

JUNE 13, 2018

RULES COMMITTEE PRINT 115–76
TEXT OF H.R. 6, SUBSTANCE USE-DISORDER PRE-
VENTION THAT PROMOTES OPIOID RECOVERY
AND TREATMENT FOR PATIENTS AND COMMU-
NITIES ACT

[Showing the text of H.R. 6, as introduced]

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

7 (b) TABLE OF CONTENTS.—The table of contents for
8 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 Welcome 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 substances.
- Sec. 206. Requiring prescription drug plan sponsors under Medicare to establish 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 therapies.
- Sec. 302. Surveillance and Testing of Opioids to Prevent Fentanyl Deaths.
- Sec. 303. Allowing for more flexibility with respect to medication-assisted treatment 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);

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

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

5 “(84) provide that—

6 (A) the State shall not terminate eligi-
7 bility for medical assistance under the State
8 plan for an individual who is an eligible juvenile
9 (as defined in subsection (nn)(2)) because the
10 juvenile is an inmate of a public institution (as
11 defined in subsection (nn)(3)), but may suspend
12 coverage during the period the juvenile is such
13 an inmate;

14 (B) in the case of an individual who is an
15 eligible juvenile described in paragraph (2)(A)
16 of subsection (nn), the State shall, prior to the
17 individual’s release from such a public institu-
18 tion, conduct a redetermination of eligibility for
19 such individual with respect to such medical as-
20 sistance (without requiring a new application
21 from the individual) and, if the State deter-
22 mines pursuant to such redetermination that
23 the individual continues to meet the eligibility
24 requirements for such medical assistance, the
25 State shall restore coverage for such medical

1 assistance to such an individual upon the indi-
2 vidual's release from such public institution;
3 and

4 “(C) in the case of an individual who is an
5 eligible juvenile described in paragraph (2)(B)
6 of subsection (nn), the State shall process any
7 application for medical assistance submitted by,
8 or on behalf of, such individual such that the
9 State makes a determination of eligibility for
10 such individual with respect to such medical as-
11 sistance upon release of such individual from
12 such public institution.”; and

13 (2) by adding at the end the following new sub-
14 section:

15 “(nn) **JUVENILE; ELIGIBLE JUVENILE; PUBLIC IN-**
16 **STITUTION.**—For purposes of subsection (a)(84) and this
17 subsection:

18 “(1) **JUVENILE.**—The term ‘juvenile’ means an
19 individual who is—

20 “(A) under 21 years of age; or

21 “(B) described in subsection
22 (a)(10)(A)(i)(IX).

23 “(2) **ELIGIBLE JUVENILE.**—The term ‘eligible
24 juvenile’ means a juvenile who is an inmate of a
25 public institution and who—

1 “(A) was determined eligible for medical
2 assistance under the State plan immediately be-
3 fore becoming an inmate of such a public insti-
4 tution; or

5 “(B) is determined eligible for such med-
6 ical assistance while an inmate of a public insti-
7 tution.

8 “(3) INMATE OF A PUBLIC INSTITUTION.—The
9 term ‘inmate of a public institution’ has the meaning
10 given such term for purposes of applying the sub-
11 division (A) following paragraph (29) of section
12 1905(a), taking into account the exception in such
13 subdivision for a patient of a medical institution.”.

14 (b) NO CHANGE IN EXCLUSION FROM MEDICAL AS-
15 SISTANCE FOR INMATES OF PUBLIC INSTITUTIONS.—
16 Nothing in this section shall be construed as changing the
17 exclusion from medical assistance under the subdivision
18 (A) following paragraph (29) of section 1905(a) of the So-
19 cial Security Act (42 U.S.C. 1396d(a)), including any ap-
20 plicable restrictions on a State submitting claims for Fed-
21 eral financial participation under title XIX of such Act
22 for such assistance.

23 (c) NO CHANGE IN CONTINUITY OF ELIGIBILITY BE-
24 FORE ADJUDICATION OR SENTENCING.—Nothing in this
25 section shall be construed to mandate, encourage, or sug-

1 gest that a State suspend or terminate coverage for indi-
2 viduals before they have been adjudicated or sentenced.

3 (d) EFFECTIVE DATE.—

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

9 (2) RULE FOR CHANGES REQUIRING STATE
10 LEGISLATION.—In the case of a State plan for med-
11 ical assistance under title XIX of the Social Security
12 Act which the Secretary of Health and Human Serv-
13 ices determines requires State legislation (other than
14 legislation appropriating funds) in order for the plan
15 to meet the additional requirements imposed by the
16 amendments made by subsection (a), the State plan
17 shall not be regarded as failing to comply with the
18 requirements of such title solely on the basis of its
19 failure to meet these additional requirements before
20 the first day of the first calendar quarter beginning
21 after the close of the first regular session of the
22 State legislature that begins after the date of the en-
23 actment of this Act. For purposes of the previous
24 sentence, in the case of a State that has a 2-year
25 legislative session, each year of such session shall be

1 deemed to be a separate regular session of the State
2 legislature.

3 **SEC. 102. HEALTH INSURANCE FOR FORMER FOSTER**
4 **YOUTH.**

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

7 (1) IN GENERAL.—Section
8 1902(a)(10)(A)(i)(IX) of the Social Security Act (42
9 U.S.C. 1396a(a)(10)(A)(i)(IX)) is amended—

10 (A) in item (bb), by striking “are not de-
11 scribed in or enrolled under” and inserting “are
12 not described in and are not enrolled under”;

13 (B) in item (cc), by striking “responsibility
14 of the State” and inserting “responsibility of a
15 State”; and

16 (C) in item (dd), by striking “the State
17 plan under this title or under a waiver of the”
18 and inserting “a State plan under this title or
19 under a waiver of such a”.

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

24 (b) GUIDANCE.—Not later than one year after the
25 date of the enactment of this Act, the Secretary of Health

1 and Human Services shall issue guidance to States, with
2 respect to the State Medicaid programs of such States—

3 (1) on best practices for—

4 (A) removing barriers and ensuring
5 streamlined, timely access to Medicaid coverage
6 for former foster youth up to age 26; and

7 (B) conducting outreach and raising
8 awareness among such youth regarding Med-
9 icaid coverage options for such youth; and

10 (2) which shall include examples of States that
11 have successfully extended Medicaid coverage to
12 former foster youth up to age 26.

13 **SEC. 103. DEMONSTRATION PROJECT TO INCREASE SUB-**
14 **STANCE USE PROVIDER CAPACITY UNDER**
15 **THE MEDICAID PROGRAM.**

16 Section 1903 of the Social Security Act (42 U.S.C.
17 1396b) is amended by adding at the end the following new
18 subsection:

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

21 “(1) IN GENERAL.—Not later than the date
22 that is 180 days after the date of the enactment of
23 this section, the Secretary shall, in consultation, as
24 appropriate, with the Director of the Agency for
25 Healthcare Research and Quality and the Assistant

1 Secretary for Mental Health and Substance Use,
2 conduct a 54-month demonstration project for the
3 purpose described in paragraph (2) under which the
4 Secretary shall—

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

8 “(B) for the remaining 36-month period of
9 such project, provide to each State selected
10 under paragraph (4) payments in accordance
11 with paragraph (5).

12 “(2) PURPOSE.—The purpose described in this
13 paragraph is for each State selected under para-
14 graph (4) to increase the treatment capacity of pro-
15 viders participating under the State plan (or a waiv-
16 er of such plan) to provide substance use disorder
17 treatment or recovery services under such plan (or
18 waiver) through the following activities:

19 “(A) For the purpose described in para-
20 graph (3)(C)(i), activities that support an ongo-
21 ing assessment of the behavioral health treat-
22 ment needs of the State, taking into account
23 the matters described in subclauses (I) through
24 (IV) of such paragraph.

1 “(B) Activities that, taking into account
2 the results of the assessment described in sub-
3 paragraph (A), support the recruitment, train-
4 ing, and provision of technical assistance for
5 providers participating under the State plan (or
6 a waiver of such plan) that offer substance use
7 disorder treatment or recovery services.

