and

23 (4) guidance and technical assistance to State
24 Medicaid agencies regarding additional flexibilities
25 and incentives related to screening, prevention, and

1 post-discharge services, including parenting sup-
 2 ports.

3 (b) GAO STUDY.—Not later than one year after the
 4 date of the enactment of this Act, the Comptroller General
 5 of the United States shall conduct a study, and submit
 6 to Congress a report, addressing gaps in coverage for
 7 pregnant women with substance use disorder under the
 8 Medicaid program under title XIX of the Social Security
 9 Act, and gaps in coverage for postpartum women with sub-
 10 stance use disorder who had coverage during their preg-
 11 nancy under the Medicaid program under such title.

12 **SEC. 107. MEDICAID HEALTH HOMES FOR OPIOID-USE-DIS-**
 13 **ORDER MEDICAID ENROLLEES.**

14 (a) EXTENSION OF ENHANCED FMAP FOR CERTAIN
 15 HEALTH HOMES FOR INDIVIDUALS WITH SUBSTANCE
 16 USE DISORDERS.—Section 1945 of the Social Security
 17 Act (42 U.S.C. 1396w–4) is amended—

18 (1) in subsection (c)—

19 (A) in paragraph (1), by inserting “subject
 20 to paragraph (4),” after “except that,”; and

21 (B) by adding at the end the following new
 22 paragraph:

23 “(4) SPECIAL RULE RELATING TO SUBSTANCE
 24 USE DISORDER HEALTH HOMES.—

1 “(A) IN GENERAL.—In the case of a State
2 with an SUD-focused State plan amendment
3 approved by the Secretary on or after October
4 1, 2018, the Secretary may, at the request of
5 the State, extend the application of the Federal
6 medical assistance percentage described in
7 paragraph (1) to payments for the provision of
8 health home services to SUD-eligible individuals
9 under such State plan amendment, in addition
10 to the first 8 fiscal year quarters the State plan
11 amendment is in effect, for the subsequent 2
12 fiscal year quarters that the State plan amend-
13 ment is in effect. Nothing in this section shall
14 be construed as prohibiting a State with a State
15 plan amendment that is approved under this
16 section and that is not an SUD-focused State
17 plan amendment from additionally having ap-
18 proved on or after such date an SUD-focused
19 State plan amendment under this section, in-
20 cluding for purposes of application of this para-
21 graph.

22 “(B) REPORT REQUIREMENTS.—In the
23 case of a State with an SUD-focused State plan
24 amendment for which the application of the
25 Federal medical assistance percentage has been

1 extended under subparagraph (A), such State
2 shall, at the end of the period of such State
3 plan amendment, submit to the Secretary a re-
4 port on the following, with respect to SUD-eli-
5 gible individuals provided health home services
6 under such State plan amendment:

7 “(i) The quality of health care pro-
8 vided to such individuals, with a focus on
9 outcomes relevant to the recovery of each
10 such individual.

11 “(ii) The access of such individuals to
12 health care.

13 “(iii) The total expenditures of such
14 individuals for health care.

15 For purposes of this subparagraph, the
16 Secretary shall specify all applicable meas-
17 ures for determining quality, access, and
18 expenditures.

19 “(C) BEST PRACTICES.—Not later than
20 October 1, 2020, the Secretary shall make pub-
21 licly available on the Internet website of the
22 Centers for Medicare & Medicaid Services best
23 practices for designing and implementing an
24 SUD-focused State plan amendment, based on
25 the experiences of States that have State plan

1 amendments approved under this section that
2 include SUD-eligible individuals.

3 “(D) DEFINITIONS.—For purposes of this
4 paragraph:

5 “(i) SUD-ELIGIBLE INDIVIDUALS.—
6 The term ‘SUD-eligible individual’ means,
7 with respect to a State, an individual who
8 satisfies all of the following:

9 “(I) The individual is an eligible
10 individual with chronic conditions.

11 “(II) The individual is an indi-
12 vidual with a substance use disorder.

13 “(III) The individual has not pre-
14 viously received health home services
15 under any other State plan amend-
16 ment approved for the State under
17 this section by the Secretary.

18 “(ii) SUD-FOCUSED STATE PLAN
19 AMENDMENT.—The term ‘SUD-focused
20 State plan amendment’ means a State plan
21 amendment under this section that is de-
22 signed to provide health home services pri-
23 marily to SUD-eligible individuals.”.

1 (b) REQUIREMENT FOR STATE MEDICAID PLANS TO
2 PROVIDE COVERAGE FOR MEDICATION-ASSISTED TREAT-
3 MENT.—

4 (1) REQUIREMENT FOR STATE MEDICAID PLANS
5 TO PROVIDE COVERAGE FOR MEDICATION-ASSISTED
6 TREATMENT.—Section 1902(a)(10)(A) of the Social
7 Security Act (42 U.S.C. 1396a(a)(10)(A)) is amend-
8 ed, in the matter preceding clause (i), by striking
9 “and (28)” and inserting “(28), and (29)”.

10 (2) INCLUSION OF MEDICATION-ASSISTED
11 TREATMENT AS MEDICAL ASSISTANCE.—Section
12 1905(a) of the Social Security Act (42 U.S.C.
13 1396d(a)) is amended—

14 (A) in paragraph (28), by striking “and”
15 at the end;

16 (B) by redesignating paragraph (29) as
17 paragraph (30); and

18 (C) by inserting after paragraph (28) the
19 following new paragraph:

20 “(29) subject to paragraph (2) of subsection
21 (ee), for the period beginning October 1, 2020, and
22 ending September 30, 2025, medication-assisted
23 treatment (as defined in paragraph (1) of such sub-
24 section); and”.

