

Union Calendar No. 561

115TH CONGRESS
2^D SESSION

H. R. 5808

[Report No. 115–726]

To amend title XIX of the Social Security Act to require States to operate drug management programs for at-risk beneficiaries, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 15, 2018

Mr. BILIRAKIS (for himself and Mr. BEN RAY LUJÁN of New Mexico) introduced the following bill; which was referred to the Committee on Energy and Commerce

JUNE 12, 2018

Additional sponsors: Mrs. BLACKBURN and Mr. WALDEN

JUNE 12, 2018

Committed to the Committee of the Whole House on the State of the Union
and ordered to be printed

A BILL

To amend title XIX of the Social Security Act to require States to operate drug management programs for at-risk beneficiaries, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicaid Pharma-
 5 ceutical Home Act of 2018”.

6 **SEC. 2. DRUG MANAGEMENT PROGRAM FOR AT-RISK BENE-**
 7 **FICIARIES.**

8 (a) IN GENERAL.—Title XIX of the Social Security
 9 Act is amended by inserting after section 1927 (42 U.S.C.
 10 1396r–8) the following new section:

11 **“SEC. 1927A. DRUG MANAGEMENT PROGRAM FOR AT-RISK**
 12 **BENEFICIARIES.**

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

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

23 “(1) IDENTIFICATION OF AT-RISK INDIVID-
 24 UALS.—Under the program, the State identifies, in
 25 accordance with subsection (c), individuals enrolled

1 under the State plan (or waiver of the State plan)
2 who are at-risk beneficiaries.

3 “(2) ELEMENTS OF PROGRAM.—

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

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

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

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

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

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

23 “(D) TREATMENT OF EXISTING FFS DRUG
24 MANAGEMENT PROGRAMS.—In the case of a pa-
25 tient review and restriction program (as identi-

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

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

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

24 “(A) Notice that the State has identified
25 the individual as potentially being an at-risk

1 beneficiary for abuse or misuse of a controlled
2 substance.

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

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

13 “(D) Notice of, and information about, the
14 right of the individual to—

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

20 “(ii) appeal under paragraph (4)—

21 “(I) such identification described
22 in subparagraph (A); and

23 “(II) the selection of health care
24 providers and pharmacies under para-
25 graph (2)(A).

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

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

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

17 “(A) such individual may appeal—

18 “(i) such identification; and

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

21 “(B) in the case of an appeal described in
22 subparagraph (A)(ii), the State shall accommo-
23 date the health care provider or pharmacy pre-
24 ferred by the individual for selection for pur-
25 poses of paragraph (2)(A), unless the State de-

1 termines that a change to the selection of
2 health care provider or pharmacy under such
3 paragraph is contributing or would contribute
4 to prescription drug abuse or drug diversion by
5 the individual;

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

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

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

19 “(A) in the case of such an individual who
20 does not submit an appeal under paragraph (4)
21 within the period applied by the State pursuant
22 to subparagraph (C) of such paragraph, begin-
23 ning on the day after the last day of such pe-
24 riod; and

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

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

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

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

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

22 “(7) CONTINUATION OF ENROLLMENT.—Under
23 the program, the State, with respect to an individual
24 enrolled under the program, provides for a process
25 to—

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

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

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

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

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

17 “(c) AT-RISK BENEFICIARY.—

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

24 “(A) is identified as such an at-risk bene-
25 ficiary through the use of publicly available evi-

1 dence-based guidelines that indicate misuse or
2 abuse of a controlled substance; or

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

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

15 “(A) is receiving—

16 “(i) hospice or palliative care; or

17 “(ii) treatment for cancer;

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

23 “(C) the State elects to treat as an ex-
24 empted individual for purposes of paragraph
25 (1).

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

11 “(e) REPORTS.—

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

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

23 “(B) The number of prescriptions for con-
24 trolled substances that were dispensed per
25 month during each such year per individual en-

1 rolled under the program, including the dosage
2 and pill count for each such prescription.

3 “(C) The number of pharmacies filling pre-
4 scriptions for controlled substances for individ-
5 uals enrolled under such program.

6 “(D) The number of health care providers
7 writing prescriptions for controlled substances
8 (other than prescriptions for a refill) for indi-
9 viduals enrolled under such program.

10 “(E) Any other data that the Secretary
11 may require.

12 “(F) Any report submitted by a managed
13 care entity under subsection (e)(2) with respect
14 to years.

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

21 “(2) MACPAC REPORTS AND REVIEW.—Not
22 later than two years after the date of the enactment
23 of this section, the Medicaid and CHIP Payment
24 and Access Commission (in this section referred to
25 as ‘MACPAC’), in consultation with the National

1 Association of Medicaid Directors, pharmacy benefit
2 managers, managed care organizations, health care
3 providers (including pharmacists), beneficiary advocates,
4 and other stakeholders, shall publish a report
5 that includes—

6 “(A) best practices for operating drug
7 management programs, based on a review of a
8 representative sample of States administering
9 such a program;

10 “(B) a summary of the experience of the
11 appeals process under drug management programs
12 operated by several States, such as the
13 frequency at which individuals appealed the
14 identification of being an at-risk individual, the
15 frequency at which individuals appealed the selection
16 of a health care provider or pharmacy
17 under such a program, the timeframes for such
18 appeals, a summary of the reasons for such appeals,
19 and the design of such appeals processes;

20 “(C) a summary of trends and the effectiveness
21 of qualified drug management programs operated
22 under this section; and

23 “(D) recommendations to States on how
24 improvements can be made with respect to the
25 operation of such programs.