8 “(C) Improved reimbursement for and ex-
9 pansion of, through the provision of education,
10 training, and technical assistance, the number
11 or treatment capacity of providers participating
12 under the State plan (or waiver) that—

13 “(i) are authorized to dispense drugs
14 approved by the Food and Drug Adminis-
15 tration for individuals with a substance use
16 disorder who need withdrawal management
17 or maintenance treatment for such dis-
18 order;

19 “(ii) have in effect a registration or
20 waiver under section 303(g) of the Con-
21 trolled Substances Act for purposes of dis-
22 pensing narcotic drugs to individuals for
23 maintenance treatment or detoxification
24 treatment and are in compliance with any
25 regulation promulgated by the Assistant

1 Secretary for Mental Health and Sub-
2 stance Use for purposes of carrying out
3 the requirements of such section 303(g);
4 and

5 “(iii) are qualified under applicable
6 State law to provide substance use disorder
7 treatment or recovery services.

8 “(D) Improved reimbursement for and ex-
9 pansion of, through the provision of education,
10 training, and technical assistance, the number
11 or treatment capacity of providers participating
12 under the State plan (or waiver) that have the
13 qualifications to address the treatment or recov-
14 ery needs of—

15 “(i) individuals enrolled under the
16 State plan (or a waiver of such plan) who
17 have neonatal abstinence syndrome, in ac-
18 cordance with guidelines issued by the
19 American Academy of Pediatrics and
20 American College of Obstetricians and
21 Gynecologists relating to maternal care
22 and infant care with respect to neonatal
23 abstinence syndrome;

24 “(ii) pregnant women, postpartum
25 women, and infants, particularly the con-

1 current treatment, as appropriate, and
2 comprehensive case management of preg-
3 nant women, postpartum women and in-
4 fants, enrolled under the State plan (or a
5 waiver of such plan);

6 “(iii) adolescents and young adults be-
7 tween the ages of 12 and 21 enrolled
8 under the State plan (or a waiver of such
9 plan); or

10 “(iv) American Indian and Alaska Na-
11 tive individuals enrolled under the State
12 plan (or a waiver of such plan).

13 “(3) PLANNING GRANTS.—

14 “(A) IN GENERAL.—The Secretary shall,
15 with respect to the first 18-month period of the
16 demonstration project conducted under para-
17 graph (1), award planning grants to at least 10
18 States selected in accordance with subpara-
19 graph (B) for purposes of preparing an applica-
20 tion described in paragraph (4)(C) and carrying
21 out the activities described in subparagraph
22 (C).

23 “(B) SELECTION.—In selecting States for
24 purposes of this paragraph, the Secretary
25 shall—

1 “(i) select States that have a State
2 plan (or waiver of the State plan) approved
3 under this title;

4 “(ii) select States in a manner that
5 ensures geographic diversity; and

6 “(iii) give preference to States with a
7 prevalence of substance use disorders (in
8 particular opioid use disorders) that is
9 comparable to or higher than the national
10 average prevalence, as measured by aggre-
11 gate per capita drug overdoses, or any
12 other measure that the Secretary deems
13 appropriate.

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

17 “(i) Activities that support the devel-
18 opment of an initial assessment of the be-
19 havioral health treatment needs of the
20 State to determine the extent to which pro-
21 viders are needed (including the types of
22 such providers and geographic area of
23 need) to improve the network of providers
24 that treat substance use disorders under

1 the State plan (or waiver), including the
2 following:

3 “(I) An estimate of the number
4 of individuals enrolled under the State
5 plan (or a waiver of such plan) who
6 have a substance use disorder.

7 “(II) Information on the capacity
8 of providers to provide substance use
9 disorder treatment or recovery serv-
10 ices to individuals enrolled under the
11 State plan (or waiver), including in-
12 formation on providers who provide
13 such services and their participation
14 under the State plan (or waiver).

15 “(III) Information on the gap in
16 substance use disorder treatment or
17 recovery services under the State plan
18 (or waiver) based on the information
19 described in subclauses (I) and (II).

20 “(IV) Projections regarding the
21 extent to which the State partici-
22 pating under the demonstration
23 project would increase the number of
24 providers offering substance use dis-
25 order treatment or recovery services

1 under the State plan (or waiver) dur-
2 ing the period of the demonstration
3 project.

4 “(ii) Activities that, taking into ac-
5 count the results of the assessment de-
6 scribed in clause (i), support the develop-
7 ment of State infrastructure to, with re-
8 spect to the provision of substance use dis-
9 order treatment or recovery services under
10 the State plan (or a waiver of such plan),
11 recruit prospective providers and provide
12 training and technical assistance to such
13 providers.

14 “(D) FUNDING.—For purposes of subpara-
15 graph (A), there is appropriated, out of any
16 funds in the Treasury not otherwise appro-
17 priated, \$50,000,000, to remain available until
18 expended.

19 “(4) POST-PLANNING STATES.—

20 “(A) IN GENERAL.—The Secretary shall,
21 with respect to the remaining 36-month period
22 of the demonstration project conducted under
23 paragraph (1), select not more than 5 States in
24 accordance with subparagraph (B) for purposes
25 of carrying out the activities described in para-

1 graph (2) and receiving payments in accordance
2 with paragraph (5).

3 “(B) SELECTION.—In selecting States for
4 purposes of this paragraph, the Secretary
5 shall—

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

8 “(ii) select States that submit to the
9 Secretary an application in accordance
10 with the requirements in subparagraph
11 (C), taking into consideration the quality
12 of each such application;

13 “(iii) select States in a manner that
14 ensures geographic diversity; and

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

23 “(C) APPLICATIONS.—

24 “(i) IN GENERAL.—A State seeking to
25 be selected for purposes of this paragraph

1 shall submit to the Secretary, at such time
2 and in such form and manner as the Sec-
3 retary requires, an application that in-
4 cludes such information, provisions, and
5 assurances, as the Secretary may require,
6 in addition to the following:

7 “(I) A proposed process for car-
8 rying out the ongoing assessment de-
9 scribed in paragraph (2)(A), taking
10 into account the results of the initial
11 assessment described in paragraph
12 (3)(C)(i).

13 “(II) A review of reimbursement
14 methodologies and other policies re-
15 lated to substance use disorder treat-
16 ment or recovery services under the
17 State plan (or waiver) that may create
18 barriers to increasing the number of
19 providers delivering such services.

20 “(III) The development of a plan,
21 taking into account activities carried
22 out under paragraph (3)(C)(ii), that
23 will result in long-term and sustain-
24 able provider networks under the
25 State plan (or waiver) that will offer

1 a continuum of care for substance use
2 disorders. Such plan shall include the
3 following:

4 “(aa) Specific activities to
5 increase the number of providers
6 (including providers that spe-
7 cialize in providing substance use
8 disorder treatment or recovery
9 services, hospitals, health care
10 systems, Federally qualified
11 health centers, and, as applicable,
12 certified community behavioral
13 health clinics) that offer sub-
14 stance use disorder treatment, re-
15 covery, or support services, in-
16 cluding short-term detoxification
17 services, outpatient substance use
18 disorder services, and evidence-
19 based peer recovery services.

20 “(bb) Strategies that will
21 incentivize providers described in
22 subparagraphs (C) and (D) of
23 paragraph (2) to obtain the nec-
24 essary training, education, and
25 support to deliver substance use

1 disorder treatment or recovery
2 services in the State.

3 “(cc) Milestones and timeli-
4 ness for implementing activities
5 set forth in the plan.

6 “(dd) Specific measurable
7 targets for increasing the sub-
8 stance use disorder treatment
9 and recovery provider network
10 under the State plan (or a waiver
11 of such plan).

12 “(IV) A proposed process for re-
13 porting the information required
14 under paragraph (6)(A), including in-
15 formation to assess the effectiveness
16 of the efforts of the State to expand
17 the capacity of providers to deliver
18 substance use disorder treatment or
19 recovery services during the period of
20 the demonstration project under this
21 subsection.

22 “(V) The expected financial im-
23 pact of the demonstration project
24 under this subsection on the State.

1 “(VI) A description of all funding
2 sources available to the State to pro-
3 vide substance use disorder treatment
4 or recovery services in the State.

5 “(VII) A preliminary plan for
6 how the State will sustain any in-
7 crease in the capacity of providers to
8 deliver substance use disorder treat-
9 ment or recovery services resulting
10 from the demonstration project under
11 this subsection after the termination
12 of such demonstration project.

13 “(VIII) A description of how the
14 State will coordinate the goals of the
15 demonstration project with any waiver
16 granted (or submitted by the State
17 and pending) pursuant to section
18 1115 for the delivery of substance use
19 services under the State plan, as ap-
20 plicable.