1 (3) MEDICATION-ASSISTED TREATMENT DE-
2 FINED; WAIVERS.—Section 1905 of the Social Secu-
3 rity Act (42 U.S.C. 1396d) is amended by adding at
4 the end the following new subsection:

5 “(ee) MEDICATION-ASSISTED TREATMENT.—

6 “(1) DEFINITION.—For purposes of subsection
7 (a)(29), the term ‘medication-assisted treatment’—

8 “(A) means all drugs approved under sec-
9 tion 505 of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 355), including metha-
11 done, and all biological products licensed under
12 section 351 of the Public Health Service Act
13 (42 U.S.C. 262) to treat opioid use disorders;
14 and

15 “(B) includes, with respect to the provision
16 of such drugs and biological products, coun-
17 seling services and behavioral therapy.

18 “(2) EXCEPTION.—The provisions of paragraph
19 (29) of subsection (a) shall not apply with respect to
20 a State for the period specified in such paragraph,
21 if before the beginning of such period the State cer-
22 tifies to the satisfaction of the Secretary that imple-
23 menting such provisions statewide for all individuals
24 eligible to enroll in the State plan (or waiver of the
25 State plan) would not be feasible by reason of a

1 shortage of qualified providers of medication-assisted
2 treatment, or facilities providing such treatment,
3 that will contract with the State or a managed care
4 entity with which the State has a contract under
5 section 1903(m) or under section 1905(t)(3).”.

6 (4) EFFECTIVE DATE.—

7 (A) IN GENERAL.—Subject to subpara-
8 graph (B), the amendments made by this sub-
9 section shall apply with respect to medical as-
10 sistance provided on or after October 1, 2020,
11 and before October 1, 2025.

12 (B) EXCEPTION FOR STATE LEGISLA-
13 TION.—In the case of a State plan under title
14 XIX of the Social Security Act (42 U.S.C. 1396
15 et seq.) that the Secretary of Health and
16 Human Services determines requires State leg-
17 islation in order for the respective plan to meet
18 any requirement imposed by the amendments
19 made by this subsection, the respective plan
20 shall not be regarded as failing to comply with
21 the requirements of such title solely on the
22 basis of its failure to meet such an additional
23 requirement before the first day of the first cal-
24 endar quarter beginning after the close of the
25 first regular session of the State legislature that

1 begins after the date of the enactment of this
 2 Act. For purposes of the previous sentence, in
 3 the case of a State that has a 2-year legislative
 4 session, each year of the session shall be consid-
 5 ered to be a separate regular session of the
 6 State legislature.

7 **TITLE II—MEDICARE PROVI-**
 8 **SIONS TO ADDRESS THE**
 9 **OPIOID CRISIS**

10 **SEC. 201. AUTHORITY NOT TO APPLY CERTAIN MEDICARE**
 11 **TELEHEALTH REQUIREMENTS IN THE CASE**
 12 **OF CERTAIN TREATMENT OF A SUBSTANCE**
 13 **USE DISORDER OR CO-OCCURRING MENTAL**
 14 **HEALTH DISORDER.**

15 Section 1834(m) of the Social Security Act (42
 16 U.S.C. 1395m(m)) is amended—

17 (1) in paragraph (2)(B)(i), by inserting “and
 18 paragraph (7)(E)” after “Subject to clause (ii)”;
 19 and

20 (2) by adding at the end the following new
 21 paragraphs:

22 “(7) AUTHORITY NOT TO APPLY CERTAIN RE-
 23 QUIREMENTS IN THE CASE OF CERTAIN TREATMENT
 24 OF SUBSTANCE USE DISORDER OR CO-OCCURRING
 25 MENTAL HEALTH DISORDER.—

1 “(A) IN GENERAL.—For purposes of pay-
2 ment under this subsection, in the case of tele-
3 health services described in subparagraph (C)
4 furnished on or after January 1, 2020, to an el-
5 igible beneficiary (as defined in subparagraph
6 (F)) for the treatment of a substance use dis-
7 order or a mental health disorder that is co-oc-
8 curring with a substance use disorder, the Sec-
9 retary is authorized to, through rulemaking, not
10 apply any of the requirements described in sub-
11 paragraph (B).

12 “(B) REQUIREMENTS DESCRIBED.—For
13 purposes of this paragraph, the requirements
14 described in this subparagraph are any of the
15 following:

16 “(i) Qualifications for an originating
17 site under paragraph (4)(C)(ii).

18 “(ii) Geographic limitations under
19 paragraph (4)(C)(i).

20 “(C) TELEHEALTH SERVICES DE-
21 SCRIBED.—For purposes of this paragraph, the
22 telehealth services described in this subpara-
23 graph are services that are both telehealth serv-
24 ices and identified by the Secretary, through
25 rulemaking, as services that are the most com-

1 monly furnished (as defined by the Secretary)
2 under this part to individuals diagnosed with a
3 substance use disorder or a mental health dis-
4 order that is co-occurring with a substance use
5 disorder.

6 “(D) CLARIFICATION.—Nothing in this
7 paragraph shall be construed as limiting or oth-
8 erwise affecting the authority of the Secretary
9 to limit or eliminate the non-application pursu-
10 ant to this paragraph of any of the require-
11 ments under subparagraph (B).