1 In reporting on State practices, the MACPAC shall
2 consider how such programs have been implemented
3 in rural areas, under fee-for-service as well as man-
4 aged care arrangements, and the extent to which
5 such programs have resulted in increased efficiencies
6 to such States or to the Federal Government under
7 this title.

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

16 “(A) who are enrolled under the program;
17 or

18 “(B) who are enrolled with a managed care
19 entity and enrolled under such a qualified drug
20 management program operated by such entity.

21 “(f) APPLICABILITY TO MANAGED CARE ENTI-
22 TIES.—

23 “(1) IN GENERAL.—With respect to any con-
24 tract that a State enters into on or after January
25 1, 2020, with a managed care entity (as defined in

1 section 1932(a)(1)(B)) pursuant to section 1903(m),
2 the State shall, as a condition of the contract, re-
3 quire the managed care entity—

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

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

12 “(C) to submit to the State a list (and as
13 necessary update such list) of individuals en-
14 rolled with such entity under the qualified drug
15 management program operated by such entity
16 under subparagraph (A) for purposes of allow-
17 ing State plans for which medical assistance is
18 paid on a fee-for-service basis to have access to
19 such information.

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

22 “(A) under paragraph (1)(A)—

23 “(i) the definition of the term ‘quali-
24 fied drug management program’ under

1 subsection (b), other than paragraph
2 (2)(D) of such subsection; and

3 “(ii) the provisions of paragraphs (1)
4 and (2) of subsection (c); and

5 “(B) under paragraph (1)(B), the report
6 requirements described in subparagraphs (A)
7 through (E) of subsection (e)(1);

8 each reference in such subsection (b) and para-
9 graphs of subsection (c) to ‘a State’ or ‘the State’
10 (other than to ‘a State plan’ or ‘the State plan’)
11 shall be deemed a reference to the managed care en-
12 tity, each reference under such subsection, para-
13 graphs, or subparagraphs to individuals enrolled
14 under the State plan (or waiver of the State plan)
15 shall be deemed a reference to individuals enrolled
16 with such entity, and each reference under such sub-
17 section, paragraphs, or subparagraphs to individuals
18 enrolled under the qualified drug management pro-
19 gram operated by the State shall be deemed a ref-
20 erence to individuals enrolled under the qualified
21 drug management program operated by the man-
22 aged care entity.

23 “(g) CONTROLLED SUBSTANCE DEFINED.—For pur-
24 poses of this section, the term ‘controlled substance’
25 means a drug that is included in schedule II, III, or IV

1 of section 202(c) of the Controlled Substances Act, or any
2 combination thereof, as specified by the State.”.

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

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

20 (2) for transitioning, as applicable, such indi-
21 viduals from receiving medical assistance under such
22 title through a managed care entity (as defined in
23 section 1932(a)(1)(B) of the Social Security Act)
24 with a contract that with the State pursuant to sec-
25 tion 1903(m) of such Act (and such a program oper-

1 ated by such entity) to fee-for-service Medicaid (and
2 such a program operated by the State).

3 (c) GUIDANCE ON AT-RISK POPULATION
4 TRANSITIONING TO MEDICARE.—

5 (1) IN GENERAL.—Not later than January 1,
6 2020, the Secretary of Health and Human Services,
7 after consultation with the Federal Coordinated
8 Health Care Office established under section 2602
9 of the Patient Protection and Affordable Care Act
10 (42 U.S.C. 1315b), shall issue guidance for State
11 Medicaid programs, with respect to transitioning in-
12 dividuals, providing for—

13 (A) notification to be submitted by the
14 State to the Centers for Medicare & Medicaid
15 Services and such individuals of the status of
16 such individuals as transitioning individuals;

17 (B) notification to such individuals about
18 enrollment under a prescription drug plan
19 under part D of such title or under a MA–PD
20 plan under part C of such title;

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

23 (D) best practices for coordination between
24 the qualified drug management program (as de-
25 scribed in section 1927A(b) of the Social Secu-

1 rity Act, as added by subsection (a)) carried out
2 by the State and a drug management program
3 carried out under such a plan pursuant to sec-
4 tion 1860D-4(c)(5) of the Social Security Act
5 (42 U.S.C. 1395w-10(c)(5)).

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

9 (A) is enrolled under the State plan (or
10 waiver of the State plan) and under the quali-
11 fied drug management program (as described in
12 section 1927A(b) of the Social Security Act, as
13 added by subsection (a)) carried out by the
14 State; and

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

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2D Session

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[Report No. 115-726]

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Committed to the Committee of the Whole House on the State of the Union and ordered to be printed