21 “(ii) CONSULTATION.—In completing
22 an application under clause (i), a State
23 shall consult with relevant stakeholders, in-
24 cluding Medicaid managed care plans,
25 health care providers, and Medicaid bene-

1 ficiary advocates, and include in such ap-
2 plication a description of such consultation.

3 “(5) PAYMENT.—

4 “(A) IN GENERAL.—For each quarter oc-
5 curring during the period for which the dem-
6 onstration project is conducted (after the first
7 18 months of such period), the Secretary shall
8 pay under this subsection, subject to subpara-
9 graph (C), to each State selected under para-
10 graph (4) an amount equal to 80 percent of so
11 much of the qualified sums expended during
12 such quarter.

13 “(B) QUALIFIED SUMS DEFINED.—For
14 purposes of subparagraph (A), the term ‘quali-
15 fied sums’ means, with respect to a State and
16 a quarter, the amount equal to the amount (if
17 any) by which the sums expended by the State
18 during such quarter attributable to substance
19 use treatment or recovery services furnished by
20 providers participating under the State plan (or
21 a waiver of such plan) exceeds 1/4 of such sums
22 expended by the State during fiscal year 2018
23 attributable to substance use treatment or re-
24 covery services.

1 “(C) NON-DUPLICATION OF PAYMENT.—In
2 the case that payment is made under subpara-
3 graph (A) with respect to expenditures for sub-
4 stance use treatment or recovery services fur-
5 nished by providers participating under the
6 State plan (or a waiver of such plan), payment
7 may not also be made under subsection (a) with
8 respect to expenditures for the same services so
9 furnished.

10 “(6) REPORTS.—

11 “(A) STATE REPORTS.—A State receiving
12 payments under paragraph (5) shall, for the pe-
13 riod of the demonstration project under this
14 subsection, submit to the Secretary a quarterly
15 report, with respect to expenditures for sub-
16 stance use treatment or recovery services for
17 which payment is made to the State under this
18 subsection, on the following:

19 “(i) The specific activities with re-
20 spect to which payment under this sub-
21 section was provided.

22 “(ii) The number of providers that de-
23 livered substance use disorder treatment or
24 recovery services in the State under the
25 demonstration project compared to the es-

1 timated number of providers that would
2 have otherwise delivered such services in
3 the absence of such demonstration project.

4 “(iii) The number of individuals en-
5 rolled under the State plan (or a waiver of
6 such plan) who received substance use dis-
7 order treatment or recovery services under
8 the demonstration project compared to the
9 estimated number of such individuals who
10 would have otherwise received such services
11 in the absence of such demonstration
12 project.

13 “(iv) Other matters as determined by
14 the Secretary.

15 “(B) CMS REPORTS.—

16 “(i) INITIAL REPORT.—Not later than
17 October 1, 2020, 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 an initial report on—

24 “(I) the States awarded planning
25 grants under paragraph (3);

1 “(II) the criteria used in such se-
2 lection; and

3 “(III) the activities carried out
4 by such States under such planning
5 grants.

6 “(ii) INTERIM REPORT.—Not later
7 than October 1, 2022, the Administrator
8 of the Centers for Medicare & Medicaid
9 Services shall, in consultation with the Di-
10 rector of the Agency for Healthcare Re-
11 search and Quality and the Assistant Sec-
12 retary for Mental Health and Substance
13 Use, submit to Congress an interim re-
14 port—

15 “(I) on activities carried out
16 under the demonstration project
17 under this subsection;

18 “(II) on the extent to which
19 States selected under paragraph (4)
20 have achieved the stated goals sub-
21 mitted in their applications under sub-
22 paragraph (C) of such paragraph;

23 “(III) with a description of the
24 strengths and limitations of such dem-
25 onstration project; and

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

3 “(iii) FINAL REPORT.—Not later than
4 October 1, 2024, the Administrator of the
5 Centers for Medicare & Medicaid Services
6 shall, in consultation with the Director of
7 the Agency for Healthcare Research and
8 Quality and the Assistant Secretary for
9 Mental Health and Substance Use, submit
10 to Congress a final report—

11 “(I) providing updates on the
12 matters reported in the interim report
13 under clause (ii);

14 “(II) including a description of
15 any changes made with respect to the
16 demonstration project under this sub-
17 section after the submission of such
18 interim report; and

19 “(III) evaluating such dem-
20 onstration project.

21 “(C) AHRQ REPORT.—Not later than
22 three years after the date of the enactment of
23 this subsection, the Director of the Agency for
24 Healthcare Research and Quality, on consulta-
25 tion with the Administrator of the Centers for

1 Medicare & Medicaid Services, shall submit to
2 Congress a summary on the experiences of
3 States awarded planning grants under para-
4 graph (3) and States selected under paragraph
5 (4).

6 “(7) DATA SHARING AND BEST PRACTICES.—
7 During the period of the demonstration project
8 under this subsection, the Secretary shall, in collabo-
9 ration with States selected under paragraph (4), fa-
10 cilitate data sharing and the development of best
11 practices between such States and States that were
12 not so selected.

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

19 **SEC. 104. DRUG MANAGEMENT PROGRAM FOR AT-RISK**
20 **BENEFICIARIES.**

21 (a) IN GENERAL.—Title XIX of the Social Security
22 Act is amended by inserting after section 1927 (42 U.S.C.
23 1396r–8) the following new section:

1 **“SEC. 1927A. DRUG MANAGEMENT PROGRAM FOR AT-RISK**
2 **BENEFICIARIES.**

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

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

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

18 “(2) ELEMENTS OF PROGRAM.—

19 “(A) IN GENERAL.—Under the program,
20 the State, with respect to each individual identi-
21 fied under paragraph (1) and enrolled under
22 the program under paragraph (5)—

23 “(i) subject to subparagraphs (B) and
24 (C), selects at least one, but not more than
25 three, health care providers and at least
26 one, but not more than three, pharmacies

1 for each such individual for purposes of
2 clause (ii), in accordance with a selection
3 process that takes into account reasonable
4 factors such as the individual's previous
5 utilization of items and services from
6 health care providers and pharmacies, geo-
7 graphic proximity of the individual to such
8 health care providers and pharmacies, ac-
9 cess of the individual to health care, rea-
10 sonable travel time, information regarding
11 housing status, and any known preference
12 of the individual for a certain health care
13 provider or pharmacy; and

14 “(ii) requires that any controlled sub-
15 stance furnished to such individual during
16 the period for which such individual is en-
17 rolled under the program be prescribed by
18 a health care provider selected under
19 clause (i) for such individual and dispensed
20 by a pharmacy selected under clause (i) for
21 such individual in order for such controlled
22 substance to be covered under the State
23 plan (or waiver).

24 “(B) BENEFICIARY PREFERENCE.—In the
25 case of an individual receiving a notice under

1 paragraph (3)(A) of being identified as poten-
2 tially being an at-risk beneficiary described in
3 such paragraph, such individual may submit,
4 during the 30-day period following receipt of
5 such notice, preferences for which health care
6 providers and pharmacies the individual would
7 prefer the State to select under subparagraph
8 (A). The State shall select or change the selec-
9 tion of health care providers and pharmacies
10 under subparagraph (A) for the individuals
11 based on such preferences, except that in the
12 case that State determines that such selection
13 (or change of selection) of a health care pro-
14 vider or pharmacy under subparagraph (A) is
15 contributing or would contribute to prescription
16 drug abuse or drug diversion by the individual,
17 the State may select or change the selection of
18 health care provider or pharmacy for the indi-
19 vidual without regard to the preferences of the
20 individual described in this subparagraph. If the
21 State selects or changes the selection pursuant
22 to the preceding sentence without regard to the
23 preferences of the individual, the State shall
24 provide the individual with at least 30 days
25 written notice of the selection or change of se-

1 lection and a rationale for the selection or
2 change.

3 “(C) TREATMENT OF PHARMACY WITH
4 MULTIPLE LOCATIONS.—For purposes of sub-
5 paragraph (A)(i), in the case of a pharmacy
6 that has multiple locations that share real-time
7 electronic prescription data, all such locations
8 of the pharmacy shall collectively be treated as
9 one pharmacy.