12 “(E) TREATMENT OF ORIGINATING SITE
13 FACILITY FEE.—No facility fee shall be paid
14 under paragraph (2)(B) to an originating site
15 with respect to a telehealth service described in
16 subparagraph (B) for which payment is made
17 under this subsection by reason of the non-ap-
18 plication of a requirement described in subpara-
19 graph (B) pursuant to this paragraph if pay-
20 ment for such service would not otherwise be
21 permitted under this subsection if such require-
22 ment were applied.

23 “(F) ELIGIBLE BENEFICIARY DEFINED.—
24 For purposes of this paragraph, the term ‘eligi-
25 ble beneficiary’ means an individual who—

1 “(i) is entitled to, or enrolled for, ben-
2 efits under part A and enrolled for benefits
3 under this part;

4 “(ii) has a diagnosis for a substance
5 use disorder; and

6 “(iii) meets such other criteria as the
7 Secretary determines appropriate.

8 “(G) REPORT.—Not later than 5 years
9 after the date of the enactment of this para-
10 graph, the Secretary shall submit to Congress a
11 report on the impact of any non-application
12 under this paragraph of any of the require-
13 ments described in subparagraph (B) on

14 “(i) the utilization of health care serv-
15 ices related to substance use disorder, such
16 as behavioral health services and emer-
17 gency department visits; and

18 “(ii) health outcomes related to sub-
19 stance use disorder, such as substance use
20 overdose deaths.

21 “(H) FUNDING.—For purposes of carrying
22 out this paragraph, in addition to funds other-
23 wise available, the Secretary shall provide for
24 the transfer, from the Federal Supplementary
25 Medical Insurance Trust Fund under section

1 1841, of \$3,000,000 to the Centers for Medi-
 2 care & Medicaid Services Program Management
 3 Account to remain available until expended.

4 “(8) RULE OF CONSTRUCTION.—Nothing in
 5 this subsection may be construed as waiving require-
 6 ments under this title to comply with applicable
 7 State law, including State licensure requirements.”.

8 **SEC. 202. ENCOURAGING THE USE OF NON-OPIOID ANALGE-**
 9 **SICS FOR THE MANAGEMENT OF POST-SUR-**
 10 **GICAL PAIN.**

11 Section 1833(t)(6) of the Social Security Act (42
 12 U.S.C. 1395l(t)(6)) is amended—

13 (1) in subparagraph (C)(i), by inserting “or, in
 14 the case of an eligible non-opioid analgesic (as de-
 15 fined in subparagraph (J)), during a period of 5
 16 years,” after “3 years,”; and

17 (2) by adding at the end the following new sub-
 18 paragraph:

19 “(J) ELIGIBLE NON-OPIOID ANALGESIC
 20 DEFINED.—In this paragraph, the term ‘eligible
 21 non-opioid analgesic’ means a drug or biologi-
 22 cal—

23 “(i) that is an analgesic that is not an
 24 opioid;

1 “(ii) that demonstrated substantial
2 clinical improvement; and

3 “(iii) for which payment—

4 “(I) as an outpatient hospital
5 service under this part was not being
6 made as of the date of the enactment
7 of this subparagraph; or

8 “(II) was being made under this
9 paragraph as of such date.”.

10 **SEC. 203. REQUIRING A REVIEW OF CURRENT OPIOID PRE-**
11 **SCRIPTIONS FOR CHRONIC PAIN AND**
12 **SCREENING FOR OPIOID USE DISORDER TO**
13 **BE INCLUDED IN THE WELCOME TO MEDI-**
14 **CARE INITIAL PREVENTIVE PHYSICAL EXAM-**
15 **INATION.**

16 (a) IN GENERAL.—Section 1861(ww) of the Social
17 Security Act (42 U.S.C. 1395x(ww)) is amended—

18 (1) in paragraph (1), by inserting “and a re-
19 view of current opioid prescriptions and screening
20 for opioid use disorder (as defined in paragraph
21 (4)),” before “but does not include”; and

22 (2) by adding at the end the following new
23 paragraph:

1 “(4)(A) For purposes of paragraph (1), the term ‘a
2 review of current opioid prescriptions and screening for
3 opioid use disorder’ means, with respect to an individual—

4 “(i) a review by a physician or qualified non-
5 physician practitioner of all current prescriptions of
6 the individual; and

7 “(ii) in the case of an individual determined by
8 the review of a physician or qualified non-physician
9 practitioner under subparagraph (A) to have a cur-
10 rent prescription for opioids for chronic pain that
11 has been prescribed for a minimum period of time
12 (as specified by the Secretary)—

13 “(I) a review by the physician or practi-
14 tioner of the potential risk factors to the indi-
15 vidual for opioid use disorder;

16 “(II) an evaluation by the physician or
17 practitioner of pain of the individual;

18 “(III) the provision of information regard-
19 ing non-opioid treatment options for the treat-
20 ment and management of any chronic pain of
21 the individual; and

22 “(IV) if determined necessary by the physi-
23 cian or practitioner based on the results of the
24 review and evaluation conducted as described in
25 this paragraph, an appropriate referral by the

1 physician or practitioner for additional treat-
2 ment.

3 “(B) For purposes of this paragraph, the term ‘quali-
4 fied non-physician practitioner’ means a physician assist-
5 ant, nurse practitioner, or certified clinical nurse spe-
6 cialist.”.

7 (b) EFFECTIVE DATE.—The amendments made by
8 subsection (a) shall apply with respect to initial preventive
9 physical examinations furnished on or after January 1,
10 2020.

