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(Original Signature of Member)

115TH CONGRESS
2D SESSION

H. R. 5808

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

M. _____ introduced the following bill; which was referred to the
Committee on _____

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”.

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

3 (a) IN GENERAL.—Title XIX of the Social Security
4 Act is amended by inserting after section 1927 (42 U.S.C.
5 1396r–8) the following new section:

6 **“SEC. 1927A. DRUG MANAGEMENT PROGRAM FOR AT-RISK**
7 **BENEFICIARIES.**

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

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

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

23 “(2) ELEMENTS OF PROGRAM.—

24 “(A) IN GENERAL.—Under the program,
25 the State, with respect to each individual identi-

1 fied under paragraph (1) and enrolled under
2 the program under paragraph (5)—

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

20 “(ii) requires that any controlled sub-
21 stance furnished to such individual during
22 the period for which such individual is en-
23 rolled under the program be prescribed by
24 a health care provider selected under
25 clause (i) for such individual and dispensed

1 by a pharmacy selected under clause (i) for
2 such individual in order for such controlled
3 substance to be covered under the State
4 plan (or waiver).

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

1 individual described in this subparagraph. If the
2 State selects or changes the selection pursuant
3 to the preceding sentence without regard to the
4 preferences of the individual, the State shall
5 provide the individual with at least 30 days
6 written notice of the selection or change of se-
7 lection and a rationale for the selection or
8 change.

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

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

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

13 “(3) NOTIFICATION TO IDENTIFIED INDIVID-
14 UALS.—Under the program, the State provides each
15 individual who is identified under paragraph (1),
16 prior to enrolling such individual under the program,
17 at least one notification of each of the following:

18 “(A) Notice that the State has identified
19 the individual as potentially being an at-risk
20 beneficiary for abuse or misuse of a controlled
21 substance.

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

1 “(C) Information describing all State and
2 Federal public health resources that are de-
3 signed to address such abuse or misuse to
4 which the individual has access, including men-
5 tal health services and other counseling serv-
6 ices.

7 “(D) Notice of, and information about, the
8 right of the individual to—

9 “(i) submit preferences of the indi-
10 vidual for health care providers and phar-
11 macies to be selected under paragraph
12 (2)(A), including as described in paragraph
13 (2)(B);

14 “(ii) appeal under paragraph (4)—

15 “(I) such identification described
16 in subparagraph (A); and

17 “(II) the selection of health care
18 providers and pharmacies under para-
19 graph (2)(A).

20 “(E) An explanation of the meaning and
21 consequences of the identification of the indi-
22 vidual as potentially being an at-risk beneficiary
23 for abuse or misuse of a controlled substance,
24 including an explanation of the program.

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

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

12 “(A) such individual may appeal—

13 “(i) such identification; and

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

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

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

5 “(D) the State must make a determination
6 with respect to an appeal described in subpara-
7 graph (A), and notify the individual of such de-
8 termination, prior to enrollment of such indi-
9 vidual in the program.

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

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

20 “(B) in the case of such an individual who
21 does submit an appeal under paragraph (4)
22 within the period applied by the State pursuant
23 to subparagraph (C) of such paragraph but
24 such appeal is denied, beginning not later than
25 30 days after the date of such denial.

1 “(6) NOTIFICATION OF HEALTH CARE PRO-
2 VIDERS AND PHARMACIES.—Under the program, the
3 State provides to each health care provider and
4 pharmacy selected for an individual under paragraph
5 (2)—

6 “(A) notification that the individual is an
7 at-risk beneficiary enrolled under the program
8 and that the provider or pharmacy has been se-
9 lected for the individual under paragraph (2);

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

12 “(C) a process through which the provider
13 or pharmacy can submit a concern or complaint
14 with respect to being so selected and refuse to
15 be a provider or pharmacy so selected.

16 “(7) CONTINUATION OF ENROLLMENT.—Under
17 the program, the State, with respect to an individual
18 enrolled under the program, provides for a process
19 to—

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

23 “(i) assess, in accordance with pub-
24 licly available evidence-based guidelines,
25 whether or not such individual should con-

1 tinue to be enrolled under the program;

2 and

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

5 “(B) continue, subject to subparagraph
6 (C), enrollment of such individual if such as-
7 sessment recommends such continuation; and

8 “(C) appeal the continuation of enrollment
9 in accordance with the appeals process de-
10 scribed in paragraph (4).

11 “(c) AT-RISK BENEFICIARY.—

12 “(1) IDENTIFICATION.—For purposes of this
13 section, a State shall identify an individual enrolled
14 under the State plan (or waiver of the State plan)
15 as an at-risk beneficiary if the individual is not an
16 exempted individual described in paragraph (2)
17 and—

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

22 “(B) the State received notification from a
23 PDP sponsor or Medicare Advantage organiza-
24 tion that such individual was identified as being
25 an at-risk beneficiary for prescription drug

1 abuse for enrollment in a drug management
2 program established by the sponsor or organiza-
3 tion pursuant to section 1860D-4(c)(5) and
4 such identification has not been terminated
5 under subparagraph (F) of such section.

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

9 “(A) is receiving—

10 “(i) hospice or palliative care; or

11 “(ii) treatment for cancer;

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

17 “(C) the State elects to treat as an ex-
18 empted individual for purposes of paragraph
19 (1).