10 “(D) TREATMENT OF EXISTING FFS DRUG
11 MANAGEMENT PROGRAMS.—In the case of a pa-
12 tient review and restriction program (as identi-
13 fied in the annual report submitted to the Sec-
14 retary under section 1927(g)(3)(D)) operated
15 by a State pursuant to section 1915(a)(2) be-
16 fore the date of the enactment of this section,
17 such program shall be treated as a qualified
18 drug management program.

19 “(E) REASONABLE ACCESS.—The program
20 shall ensure, including through waiver of ele-
21 ments of the program (including under sub-
22 paragraph (A)(ii)), reasonable access to health
23 care (including access to health care providers
24 and pharmacies with respect to prescription
25 drugs described in subparagraph (A)) in the

1 case of individuals with multiple residences, in
2 the case of natural disasters and similar situa-
3 tions, and in the case of the provision of emer-
4 gency services (as defined for purposes of sec-
5 tion 1860D-4(c)(5)(D)(ii)(II)).

6 “(3) NOTIFICATION TO IDENTIFIED INDIVID-
7 UALS.—Under the program, the State provides each
8 individual who is identified under paragraph (1),
9 prior to enrolling such individual under the program,
10 at least one notification of each of the following:

11 “(A) Notice that the State has identified
12 the individual as potentially being an at-risk
13 beneficiary for abuse or misuse of a controlled
14 substance.

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

19 “(C) Information describing all State and
20 Federal public health resources that are de-
21 signed to address such abuse or misuse to
22 which the individual has access, including men-
23 tal health services, substance use disorder and
24 recovery services, and other counseling services.

1 “(D) Notice of, and information about, the
2 right of the individual to—

3 “(i) submit preferences of the indi-
4 vidual for health care providers and phar-
5 macies to be selected under paragraph
6 (2)(A), including as described in paragraph
7 (2)(B);

8 “(ii) appeal under paragraph (4)—

9 “(I) such identification described
10 in subparagraph (A); and

11 “(II) the selection of health care
12 providers and pharmacies under para-
13 graph (2)(A).

14 “(E) An explanation of the meaning and
15 consequences of the identification of the indi-
16 vidual as potentially being an at-risk beneficiary
17 for abuse or misuse of a controlled substance,
18 including an explanation of the program.

19 “(F) Information, including a contact list
20 and clear instructions, that explain how the in-
21 dividual can contact the appropriate entities ad-
22 ministering the program in order to submit
23 preferences described in paragraph (2)(B) and
24 any other communications relating to the pro-
25 gram.

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

5 “(A) such individual may appeal—

6 “(i) such identification; and

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

9 “(B) in the case of an appeal described in
10 subparagraph (A)(ii), the State shall accommo-
11 date the health care provider or pharmacy pre-
12 ferred by the individual for selection for pur-
13 poses of paragraph (2)(A), unless the State de-
14 termines that a change to the selection of
15 health care provider or pharmacy under such
16 paragraph is contributing or would contribute
17 to prescription drug abuse or drug diversion by
18 the individual;

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

23 “(D) the State must make a determination
24 with respect to an appeal described in subpara-
25 graph (A), and notify the individual of such de-

1 termination, prior to enrollment of such indi-
2 vidual in the program.

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

7 “(A) in the case of such an individual who
8 does not submit an appeal under paragraph (4)
9 within the period applied by the State pursuant
10 to subparagraph (C) of such paragraph, begin-
11 ning on the day after the last day of such pe-
12 riod; and

13 “(B) in the case of such an individual who
14 does submit an appeal under paragraph (4)
15 within the period applied by the State pursuant
16 to subparagraph (C) of such paragraph but
17 such appeal is denied, beginning not later than
18 30 days after the date of such denial.

19 “(6) NOTIFICATION OF HEALTH CARE PRO-
20 VIDERS AND PHARMACIES.—Under the program, the
21 State provides to each health care provider and
22 pharmacy selected for an individual under paragraph
23 (2)—

24 “(A) notification that the individual is an
25 at-risk beneficiary enrolled under the program

1 and that the provider or pharmacy has been se-
2 lected for the individual under paragraph (2);

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

5 “(C) a process through which the provider
6 or pharmacy can submit a concern or complaint
7 with respect to being so selected.

8 “(7) CONTINUATION OF ENROLLMENT.—Under
9 the program, the State, with respect to an individual
10 enrolled under the program, provides for a process
11 to—

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

15 “(i) assess, in accordance with pub-
16 licly available evidence-based guidelines,
17 whether or not such individual should con-
18 tinue to be enrolled under the program;
19 and

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

22 “(B) continue, subject to subparagraph
23 (C), enrollment of such individual if such as-
24 sessment recommends such continuation; and

1 “(C) appeal the continuation of enrollment
2 in accordance with the appeals process de-
3 scribed in paragraph (4).

4 “(c) AT-RISK BENEFICIARY.—

5 “(1) IDENTIFICATION.—For purposes of this
6 section, a State shall identify an individual enrolled
7 under the State plan (or waiver of the State plan)
8 as an at-risk beneficiary if the individual is not an
9 exempted individual described in paragraph (2)
10 and—

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

15 “(B) the State received notification from a
16 PDP sponsor or Medicare Advantage organiza-
17 tion that such individual was identified as being
18 an at-risk beneficiary for prescription drug
19 abuse for enrollment in a drug management
20 program established by the sponsor or organiza-
21 tion pursuant to section 1860D–4(c)(5) and
22 such identification has not been terminated
23 under subparagraph (F) of such section.

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

4 “(A) is receiving—

5 “(i) hospice or palliative care; or

6 “(ii) treatment for cancer;

7 “(B) is a resident of a long-term care facil-
8 ity, of a facility described in section 1905(d), or
9 of another facility for which frequently abused
10 drugs are dispensed for residents through a
11 contract with a single pharmacy; or

12 “(C) the State elects to treat as an ex-
13 empted individual for purposes of paragraph
14 (1).

15 “(d) APPLICATION OF PRIVACY RULES CLARIFICA-
16 TION.—The Secretary shall clarify privacy requirements,
17 including requirements under the regulations promulgated
18 pursuant to section 264(c) of the Health Insurance Port-
19 ability and Accountability Act of 1996 (42 U.S.C. 1320d-
20 2 note), related to the sharing of data under subsection
21 (b)(6) in the same manner as the Secretary is required
22 under subparagraph (J) of section 1860D-4(c)(5) to clar-
23 ify privacy requirements related to the sharing of data de-
24 scribed in such subparagraph.

25 “(e) REPORTS.—

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

6 “(A) The number of individuals enrolled
7 under the State plan (or waiver of the State
8 plan) who are enrolled under the program and
9 the percentage of individuals enrolled under the
10 State plan (or waiver) who are enrolled under
11 such program.

12 “(B) The number of prescriptions for con-
13 trolled substances that were dispensed per
14 month during each such year per individual en-
15 rolled under the program, including the daily
16 morphine milligram equivalents and the quan-
17 tity prescribed for each such prescription.

18 “(C) The number of pharmacies filling pre-
19 scriptions for controlled substances for individ-
20 uals enrolled under such program.

21 “(D) The number of health care providers
22 writing prescriptions for controlled substances
23 (other than prescriptions for a refill) for indi-
24 viduals enrolled under such program.

1 “(E) Any other data that the Secretary
2 may require.

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

6 For each such report for a year after 2021, the in-
7 formation described in this paragraph shall be pro-
8 vided in a manner that compares such information
9 with respect to the prior calendar year to such infor-
10 mation with respect to the second prior calendar
11 year.

12 “(2) MACPAC REPORTS AND REVIEW.—Not
13 later than two years after the date of the enactment
14 of this section, the Medicaid and CHIP Payment
15 and Access Commission (in this section referred to
16 as ‘MACPAC’), in consultation with the National
17 Association of Medicaid Directors, pharmacy benefit
18 managers, managed care organizations, health care
19 providers (including pharmacists), beneficiary advo-
20 cates, and other stakeholders, shall publish a report
21 that includes—

22 “(A) best practices for operating drug
23 management programs, based on a review of a
24 representative sample of States administering
25 such a program;

1 “(B) a summary of the experience of the
2 appeals process under drug management pro-
3 grams operated by several States, such as the
4 frequency at which individuals appealed the
5 identification of being an at-risk individual, the
6 frequency at which individuals appealed the se-
7 lection of a health care provider or pharmacy
8 under such a program, the timeframes for such
9 appeals, a summary of the reasons for such ap-
10 peals, and the design of such appeals processes;

11 “(C) a summary of trends and the effec-
12 tiveness of qualified drug management pro-
13 grams operated under this section; and

14 “(D) recommendations to States on how
15 improvements can be made with respect to the
16 operation of such programs.