11 **SEC. 204. MODIFICATION OF PAYMENT FOR CERTAIN OUT-**
12 **PATIENT SURGICAL SERVICES.**

13 (a) FREEZE OF PAYMENT FOR CERTAIN SERVICES
14 FURNISHED IN AMBULATORY SURGICAL CENTERS.—Sec-
15 tion 1833(i)(2) of the Social Security Act (42 U.S.C.
16 1395l(i)(2)) is amended by adding at the end the following
17 new subparagraph:

18 “(F)(i) With respect to a targeted procedure
19 (as defined in clause (ii)) furnished during 2020 or
20 a subsequent year (before 2024) to an individual in
21 an ambulatory surgical center, the payment amount
22 for such procedure that would otherwise be deter-
23 mined under the revised payment system under sub-
24 paragraph (D), without application of this subpara-

graph, shall be equal to the payment amount for such procedure furnished in 2016.

“(ii) For purposes of clause (i), the term ‘targeted procedure’ means a procedure to which Healthcare Common Procedure Coding System 62310 (or, for years beginning after 2016, 62321), 62311 (or, for years beginning after 2016, 62323), 62264, 64490, 64493, or G0260 (or any successor code) applies.

“(iii) This subparagraph shall not be applied in a budget-neutral manner.”.

(b) DATA COLLECTION.—

(1) IN GENERAL.—The Comptroller General shall collect data relating to the cost differential between targeted procedures (as defined in section 1833(i)(2)(F)(ii) of the Social Security Act, as added by subsection (a)) that are performed in a hospital operating room and such procedures that are performed in an office setting within a hospital in order to determine whether such procedures are being properly coded for claims, based on setting, for payment under section 1833(i)(2)(D) of the Social Security Act (42 U.S.C. 1395l(i)(2)(D)) and to determine if further changes are needed in the classification system for covered outpatient department

1 services (as described in section 1833(t)(2)(A) of the
2 Social Security Act (42 U.S.C. 1395l(t)(2)(A))).

3 (2) REPORT.—Not later than 4 years after the
4 date of the enactment of this Act, the Comptroller
5 General shall submit a report to the Committee on
6 Energy and Commerce and the Committee on Ways
7 and Means of the House of Representatives and the
8 Committee on Finance of the Senate containing—

9 (A) a determination of whether procedures
10 described in paragraph (1) are being properly
11 coded for claims, based on setting, for payment
12 under section 1833(i)(2)(D) of the Social Secu-
13 rity Act (42 U.S.C. 1395l(i)(2)(D)); and

14 (B) recommendations on any changes the
15 Comptroller General determines are needed in
16 the classification system for covered outpatient
17 department services (as described in section
18 1833(t)(2)(A) of the Social Security Act (42
19 U.S.C. 1395l(t)(2)(A))).

20 (c) STUDY.—Not later than 3 years after the date
21 of the enactment of this Act, the Secretary of Health and
22 Human Services shall conduct a study and submit to Con-
23 gress a report on the extent to which procedures described
24 in section 1833(i)(2)(F)(ii) of the Social Security Act, as

1 added by subsection (a), are effective at preventing the
2 need for opioids for individuals furnished such procedures.

3 **SEC. 205. REQUIRING E-PRESCRIBING FOR COVERAGE OF**
4 **COVERED PART D CONTROLLED SUB-**
5 **STANCES.**

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

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

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

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

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

1 **SEC. 206. REQUIRING PRESCRIPTION DRUG PLAN SPON-**
2 **SORS UNDER MEDICARE TO ESTABLISH**
3 **DRUG MANAGEMENT PROGRAMS FOR AT-**
4 **RISK BENEFICIARIES.**

5 Section 1860D–4(c) of the Social Security Act (42
6 U.S.C. 1395w–104(c)) is amended—

7 (1) in paragraph (1), by inserting after sub-
8 paragraph (E) the following new subparagraph:

9 “(F) With respect to plan years beginning
10 on or after January 1, 2021, a drug manage-
11 ment program for at-risk beneficiaries described
12 in paragraph (5).”; and

13 (2) in paragraph (5)(A), by inserting “(and for
14 plan years beginning on or after January 1, 2021,
15 a PDP sponsor shall)” after “A PDP sponsor may”.

16 **SEC. 207. MEDICARE COVERAGE OF CERTAIN SERVICES**
17 **FURNISHED BY OPIOID TREATMENT PRO-**
18 **GRAMS.**

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

21 (1) in subparagraph (FF), by striking at the
22 end “and”;

23 (2) in subparagraph (GG), by inserting at the
24 end “; and”; and

25 (3) by adding at the end the following new sub-
26 paragraph:

1 “(HH) opioid use disorder treatment serv-
2 ices (as defined in subsection (jjj)).”.

3 (b) OPIOID USE DISORDER TREATMENT SERVICES
4 AND OPIOID TREATMENT PROGRAM DEFINED.—Section
5 1861 of the Social Security Act is amended by adding at
6 the end the following new subsection:

7 “(jjj) OPIOID USE DISORDER TREATMENT SERV-
8 ICES; OPIOID TREATMENT PROGRAM.—

9 “(1) OPIOID USE DISORDER TREATMENT SERV-
10 ICES.—The term ‘opioid use disorder treatment serv-
11 ices’ means items and services that are furnished by
12 an opioid treatment program for the treatment of
13 opioid use disorder, including—

14 “(A) opioid agonist and antagonist treat-
15 ment medications (including oral, injected, or
16 implanted versions) that are approved by the
17 Food and Drug Administration under section
18 505 of the Federal Food, Drug and Cosmetic
19 Act for use in the treatment of opioid use dis-
20 order;

21 “(B) dispensing and administration of
22 such medications, if applicable;

23 “(C) substance use counseling by a profes-
24 sional to the extent authorized under State law
25 to furnish such services;

1 “(D) individual and group therapy with a
2 physician or psychologist (or other mental
3 health professional to the extent authorized
4 under State law);

5 “(E) toxicology testing, and

6 “(F) other items and services that the Sec-
7 retary determines are appropriate (but in no
8 event to include meals or transportation).