17 In reporting on State practices, the MACPAC shall
18 consider how such programs have been implemented
19 in rural areas, under fee-for-service as well as man-
20 aged care arrangements, and the extent to which
21 such programs have resulted in increased efficiencies
22 to such States or to the Federal Government under
23 this title.

24 “(3) REPORT ON PLAN FOR COORDINATED
25 CARE.—Not later than January 1, 2021, each State

1 operating a qualified drug management program
2 shall submit to the Administrator of the Centers for
3 Medicare & Medicaid Services a report on how such
4 State plans to provide coordinated care for individ-
5 uals enrolled under the State plan (or waiver of the
6 State plan) and—

7 “(A) who are enrolled under the program;

8 or

9 “(B) who are enrolled with a managed care
10 entity and enrolled under such a qualified drug
11 management program operated by such entity.

12 “(f) APPLICABILITY TO MANAGED CARE ENTI-
13 TIES.—

14 “(1) IN GENERAL.—With respect to any con-
15 tract that a State enters into on or after January
16 1, 2020, with a managed care entity (as defined in
17 section 1932(a)(1)(B)) pursuant to section 1903(m),
18 the State shall, as a condition of the contract, re-
19 quire the managed care entity—

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

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

4 “(C) to submit to the State a list (and as
5 necessary update such list) of individuals en-
6 rolled with such entity under the qualified drug
7 management program operated by such entity
8 under subparagraph (A) for purposes of allow-
9 ing State plans for which medical assistance is
10 paid on a fee-for-service basis to have access to
11 such information.

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

14 “(A) under paragraph (1)(A)—

15 “(i) the definition of the term ‘quali-
16 fied drug management program’ under
17 subsection (b), other than paragraph
18 (2)(D) of such subsection; and

19 “(ii) the provisions of paragraphs (1)
20 and (2) of subsection (c); and

21 “(B) under paragraph (1)(B), the report
22 requirements described in subparagraphs (A)
23 through (E) of subsection (e)(1);

24 each reference in such subsection (b) and para-
25 graphs of subsection (c) to ‘a State’ or ‘the State’

1 (other than to ‘a State plan’ or ‘the State plan’)
2 shall be deemed a reference to the managed care en-
3 tity, each reference under such subsection, para-
4 graphs, or subparagraphs to individuals enrolled
5 under the State plan (or waiver of the State plan)
6 shall be deemed a reference to individuals enrolled
7 with such entity, and each reference under such sub-
8 section, paragraphs, or subparagraphs to individuals
9 enrolled under the qualified drug management pro-
10 gram operated by the State shall be deemed a ref-
11 erence to individuals enrolled under the qualified
12 drug management program operated by the man-
13 aged care entity.

14 “(g) CONTROLLED SUBSTANCE DEFINED.—For pur-
15 poses of this section, the term ‘controlled substance’
16 means a drug that is included in schedule II, III, or IV
17 of section 202(e) of the Controlled Substances Act, or any
18 combination thereof, as specified by the State.”.

19 (b) GUIDANCE ON AT-RISK POPULATION
20 TRANSITIONING BETWEEN MEDICAID FFS AND MAN-
21 AGED CARE.—Not later than October 1, 2019, the Sec-
22 retary of Health and Human Services shall issue guidance
23 for State Medicaid programs, with respect to individuals
24 who are enrolled under a State plan (or waiver of such
25 plan) under title XIX of the Social Security Act and under

1 a drug management program, for purposes of providing
2 best practices—

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

11 (2) for transitioning, as applicable, such indi-
12 viduals from receiving medical assistance under such
13 title through a managed care entity (as defined in
14 section 1932(a)(1)(B) of the Social Security Act)
15 with a contract that with the State pursuant to sec-
16 tion 1903(m) of such Act (and such a program oper-
17 ated by such entity) to fee-for-service Medicaid (and
18 such a program operated by the State).

19 (c) GUIDANCE ON AT-RISK POPULATION
20 TRANSITIONING TO MEDICARE.—

21 (1) IN GENERAL.—Not later than January 1,
22 2020, the Secretary of Health and Human Services,
23 after consultation with the Federal Coordinated
24 Health Care Office established under section 2602
25 of the Patient Protection and Affordable Care Act

1 (42 U.S.C. 1315b), shall issue guidance for State
2 Medicaid programs, with respect to transitioning in-
3 dividuals, providing for—

4 (A) notification to be submitted by the
5 State to the Centers for Medicare & Medicaid
6 Services and such individuals of the status of
7 such individuals as transitioning individuals;

8 (B) notification to such individuals about
9 enrollment under a prescription drug plan
10 under part D of such title or under a MA–PD
11 plan under part C of such title;

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

14 (D) best practices for coordination between
15 the qualified drug management program (as de-
16 scribed in section 1927A(b) of the Social Secu-
17 rity Act, as added by subsection (a)) carried out
18 by the State and a drug management program
19 carried out under such a plan pursuant to sec-
20 tion 1860D–4(c)(5) of the Social Security Act
21 (42 U.S.C. 1395w–10(c)(5)).

22 (2) **TRANSITIONING INDIVIDUALS.**—For pur-
23 poses of paragraph (1), a transitioning individual is
24 an individual who, with respect to a month—

1 (A) is enrolled under the State plan (or
2 waiver of the State plan) and under the quali-
3 fied drug management program (as described in
4 section 1927A(b) of the Social Security Act, as
5 added by subsection (a)) carried out by the
6 State; and

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

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

11 (a) MEDICAID DRUG UTILIZATION REVIEW.—

12 (1) STATE PLAN REQUIREMENT.—Section
13 1902(a) of the Social Security Act (42 U.S.C.
14 1396a(a)), as amended by section 101, is further
15 amended—

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

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

20 (C) by inserting after paragraph (84) the
21 following new paragraph:

22 “(85) provide that the State is in compliance
23 with the drug review and utilization requirements
24 under subsection (oo)(1).”.

1 (2) DRUG REVIEW AND UTILIZATION REQUIRE-
2 MENTS.—Section 1902 of the Social Security Act
3 (42 U.S.C. 1396a), as amended by section 101, is
4 further amended by adding at the end the following
5 new subsection:

6 “(00) DRUG REVIEW AND UTILIZATION REQUIRE-
7 MENTS.—

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

12 “(A) CLAIMS REVIEW LIMITATIONS.—

13 “(i) IN GENERAL.—The State has in
14 place—

15 “(I) safety edits (as specified by
16 the State) for subsequent fills for
17 opioids and a claims review automated
18 process (as designed and implemented
19 by the State) that indicates when an
20 individual enrolled under the State
21 plan (or under a waiver of the State
22 plan) is prescribed a subsequent fill of
23 opioids in excess of any limitation
24 that may be identified by the State;

1 “(II) safety edits (as specified by
2 the State) on the maximum daily mor-
3 phine equivalent that can be pre-
4 scribed to an individual enrolled under
5 the State plan (or under a waiver of
6 the State plan) for treatment of
7 chronic pain and a claims review auto-
8 mated process (as designed and imple-
9 mented by the State) that indicates
10 when an individual enrolled under the
11 plan (or waiver) is prescribed the mor-
12 phine equivalent for such treatment in
13 excess of any limitation that may be
14 identified by the State; and

15 “(III) a claims review automated
16 process (as designed and implemented
17 by the State) that monitors when an
18 individual enrolled under the State
19 plan (or under a waiver of the State
20 plan) is concurrently prescribed
21 opioids and—

22 “(aa) benzodiazepines; or

23 “(bb) antipsychotics.

24 “(ii) MANAGED CARE ENTITIES.—The
25 State requires each managed care entity

1 (as defined in section 1932(a)(1)(B)) with
2 respect to which the State has a contract
3 under section 1903(m) or under section
4 1905(t)(3) to have in place, subject to
5 paragraph (3), with respect to individuals
6 who are eligible for medical assistance
7 under the State plan (or under a waiver of
8 the State plan) and who are enrolled with
9 the entity, the limitations described in sub-
10 clauses (I) and (II) of clause (i) and a
11 claims review automated process described
12 in subclause (III) of such clause.

13 “(iii) RULES OF CONSTRUCTION.—
14 Nothing in this subparagraph may be con-
15 strued as prohibiting a State or managed
16 care entity from designing and imple-
17 menting a claims review automated process
18 under this subparagraph that provides for
19 prospective or retrospective reviews of
20 claims. Nothing in this subparagraph shall
21 be understood as prohibiting the exercise
22 of clinical judgment from a provider en-
23 rolled as a participating provider in a
24 State plan (or waiver of the State plan) or
25 contracting with a managed care entity re-

1 garding the best items and services for an
2 individual enrolled under such State plan
3 (or waiver).

4 “(B) PROGRAM TO MONITOR
5 ANTIPSYCHOTIC MEDICATIONS BY CHILDREN.—
6 The State has in place a program (as designed
7 and implemented by the State) to monitor and
8 manage the appropriate use of antipsychotic
9 medications by children enrolled under the
10 State plan (or under a waiver of the State plan)
11 and submits annually to the Secretary such in-
12 formation as the Secretary may require on ac-
13 tivities carried out under such program for indi-
14 viduals not more than the age of 18 years gen-
15 erally and children in foster care specifically.

16 “(C) FRAUD AND ABUSE IDENTIFICA-
17 TION.—The State has in place a process (as de-
18 signed and implemented by the State) that
19 identifies potential fraud or abuse of controlled
20 substances by individuals enrolled under the
21 State plan (or under a waiver of the State
22 plan), health care providers prescribing drugs
23 to individuals so enrolled, and pharmacies dis-
24 pensing drugs to individuals so enrolled.

1 “(D) REPORTS.—The State shall include
2 in the annual report submitted to the Secretary
3 under section 1927(g)(3)(D) information on the
4 limitations, requirement, program, and proc-
5 esses applied by the State under subparagraphs
6 (A) through (C) in accordance with such man-
7 ner and time as specified by the Secretary.

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

10 “(i) described in subparagraph (A) by
11 having safety edits or a claims review auto-
12 mated process described in such subpara-
13 graph that was in place before October 1,
14 2019;

15 “(ii) described in subparagraph (B)
16 by having a program described in such
17 subparagraph that was in place before
18 such date; or

19 “(iii) described in subparagraph (C)
20 by having a process described in such sub-
21 paragraph that was in place before such
22 date.

23 “(2) ANNUAL REPORT BY SECRETARY.—For
24 each fiscal year beginning with fiscal year 2020, the
25 Secretary shall submit to Congress a report on the

1 most recent information submitted by States under
2 paragraph (1)(D).

3 “(3) EXCEPTIONS.—

4 “(A) CERTAIN INDIVIDUALS EXEMPTED.—

5 The drug review and utilization requirements
6 under this subsection shall not apply with re-
7 spect to an individual who—

8 “(i) is receiving—

9 “(I) hospice or palliative care; or

10 “(II) treatment for cancer;

11 “(ii) is a resident of a long-term care
12 facility, of a facility described in section
13 1905(d), or of another facility for which
14 frequently abused drugs are dispensed for
15 residents through a contract with a single
16 pharmacy; or

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

19 “(B) EXCEPTION RELATING TO ENSURING
20 ACCESS.—In order to ensure reasonable access
21 to health care, the Secretary shall waive the
22 drug review and utilization requirements under
23 this subsection, with respect to a State, in the
24 case of natural disasters and similar situations,
25 and in the case of the provision of emergency

1 services (as defined for purposes of section
2 1860D–4(c)(5)(D)(ii)(II)).”.

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

7 “(i) DRUG UTILIZATION REVIEW ACTIVITIES AND
8 REQUIREMENTS.—Beginning not later than October 1,
9 2019, each contract under a State plan with a managed
10 care entity (other than a primary care case manager)
11 under section 1903(m) shall provide that the entity is in
12 compliance with the applicable provisions of section
13 438.3(s)(2) of title 42 of the Code of Federal Regulations,
14 section 483.3(s)(4) of such title, and section 483.3(s)(5)
15 of such title, as such provisions were in effect on March
16 31, 2018.”.

17 (b) IDENTIFYING AND ADDRESSING INAPPROPRIATE
18 PRESCRIBING AND BILLING PRACTICES UNDER MED-
19 ICAID.—

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

23 (A) in paragraph (1)(A)—

1 (i) by striking “of section
2 1903(i)(10)(B)” and inserting “of section
3 1902(a)(54)”;

4 (ii) by striking “, by not later than
5 January 1, 1993,”;

6 (iii) by inserting after “gross over-
7 use,” the following: “excessive utilization,”;
8 and

9 (iv) by striking “or inappropriate or
10 medically unnecessary care” and inserting
11 “inappropriate or medically unnecessary
12 care, or prescribing or billing practices
13 that indicate abuse or excessive utiliza-
14 tion”;

15 (B) in paragraph (2)(B)—

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

18 (ii) by striking “or inappropriate or
19 medically unnecessary care” and inserting
20 “inappropriate or medically unnecessary
21 care, or prescribing or billing practices
22 that indicate abuse or excessive utiliza-
23 tion”.

24 (2) EFFECTIVE DATE.—The amendments made
25 by paragraph (1) shall take effect with respect to

1 retrospective drug use reviews conducted on or after
2 October 1, 2020.

3 **SEC. 106. GUIDANCE TO IMPROVE CARE FOR INFANTS WITH**
4 **NEONATAL ABSTINENCE SYNDROME AND**
5 **THEIR MOTHERS; GAO STUDY ON GAPS IN**
6 **MEDICAID COVERAGE FOR PREGNANT AND**
7 **POSTPARTUM WOMEN WITH SUBSTANCE USE**
8 **DISORDER.**

9 (a) GUIDANCE.—Not later than one year after the
10 date of the enactment of this Act, the Secretary of Health
11 and Human Services shall issue guidance to improve care
12 for infants with neonatal abstinence syndrome and their
13 families. Such guidance shall include—

14 (1) the types of services, including post-dis-
15 charge services and parenting supports, for families
16 of babies with neonatal abstinence syndrome that
17 States may cover under the Medicaid program under
18 title XIX of the Social Security Act;

19 (2) best practices from States with respect to
20 innovative or evidenced-based payment models that
21 focus on prevention, screening, treatment, plans of
22 safe care, and post-discharge services for mothers
23 and fathers with substance use disorders and babies
24 with neonatal abstinence syndrome that improve
25 care and clinical outcomes;

1 (3) recommendations for States on available fi-
2 nancing options under the Medicaid program under
3 title XIX of such Act and under the Children’s
4 Health Insurance Program under title XXI of such
5 Act for Children’s Health Insurance Program
6 Health Services Initiative funds for parents with
7 substance use disorders, infants with neonatal absti-
8 nence syndrome, and home visiting services; and

9 (4) guidance and technical assistance to State
10 Medicaid agencies regarding additional flexibilities
11 and incentives related to screening, prevention, and
12 post-discharge services, including parenting sup-
13 ports.

14 (b) GAO STUDY.—Not later than one year after the
15 date of the enactment of this Act, the Comptroller General
16 of the United States shall conduct a study, and submit
17 to Congress a report, addressing gaps in coverage for
18 pregnant women with substance use disorder under the
19 Medicaid program under title XIX of the Social Security
20 Act, and gaps in coverage for postpartum women with sub-
21 stance use disorder who had coverage during their preg-
22 nancy under the Medicaid program under such title.

1 **SEC. 107. MEDICAID HEALTH HOMES FOR OPIOID-USE-DIS-**
2 **ORDER MEDICAID ENROLLEES.**

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

7 (1) in subsection (c)—

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

10 (B) by adding at the end the following new
11 paragraph:

12 “(4) SPECIAL RULE RELATING TO SUBSTANCE
13 USE DISORDER HEALTH HOMES.—

14 “(A) IN GENERAL.—In the case of a State
15 with an SUD-focused State plan amendment
16 approved by the Secretary on or after October
17 1, 2018, the Secretary may, at the request of
18 the State, extend the application of the Federal
19 medical assistance percentage described in
20 paragraph (1) to payments for the provision of
21 health home services to SUD-eligible individuals
22 under such State plan amendment, in addition
23 to the first 8 fiscal year quarters the State plan
24 amendment is in effect, for the subsequent 2
25 fiscal year quarters that the State plan amend-
26 ment is in effect. Nothing in this section shall

1 be construed as prohibiting a State with a State
2 plan amendment that is approved under this
3 section and that is not an SUD-focused State
4 plan amendment from additionally having ap-
5 proved on or after such date an SUD-focused
6 State plan amendment under this section, in-
7 cluding for purposes of application of this para-
8 graph.