9 “(2) OPIOID TREATMENT PROGRAM.—The term
10 ‘opioid treatment program’ means an entity that is
11 opioid treatment program (as defined in section 8.2
12 of title 42 of the Code of Federal Regulations, or
13 any successor regulation) that—

14 “(A) is enrolled under section 1866(j);

15 “(B) has in effect a certification by the
16 Substance Abuse and Mental Health Services
17 Administration for such a program;

18 “(C) is accredited by an accrediting body
19 approved by the Substance Abuse and Mental
20 Health Services Administration; and

21 “(D) meets such additional conditions as
22 the Secretary may find necessary to ensure—

23 “(i) the health and safety of individ-
24 uals being furnished services under such
25 program; and

1 “(ii) the effective and efficient fur-
 2 nishing of such services.”.

3 (c) PAYMENT.—

4 (1) IN GENERAL.—Section 1833(a)(1) of the
 5 Social Security Act (42 U.S.C. 1395l(a)(1)) is
 6 amended—

7 (A) by striking “and (BB)” and inserting
 8 “(BB)”; and

9 (B) by inserting before the semicolon at
 10 the end the following “, and (CC) with respect
 11 to opioid use disorder treatment services fur-
 12 nished during an episode of care, the amount
 13 paid shall be equal to the amount payable under
 14 section 1834(w) less any copayment required as
 15 specified by the Secretary”.

16 (2) PAYMENT DETERMINATION.—Section 1834
 17 of the Social Security Act (42 U.S.C. 1395m) is
 18 amended by adding at the end the following new
 19 subsection:

20 “(w) OPIOID USE DISORDER TREATMENT SERV-
 21 ICES.—

22 “(1) IN GENERAL.—The Secretary shall pay to
 23 an opioid treatment program (as defined in para-
 24 graph (2) of section 1861(jjj)) an amount that is
 25 equal to 100 percent of a bundled payment under

1 this part for opioid use disorder treatment services
2 (as defined in paragraph (1) of such section) that
3 are furnished by such program to an individual dur-
4 ing an episode of care (as defined by the Secretary)
5 beginning on or after January 1, 2020. The Sec-
6 retary shall ensure, as determined appropriate by
7 the Secretary, that no duplicative payments are
8 made under this part or part D for items and serv-
9 ices furnished by an opioid treatment program.

10 “(2) CONSIDERATIONS.—The Secretary may
11 implement this subsection through one or more bun-
12 dles based on the type of medication provided (such
13 as buprenorphine, methadone, naltrexone, or a new
14 innovative drug), the frequency of services, the scope
15 of services furnished, characteristics of the individ-
16 uals furnished such services, or other factors as the
17 Secretary determine appropriate. In developing such
18 bundles, the Secretary may consider payment rates
19 paid to opioid treatment programs for comparable
20 services under State plans under title XIX or under
21 the TRICARE program under chapter 55 of title 10
22 of the United States Code.

23 “(3) ANNUAL UPDATES.—The Secretary shall
24 provide an update each year to the bundled payment
25 amounts under this subsection.”.

1 (d) INCLUDING OPIOID TREATMENT PROGRAMS AS
 2 MEDICARE PROVIDERS.—Section 1866(e) of the Social
 3 Security Act (42 U.S.C. 1395cc(e)) is amended—

4 (1) in paragraph (1), by striking at the end
 5 “and”;

6 (2) in paragraph (2), by striking the period at
 7 the end and inserting “; and”; and

8 (3) by adding at the end the following new
 9 paragraph:

10 “(3) opioid treatment programs (as defined in
 11 paragraph (2) of section 1861(jjj)), but only with re-
 12 spect to the furnishing of opioid use disorder treat-
 13 ment services (as defined in paragraph (1) of such
 14 section).”.

15 **TITLE III—OTHER HEALTH PRO-** 16 **VISIONS TO ADDRESS THE** 17 **OPIOID CRISIS**

18 **SEC. 301. CLARIFYING FDA REGULATION OF NON-ADDICT-** 19 **IVE PAIN AND ADDICTION THERAPIES.**

20 (a) PUBLIC MEETINGS.—Not later than 1 year after
 21 the date of enactment of this Act, the Secretary of Health
 22 and Human Services, acting through the Commissioner of
 23 Food and Drugs, shall hold not less than one public meet-
 24 ing to address the challenges and barriers of developing

1 non-addictive medical products intended to treat pain or
2 addiction, which may include—

3 (1) the application of novel clinical trial designs
4 (consistent with section 3021 of the 21st Century
5 Cures Act (Public Law 114–255)), use of real world
6 evidence (consistent with section 505F of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C.
8 355g)), and use of patient experience data (con-
9 sistent with section 569C of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c)) for
11 the development of non-addictive medical products
12 intended to treat pain or addiction; and

13 (2) the application of eligibility criteria under
14 sections 506 and 515B of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 356, 360e–3) for non-
16 addictive medical products intended to treat pain or
17 addiction.

18 (b) GUIDANCE.—Not later than one year after the
19 public meetings are conducted under subsection (a) the
20 Secretary shall issue one or more final guidance docu-
21 ments, or update existing guidance documents, to help ad-
22 dress challenges to developing non-addictive medical prod-
23 ucts to treat pain or addiction. Such guidance documents
24 shall include information regarding—

1 (1) how the Food and Drug Administration
2 may apply sections 506 and 515B of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 356,
4 360e–3) to non-addictive medical products intended
5 to treat pain or addiction, including the cir-
6 cumstances under which the Secretary—

7 (A) may apply the eligibility criteria under
8 such sections 506 and 515B to non-opioid or
9 non-addictive medical products intended to
10 treat pain or addiction;

11 (B) considers the risk of addiction of con-
12 trolled substances approved to treat pain when
13 establishing unmet medical need; and

14 (C) considers pain, pain control, or pain
15 management in assessing whether a disease or
16 condition is a serious or life-threatening disease
17 or condition; and

18 (2) the methods by which sponsors may evalu-
19 ate acute and chronic pain, endpoints for non-addict-
20 ive medical products intended to treat pain, the
21 manner in which endpoints and evaluations of effi-
22 cacy will be applied across and within review divi-
23 sions, taking into consideration the etiology of the
24 underlying disease, and the manner in which spon-

1 sors may use surrogate endpoints, intermediate
2 endpoints, and real world evidence.

3 (c) MEDICAL PRODUCT DEFINED.—In this section,
4 the term “medical product” means a drug (as defined in
5 section 201(g)(1) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 321(g)(1))), biological product (as
7 defined in section 351(i) of the Public Health Service Act
8 (42 U.S.C. 262(i))), or device (as defined in section
9 201(h) of the Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 321(h))).

11 **SEC. 302. SURVEILLANCE AND TESTING OF OPIOIDS TO**
12 **PREVENT FENTANYL DEATHS.**

13 (a) PUBLIC HEALTH LABORATORIES TO DETECT
14 FENTANYL.—Part F of title III of the Public Health Serv-
15 ice Act (42 U.S.C. 262 et seq.) is amended—

16 (1) in the heading of part F, by striking “AND
17 CLINICAL LABORATORIES” and inserting “, CLIN-
18 ICAL LABORATORIES, AND PUBLIC HEALTH LAB-
19 ORATORIES”; and

20 (2) by adding at the end the following new sub-
21 part:

1 **“Subpart 4—Public Health Laboratories**

2 **“SEC. 355. PUBLIC HEALTH LABORATORIES TO DETECT**
3 **FENTANYL.**

4 “(a) IN GENERAL.—The Secretary shall establish a
5 program to award grants to Federal, State, and local
6 agencies to support the establishment or operation of pub-
7 lic health laboratories to detect fentanyl, its analogues,
8 and other synthetic opioids, as described in subsection (b).

9 “(b) STANDARDS.—The Secretary, in consultation
10 with the Director of the National Institute of Standards
11 and Technology, shall—

12 “(1) develop standards for safely and effectively
13 handling and testing fentanyl, its analogues, and
14 other synthetic opioids;

15 “(2) develop fentanyl and fentanyl analog ref-
16 erence materials and quality control standards and
17 protocols to calibrate instrumentation for clinical
18 diagnostics and postmortem surveillance; and

19 “(3) include in the standards developed pursu-
20 ant to paragraph (1) procedures for encountering
21 new and emerging synthetic opioid formulations and
22 reporting those findings to other Federal, State, and
23 local public health laboratories.

24 “(c) LABORATORIES.—The Secretary shall require
25 grantees under subsection (a) to—

1 “(1) follow the standards established under
2 subsection (b) and be capable of providing system-
3 atic and routine laboratory testing of drugs for the
4 purposes of obtaining and disseminating public
5 health information to Federal, State, and local pub-
6 lic health officials, laboratories, and other entities
7 the Secretary deems appropriate;

8 “(2) work with law enforcement agencies and
9 public health authorities, as feasible, to develop real-
10 time information on the purity and movement of
11 fentanyl, its analogues, and other synthetic opioids;

12 “(3) assist State and local law enforcement
13 agencies in testing seized drugs when State and local
14 forensic laboratories request additional assistance;

15 “(4) provide early warning information and ad-
16 vice to Federal, State, and local law enforcement
17 agencies and public health authorities regarding po-
18 tential significant changes in the supply of fentanyl,
19 its analogues, and other synthetic opioids;

20 “(5) provide biosurveillance for non-fatal expo-
21 sures; and

22 “(6) provide diagnostic testing for non-fatal ex-
23 posures of emergency personnel.

24 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
25 carry out this section, there is authorized to be appro-

1 priated \$15,000,000 for each of fiscal years 2019 through
2 2023.”.

3 (b) ENHANCED FENTANYL SURVEILLANCE.—Title
4 III of the Public Health Service Act is amended by insert-
5 ing after section 317T of such Act (42 U.S.C. 247b–22)
6 the following new section:

7 **“SEC. 317U. ENHANCED FENTANYL SURVEILLANCE.**

8 “(a) IN GENERAL.—The Director of the Centers for
9 Disease Control and Prevention shall enhance its drug
10 surveillance program by—

11 “(1) expanding its surveillance program to in-
12 clude all 50 States and the territories of the United
13 States;

14 “(2) increasing and accelerating the collection
15 of data on fentanyl, its analogues, and other syn-
16 thetic opioids and new emerging drugs of abuse, in-
17 cluding related overdose data from medical exam-
18 iners and drug treatment admissions; and

19 “(3) utilizing available and emerging informa-
20 tion on fentanyl, its analogues, and other synthetic
21 opioids and new emerging drugs of abuse, including
22 information from—

23 “(A) the National Drug Early Warning
24 System;

1 “(B) State and local public health authori-
 2 ties; and

3 “(C) Federal, State, and local public
 4 health laboratories.