9 “(B) REPORT REQUIREMENTS.—In the
10 case of a State with an SUD-focused State plan
11 amendment for which the application of the
12 Federal medical assistance percentage has been
13 extended under subparagraph (A), such State
14 shall, at the end of the period of such State
15 plan amendment, submit to the Secretary a re-
16 port on the following, with respect to SUD-eli-
17 gible individuals provided health home services
18 under such State plan amendment:

19 “(i) The quality of health care pro-
20 vided to such individuals, with a focus on
21 outcomes relevant to the recovery of each
22 such individual.

23 “(ii) The access of such individuals to
24 health care.

1 “(iii) The total expenditures of such
2 individuals for health care.

3 For purposes of this subparagraph, the
4 Secretary shall specify all applicable meas-
5 ures for determining quality, access, and
6 expenditures.

7 “(C) BEST PRACTICES.—Not later than
8 October 1, 2020, the Secretary shall make pub-
9 licly available on the Internet website of the
10 Centers for Medicare & Medicaid Services best
11 practices for designing and implementing an
12 SUD-focused State plan amendment, based on
13 the experiences of States that have State plan
14 amendments approved under this section that
15 include SUD-eligible individuals.

16 “(D) DEFINITIONS.—For purposes of this
17 paragraph:

18 “(i) SUD-ELIGIBLE INDIVIDUALS.—
19 The term ‘SUD-eligible individual’ means,
20 with respect to a State, an individual who
21 satisfies all of the following:

22 “(I) The individual is an eligible
23 individual with chronic conditions.

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

1 “(III) The individual has not pre-
2 viously received health home services
3 under any other State plan amend-
4 ment approved for the State under
5 this section by the Secretary.

6 “(ii) SUD-FOCUSED STATE PLAN
7 AMENDMENT.—The term ‘SUD-focused
8 State plan amendment’ means a State plan
9 amendment under this section that is de-
10 signed to provide health home services pri-
11 marily to SUD-eligible individuals.”.

12 (b) REQUIREMENT FOR STATE MEDICAID PLANS TO
13 PROVIDE COVERAGE FOR MEDICATION-ASSISTED TREAT-
14 MENT.—

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

21 (2) INCLUSION OF MEDICATION-ASSISTED
22 TREATMENT AS MEDICAL ASSISTANCE.—Section
23 1905(a) of the Social Security Act (42 U.S.C.
24 1396d(a)) is amended—

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

3 (B) by redesignating paragraph (29) as
4 paragraph (30); and

5 (C) by inserting after paragraph (28) the
6 following new paragraph:

7 “(29) subject to paragraph (2) of subsection
8 (ee), for the period beginning October 1, 2020, and
9 ending September 30, 2025, medication-assisted
10 treatment (as defined in paragraph (1) of such sub-
11 section); and”.

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

16 “(ee) MEDICATION-ASSISTED TREATMENT.—

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

19 “(A) means all drugs approved under sec-
20 tion 505 of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 355), including metha-
22 done, and all biological products licensed under
23 section 351 of the Public Health Service Act
24 (42 U.S.C. 262) to treat opioid use disorders;
25 and

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

4 “(2) EXCEPTION.—The provisions of paragraph
5 (29) of subsection (a) shall not apply with respect to
6 a State for the period specified in such paragraph,
7 if before the beginning of such period the State cer-
8 tifies to the satisfaction of the Secretary that imple-
9 menting such provisions statewide for all individuals
10 eligible to enroll in the State plan (or waiver of the
11 State plan) would not be feasible by reason of a
12 shortage of qualified providers of medication-assisted
13 treatment, or facilities providing such treatment,
14 that will contract with the State or a managed care
15 entity with which the State has a contract under
16 section 1903(m) or under section 1905(t)(3).”.

17 (4) EFFECTIVE DATE.—

18 (A) IN GENERAL.—Subject to subpara-
19 graph (B), the amendments made by this sub-
20 section shall apply with respect to medical as-
21 sistance provided on or after October 1, 2020,
22 and before October 1, 2025.

23 (B) EXCEPTION FOR STATE LEGISLA-
24 TION.—In the case of a State plan under title
25 XIX of the Social Security Act (42 U.S.C. 1396

1 et seq.) that the Secretary of Health and
2 Human Services determines requires State leg-
3 islation in order for the respective plan to meet
4 any requirement imposed by the amendments
5 made by this subsection, the respective plan
6 shall not be regarded as failing to comply with
7 the requirements of such title solely on the
8 basis of its failure to meet such an additional
9 requirement before the first day of the first cal-
10 endar quarter beginning after the close of the
11 first regular session of the State legislature that
12 begins after the date of the enactment of this
13 Act. For purposes of the previous sentence, in
14 the case of a State that has a 2-year legislative
15 session, each year of the session shall be consid-
16 ered to be a separate regular session of the
17 State legislature.

1 **TITLE II—MEDICARE PROVI-**
2 **SIONS TO ADDRESS THE**
3 **OPIOID CRISIS**

4 **SEC. 201. AUTHORITY NOT TO APPLY CERTAIN MEDICARE**
5 **TELEHEALTH REQUIREMENTS IN THE CASE**
6 **OF CERTAIN TREATMENT OF A SUBSTANCE**
7 **USE DISORDER OR CO-OCCURRING MENTAL**
8 **HEALTH DISORDER.**

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

11 (1) in paragraph (2)(B)(i), by inserting “and
12 paragraph (7)(E)” after “Subject to clause (ii)”;
13 and

14 (2) by adding at the end the following new
15 paragraphs:

16 “(7) AUTHORITY NOT TO APPLY CERTAIN RE-
17 QUIREMENTS IN THE CASE OF CERTAIN TREATMENT
18 OF SUBSTANCE USE DISORDER OR CO-OCCURRING
19 MENTAL HEALTH DISORDER.—

20 “(A) IN GENERAL.—For purposes of pay-
21 ment under this subsection, in the case of tele-
22 health services described in subparagraph (C)
23 furnished on or after January 1, 2020, to an el-
24 igible beneficiary (as defined in subparagraph
25 (F)) for the treatment of a substance use dis-

1 order or a mental health disorder that is co-oc-
2 ccurring with a substance use disorder, the Sec-
3 retary is authorized to, through rulemaking, not
4 apply any of the requirements described in sub-
5 paragraph (B).

6 “(B) REQUIREMENTS DESCRIBED.—For
7 purposes of this paragraph, the requirements
8 described in this subparagraph are any of the
9 following:

10 “(i) Qualifications for an originating
11 site under paragraph (4)(C)(ii).

12 “(ii) Geographic limitations under
13 paragraph (4)(C)(i).

14 “(C) TELEHEALTH SERVICES DE-
15 SCRIBED.—For purposes of this paragraph, the
16 telehealth services described in this subpara-
17 graph are services that are both telehealth serv-
18 ices and identified by the Secretary, through
19 rulemaking, as services that are the most com-
20 monly furnished (as defined by the Secretary)
21 under this part to individuals diagnosed with a
22 substance use disorder or a mental health dis-
23 order that is co-occurring with a substance use
24 disorder.

1 “(D) CLARIFICATION.—Nothing in this
2 paragraph shall be construed as limiting or oth-
3 erwise affecting the authority of the Secretary
4 to limit or eliminate the non-application pursu-
5 ant to this paragraph of any of the require-
6 ments under subparagraph (B).

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

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

21 “(i) is entitled to, or enrolled for, ben-
22 efits under part A and enrolled for benefits
23 under this part;

24 “(ii) has a diagnosis for a substance
25 use disorder; and

1 “(iii) meets such other criteria as the
2 Secretary determines appropriate.

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

9 “(i) the utilization of health care serv-
10 ices related to substance use disorder, such
11 as behavioral health services and emer-
12 gency department visits; and

13 “(ii) health outcomes related to sub-
14 stance use disorder, such as substance use
15 overdose deaths.