5 “(b) AUTHORIZATION OF APPROPRIATIONS.—To
 6 carry out this section, there is authorized to be appro-
 7 priated \$10,000,000 for each of fiscal years 2019 through
 8 2023.”.

9 (c) PILOT PROGRAM FOR POINT-OF-USE TESTING OF
 10 ILLICIT DRUGS FOR DANGEROUS CONTAMINANTS.—Part
 11 P of title III of the Public Health Service Act (42 U.S.C.
 12 280g et seq.) is amended by adding at the end the fol-
 13 lowing new section:

14 **“SEC. 399V-7. PILOT PROGRAM FOR POINT-OF-USE TESTING**
 15 **OF ILLICIT DRUGS FOR DANGEROUS CON-**
 16 **TAMINANTS.**

17 “(a) IN GENERAL.—The Secretary shall—

18 “(1) establish a pilot program through which 5
 19 State or local agencies conduct, in 5 States, point-
 20 of-use testing of illicit drugs for dangerous contami-
 21 nants;

22 “(2) establish metrics to evaluate the success of
 23 the pilot program in reducing drug overdose rates;
 24 and

1 “(3) based on such metrics, conduct an annual
 2 evaluation of the pilot program and submit an an-
 3 nual report to the Congress containing the results of
 4 such evaluation.

5 “(b) AUTHORIZATION OF APPROPRIATIONS.—To
 6 carry out this section, there is authorized to be appro-
 7 priated \$5,000,000 for each of fiscal years 2019 through
 8 2023.”.

9 **SEC. 303. ALLOWING FOR MORE FLEXIBILITY WITH RE-**
 10 **SPECT TO MEDICATION-ASSISTED TREAT-**
 11 **MENT FOR OPIOID USE DISORDERS.**

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

16 “(II) The applicable number is—

17 “(aa) 100 if, not sooner than 1 year after
 18 the date on which the practitioner submitted
 19 the initial notification, the practitioner submits
 20 a second notification to the Secretary of the
 21 need and intent of the practitioner to treat up
 22 to 100 patients;

23 “(bb) 100 if the practitioner holds addi-
 24 tional credentialing, as defined in section 8.2 of

1 title 42, Code of Federal Regulations (or suc-
 2 cessor regulations); or

3 “(cc) 100 if the practitioner provides medi-
 4 cation-assisted treatment (MAT) using covered
 5 medications (as such terms are defined in sec-
 6 tion 8.2 of title 42, Code of Federal Regula-
 7 tions (or successor regulations)) in a qualified
 8 practice setting (as described in section 8.615
 9 of title 42, Code of Federal Regulations (or suc-
 10 cessor regulations)).”.

11 (b) ELIMINATING ANY TIME LIMITATION FOR NURSE
 12 PRACTITIONERS AND PHYSICIAN ASSISTANTS TO BE-
 13 COME QUALIFYING PRACTITIONERS.—Clause (iii) of sec-
 14 tion 303(g)(2)(G) of the Controlled Substances Act (21
 15 U.S.C. 823(g)(2)(G)) is amended—

16 (1) in subclause (I), by striking “or” at the
 17 end; and

18 (2) by amending subclause (II) to read as fol-
 19 lows:

20 “(II) a qualifying other practitioner, as de-
 21 fined in clause (iv), who is a nurse practitioner
 22 or physician assistant; or”.

23 (c) IMPOSING A TIME LIMITATION FOR CLINICAL
 24 NURSE SPECIALISTS, CERTIFIED REGISTERED NURSE
 25 ANESTHETISTS, AND CERTIFIED NURSE MIDWIVES TO

1 BECOME QUALIFYING PRACTITIONERS.—Clause (iii) of
 2 section 303(g)(2)(G) of the Controlled Substances Act (21
 3 U.S.C. 823(g)(2)(G)), as amended by subsection (b), is
 4 further amended by adding at the end the following:

5 “(III) for the period beginning on October
 6 1, 2018, and ending on October 1, 2023, a
 7 qualifying other practitioner, as defined in
 8 clause (iv), who is a clinical nurse specialist,
 9 certified registered nurse anesthetist, or cer-
 10 tified nurse midwife.”.

11 (d) DEFINITION OF QUALIFYING OTHER PRACTI-
 12 TIONER.—Section 303(g)(2)(G)(iv) of the Controlled Sub-
 13 stances Act (21 U.S.C. 823(g)(2)(G)(iv)) is amended by
 14 striking “nurse practitioner or physician assistant” each
 15 place it appears and inserting “nurse practitioner, clinical
 16 nurse specialist, certified registered nurse anesthetist, cer-
 17 tified nurse midwife, or physician assistant”.

18 (e) REPORT BY SECRETARY.—Not later than two
 19 years after the date of the enactment of this Act, the Sec-
 20 retary of Health and Human Services, in consultation with
 21 the Drug Enforcement Administration, shall submit to
 22 Congress a report that assesses the care provided by quali-
 23 fying practitioners (as defined in section 303(g)(2)(G)(iii)
 24 of the Controlled Substances Act (21 U.S.C.
 25 823(g)(2)(G)(iii))) who are treating, in the case of physi-

1 cians, 100 or more patients, and in the case of qualifying
2 practitioners who are not physicians, 30 or more patients.
3 Such report shall include recommendations on future ap-
4 plicable patient number levels and limits. In preparing
5 such report, the Secretary shall study, with respect to
6 opioid use disorder treatment—

7 (1) the average frequency with which qualifying
8 practitioners see their patients;

9 (2) the average frequency with which patients
10 receive counseling, including the rates by which such
11 counseling is provided by such a qualifying practi-
12 tioner directly, or by referral;

13 (3) the average frequency with which random
14 toxicology testing is administered;

15 (4) the average monthly patient caseload for
16 each type of qualifying practitioner;

17 (5) the treatment retention rates for patients;

18 (6) overdose and mortality rates; and

19 (7) any available information regarding the di-
20 version of drugs by patients receiving such treat-
21 ment from such a qualifying practitioner.

TITLE IV—OFFSETS

SEC. 401. PROMOTING VALUE IN MEDICAID MANAGED CARE.

Section 1903(m) of the Social Security Act (42 U.S.C. 1396b(m)) is amended by adding at the end the following new paragraph:

“(7)(A) With respect to expenditures described in subparagraph (B) that are incurred by a State for any fiscal year after fiscal year 2020 (and before fiscal year 2025), in determining the pro rata share to which the United States is equitably entitled under subsection (d)(3), the Secretary shall substitute the Federal medical assistance percentage that applies for such fiscal year to the State under section 1905(b) (without regard to any adjustments to such percentage applicable under such section or any other provision of law) for the percentage that applies to such expenditures under section 1905(y).

“(B) Expenditures described in this subparagraph, with respect to a fiscal year to which subparagraph (A) applies, are expenditures incurred by a State for payment for medical assistance provided to individuals described in subclause (VIII) of section 1902(a)(10)(A)(i) by a managed care entity, or other specified entity (as defined in subparagraph (D)(iii)), that are treated as remittances because the State—

1 “(i) has satisfied the requirement of section
2 438.8 of title 42, Code of Federal Regulations (or
3 any successor regulation), by electing—

4 “(I) in the case of a State described in
5 subparagraph (C), to apply a minimum medical
6 loss ratio (as defined in subparagraph (D)(ii))
7 that is equal to or greater than 85 percent; or

8 “(II) in the case of a State not described
9 in subparagraph (C), to apply a minimum med-
10 ical loss ratio that is equal to 85 percent; and

11 “(ii) recovered all or a portion of the expendi-
12 tures as a result of the entity’s failure to meet such
13 ratio.

14 “(C) For purposes of subparagraph (B), a State de-
15 scribed in this subparagraph is a State that as of May
16 31, 2018, applied a minimum medical loss ratio (as cal-
17 culated under subsection (d) of section 438.8 of title 42,
18 Code of Federal Regulations (as in effect on June 1,
19 2018)) for payment for services provided by entities de-
20 scribed in such subparagraph under the State plan under
21 this title (or a waiver of the plan) that is equal to or great-
22 er than 85 percent.

23 “(D) For purposes of this paragraph:

1 “(i) The term ‘managed care entity’ means a
2 medicaid managed care organization described in
3 section 1932(a)(1)(B)(i).

4 “(ii) The term ‘minimum medical loss ratio’
5 means, with respect to a State, a minimum medical
6 loss ratio (as calculated under subsection (d) of sec-
7 tion 438.8 of title 42, Code of Federal Regulations
8 (as in effect on June 1, 2018)) for payment for serv-
9 ices provided by entities described in subparagraph
10 (B) under the State plan under this title (or a waiv-
11 er of the plan).

12 “(iii) The term ‘other specified entity’ means—

13 “(I) a prepaid inpatient health plan, as de-
14 fined in section 438.2 of title 42, Code of Fed-
15 eral Regulations (or any successor regulation);
16 and

17 “(II) a prepaid ambulatory health plan, as
18 defined in such section (or any successor regu-
19 lation).”.

20 **SEC. 402. EXTENDING PERIOD OF APPLICATION OF MEDI-**
21 **CARE SECONDARY PAYER RULES FOR INDI-**
22 **VIDUALS WITH END STAGE RENAL DISEASE.**

23 Section 1862(b)(1)(C) of the Social Security Act (42
24 U.S.C. 1395y(b)(1)(C)) is amended—

1 (1) in the last sentence, by inserting “and be-
 2 fore January 1, 2020” after “date of enactment of
 3 the Balanced Budget Act of 1997”; and

4 (2) by adding at the end the following new sen-
 5 tence: “Effective for items and services furnished on
 6 or after January 1, 2020 (with respect to periods
 7 beginning on or after July 1, 2018), clauses (i) and
 8 (ii) shall be applied by substituting ‘33-month’ for
 9 ‘12-month’ each place it appears.”.

10 **SEC. 403. REQUIRING REPORTING BY GROUP HEALTH**
 11 **PLANS OF PRESCRIPTION DRUG COVERAGE**
 12 **INFORMATION FOR PURPOSES OF IDENTI-**
 13 **FYING PRIMARY PAYER SITUATIONS UNDER**
 14 **THE MEDICARE PROGRAM.**

15 Clause (i) of section 1862(b)(7)(A) of the Social Se-
 16 curity Act (42 U.S.C. 1395y(b)(7)(A)) is amended to read
 17 as follows:

18 “(i) secure from the plan sponsor and
 19 plan participants such information as the
 20 Secretary shall specify for the purpose of
 21 identifying situations where the group
 22 health plan is or has been—

23 “(I) a primary plan to the pro-
 24 gram under this title; or

1 “(II) for calendar quarters begin-
2 ning on or after January 1, 2020, a
3 primary payer with respect to benefits
4 relating to prescription drug coverage
5 under part D; and”.

○