16 “(H) FUNDING.—For purposes of carrying
17 out this paragraph, in addition to funds other-
18 wise available, the Secretary shall provide for
19 the transfer, from the Federal Supplementary
20 Medical Insurance Trust Fund under section
21 1841, of \$3,000,000 to the Centers for Medi-
22 care & Medicaid Services Program Management
23 Account to remain available until expended.

24 “(8) RULE OF CONSTRUCTION.—Nothing in
25 this subsection may be construed as waiving require-

1 ments under this title to comply with applicable
2 State law, including State licensure requirements.”.

3 **SEC. 202. ENCOURAGING THE USE OF NON-OPIOID ANALGE-**
4 **SICS FOR THE MANAGEMENT OF POST-SUR-**
5 **GICAL PAIN.**

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

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

12 (2) by adding at the end the following new sub-
13 paragraph:

14 “(J) ELIGIBLE NON-OPIOID ANALGESIC
15 DEFINED.—In this paragraph, the term ‘eligible
16 non-opioid analgesic’ means a drug or biologi-
17 cal—

18 “(i) that is an analgesic that is not an
19 opioid;

20 “(ii) that demonstrated substantial
21 clinical improvement; and

22 “(iii) for which payment—

23 “(I) as an outpatient hospital
24 service under this part was not being

1 made as of the date of the enactment
2 of this subparagraph; or

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

5 **SEC. 203. REQUIRING A REVIEW OF CURRENT OPIOID PRE-**
6 **SCRIPTIONS FOR CHRONIC PAIN AND**
7 **SCREENING FOR OPIOID USE DISORDER TO**
8 **BE INCLUDED IN THE WELCOME TO MEDI-**
9 **CARE INITIAL PREVENTIVE PHYSICAL EXAM-**
10 **INATION.**

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

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

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

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

22 “(i) a review by a physician or qualified non-
23 physician practitioner of all current prescriptions of
24 the individual; and

1 “(ii) in the case of an individual determined by
2 the review of a physician or qualified non-physician
3 practitioner under subparagraph (A) to have a cur-
4 rent prescription for opioids for chronic pain that
5 has been prescribed for a minimum period of time
6 (as specified by the Secretary)—

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

10 “(II) an evaluation by the physician or
11 practitioner of pain of the individual;

12 “(III) the provision of information regard-
13 ing non-opioid treatment options for the treat-
14 ment and management of any chronic pain of
15 the individual; and

16 “(IV) if determined necessary by the physi-
17 cian or practitioner based on the results of the
18 review and evaluation conducted as described in
19 this paragraph, an appropriate referral by the
20 physician or practitioner for additional treat-
21 ment.

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

1 (b) EFFECTIVE DATE.—The amendments made by
2 subsection (a) shall apply with respect to initial preventive
3 physical examinations furnished on or after January 1,
4 2020.

5 **SEC. 204. MODIFICATION OF PAYMENT FOR CERTAIN OUT-**
6 **PATIENT SURGICAL SERVICES.**

7 (a) FREEZE OF PAYMENT FOR CERTAIN SERVICES
8 FURNISHED IN AMBULATORY SURGICAL CENTERS.—Sec-
9 tion 1833(i)(2) of the Social Security Act (42 U.S.C.
10 1395l(i)(2)) is amended by adding at the end the following
11 new subparagraph:

12 “(F)(i) With respect to a targeted procedure
13 (as defined in clause (ii)) furnished during 2020 or
14 a subsequent year (before 2024) to an individual in
15 an ambulatory surgical center, the payment amount
16 for such procedure that would otherwise be deter-
17 mined under the revised payment system under sub-
18 paragraph (D), without application of this subpara-
19 graph, shall be equal to the payment amount for
20 such procedure furnished in 2016.

21 “(ii) For purposes of clause (i), the term ‘tar-
22 geted procedure’ means a procedure to which
23 Healthcare Common Procedure Coding System
24 62310 (or, for years beginning after 2016, 62321),
25 62311 (or, for years beginning after 2016, 62323),

1 62264, 64490, 64493, or G0260 (or any successor
2 code) applies.

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

5 (b) DATA COLLECTION.—

6 (1) IN GENERAL.—The Comptroller General
7 shall collect data relating to the cost differential be-
8 tween targeted procedures (as defined in section
9 1833(i)(2)(F)(ii) of the Social Security Act, as
10 added by subsection (a)) that are performed in a
11 hospital operating room and such procedures that
12 are performed in an office setting within a hospital
13 in order to determine whether such procedures are
14 being properly coded for claims, based on setting, for
15 payment under section 1833(i)(2)(D) of the Social
16 Security Act (42 U.S.C. 1395l(i)(2)(D)) and to de-
17 termine if further changes are needed in the classi-
18 fication system for covered outpatient department
19 services (as described in section 1833(t)(2)(A) of the
20 Social Security Act (42 U.S.C. 1395l(t)(2)(A)).

21 (2) REPORT.—Not later than 4 years after the
22 date of the enactment of this Act, the Comptroller
23 General shall submit a report to the Committee on
24 Energy and Commerce and the Committee on Ways

1 and Means of the House of Representatives and the
2 Committee on Finance of the Senate containing—

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

8 (B) recommendations on any changes the
9 Comptroller General determines are needed in
10 the classification system for covered outpatient
11 department services (as described in section
12 1833(t)(2)(A) of the Social Security Act (42
13 U.S.C. 1395l(t)(2)(A)).

14 (c) STUDY.—Not later than 3 years after the date
15 of the enactment of this Act, the Secretary of Health and
16 Human Services shall conduct a study and submit to Con-
17 gress a report on the extent to which procedures described
18 in section 1833(i)(2)(F)(ii) of the Social Security Act, as
19 added by subsection (a), are effective at preventing the
20 need for opioids for individuals furnished such procedures.

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

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

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

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

18 “(B) EXCEPTION FOR CERTAIN CIR-
19 CUMSTANCES.—The Secretary shall, pursuant
20 to rulemaking, specify circumstances with re-
21 spect to which the Secretary may waive the re-
22 quirement under subparagraph (A), with re-
23 spect to a covered part D drug, including in the
24 case of—

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

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

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

21 “(iv) a prescription issued by a practi-
22 tioner under circumstances in which, not-
23 withstanding the practitioner’s ability to
24 submit a prescription electronically as re-
25 quired by this subsection, such practitioner

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

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

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

20 “(vii) a prescription issued by a prac-
21 titioner for a drug for which the Food and
22 Drug Administration requires a prescrip-
23 tion to contain elements that are not able
24 to be included in electronic prescribing,
25 such as a drug with risk evaluation and

1 mitigation strategies that include elements
2 to assure safe use; and

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

5 “(I) receives hospice care under
6 this title; or

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

18 “(C) DISPENSING.—Nothing in this para-
19 graph shall be construed as requiring a sponsor
20 of a prescription drug plan under this part, MA
21 organization offering an MA–PD plan under
22 part C, or a pharmacist to verify that a practi-
23 tioner, with respect to a prescription for a cov-
24 ered part D drug, has a waiver (or is otherwise
25 exempt) under subparagraph (B) from the re-

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

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

18 (b) EFFECTIVE DATE.—The amendment made by
19 subsection (a) shall apply to coverage of drugs prescribed
20 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.

1 **TITLE IV—OFFSETS**
2 **SEC. 401. PROMOTING VALUE IN MEDICAID MANAGED**
3 **CARE.**

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

7 “(7)(A) With respect to expenditures described in
8 subparagraph (B) that are incurred by a State for any
9 fiscal year after fiscal year 2020 (and before fiscal year
10 2025), in determining the pro rata share to which the
11 United States is equitably entitled under subsection
12 (d)(3), the Secretary shall substitute the Federal medical
13 assistance percentage that applies for such fiscal year to
14 the State under section 1905(b) (without regard to any
15 adjustments to such percentage applicable under such sec-
16 tion or any other provision of law) for the percentage that
17 applies to such expenditures under section 1905(y).

18 “(B) Expenditures described in this subparagraph,
19 with respect to a fiscal year to which subparagraph (A)
20 applies, are expenditures incurred by a State for payment
21 for medical assistance provided to individuals described in
22 subclause (VIII) of section 1902(a)(10)(A)(i) by a man-
23 aged care entity, or other specified entity (as defined in
24 subparagraph (D)(iii)), that are treated as remittances be-
25 cause 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”.