20 “(d) APPLICATION OF PRIVACY RULES CLARIFICA-
21 TION.—The Secretary shall clarify privacy requirements,
22 including requirements under the regulations promulgated
23 pursuant to section 264(c) of the Health Insurance Port-
24 ability and Accountability Act of 1996 (42 U.S.C. 1320d-
25 2 note), related to the sharing of data under subsection

1 (b)(6) in the same manner as the Secretary is required
2 under subparagraph (J) of section 1860D–4(c)(5) to clar-
3 ify privacy requirements related to the sharing of data de-
4 scribed in such subparagraph.

5 “(e) REPORTS.—

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

11 “(A) The number of individuals enrolled
12 under the State plan (or waiver of the State
13 plan) who are enrolled under the program and
14 the percentage of individuals enrolled under the
15 State plan (or waiver) who are enrolled under
16 such program.

17 “(B) The number of prescriptions for con-
18 trolled substances that were dispensed per
19 month during each such year per individual en-
20 rolled under the program, including the dosage
21 and pill count for each such prescription.

22 “(C) The number of pharmacies filling pre-
23 scriptions for controlled substances for individ-
24 uals enrolled under such program.

1 “(D) The number of health care providers
2 writing prescriptions for controlled substances
3 (other than prescriptions for a refill) for indi-
4 viduals enrolled under such program.

5 “(E) Any other data that the Secretary
6 may require.

7 “(F) Any report submitted by a managed
8 care entity under subsection (e)(2) with respect
9 to years.

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

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

1 “(A) best practices for operating drug
2 management programs, based on a review of a
3 representative sample of States administering
4 such a program;

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

15 “(C) a summary of trends and the effec-
16 tiveness of qualified drug management pro-
17 grams operated under this section; and

18 “(D) recommendations to States on how
19 improvements can be made with respect to the
20 operation of such programs.

21 In reporting on State practices, the MACPAC shall
22 consider how such programs have been implemented
23 in rural areas, under fee-for-service as well as man-
24 aged care arrangements, and the extent to which
25 such programs have resulted in increased efficiencies

1 to such States or to the Federal Government under
2 this title.

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

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

12 or

13 “(B) who are enrolled with a managed care
14 entity and enrolled under such a qualified drug
15 management program operated by such entity.

16 “(f) APPLICABILITY TO MANAGED CARE ENTI-
17 TIES.—

18 “(1) IN GENERAL.—With respect to any con-
19 tract that a State enters into on or after January
20 1, 2020, with a managed care entity (as defined in
21 section 1932(a)(1)(B)) pursuant to section 1903(m),
22 the State shall, as a condition of the contract, re-
23 quire the managed care entity—

24 “(A) to operate a qualified drug manage-
25 ment program (as defined in subsection (b)) for

1 at-risk beneficiaries who are enrolled with such
2 entity and identified by the managed care entity
3 by means of application of paragraph (2);

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

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

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

17 “(A) under paragraph (1)(A)—

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

22 “(ii) the provisions of paragraphs (1)
23 and (2) of subsection (c); and

1 “(B) under paragraph (1)(B), the report
2 requirements described in subparagraphs (A)
3 through (E) of subsection (e)(1);
4 each reference in such subsection (b) and para-
5 graphs of subsection (c) to ‘a State’ or ‘the State’
6 (other than to ‘a State plan’ or ‘the State plan’)
7 shall be deemed a reference to the managed care en-
8 tity, each reference under such subsection, para-
9 graphs, or subparagraphs to individuals enrolled
10 under the State plan (or waiver of the State plan)
11 shall be deemed a reference to individuals enrolled
12 with such entity, and each reference under such sub-
13 section, paragraphs, or subparagraphs to individuals
14 enrolled under the qualified drug management pro-
15 gram operated by the State shall be deemed a ref-
16 erence to individuals enrolled under the qualified
17 drug management program operated by the man-
18 aged care entity.

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

24 (b) GUIDANCE ON AT-RISK POPULATION
25 TRANSITIONING BETWEEN MEDICAID FFS AND MAN-

1 AGED CARE.—Not later than October 1, 2019, the Sec-
2 retary of Health and Human Services shall issue guidance
3 for State Medicaid programs, with respect to individuals
4 who are enrolled under a State plan (or waiver of such
5 plan) under title XIX of the Social Security Act and under
6 a drug management program, for purposes of providing
7 best practices—

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

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

24 (c) GUIDANCE ON AT-RISK POPULATION
25 TRANSITIONING TO MEDICARE.—

1 (1) IN GENERAL.—Not later than January 1,
2 2020, the Secretary of Health and Human Services,
3 after consultation with the Federal Coordinated
4 Health Care Office established under section 2602
5 of the Patient Protection and Affordable Care Act
6 (42 U.S.C. 1315b), shall issue guidance for State
7 Medicaid programs, with respect to transitioning in-
8 dividuals, providing for—

9 (A) notification to be submitted by the
10 State to the Centers for Medicare & Medicaid
11 Services and such individuals of the status of
12 such individuals as transitioning individuals;

13 (B) notification to such individuals about
14 enrollment under a prescription drug plan
15 under part D of such title or under a MA–PD
16 plan under part C of such title;

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

19 (D) best practices for coordination between
20 the qualified drug management program (as de-
21 scribed in section 1927A(b) of the Social Secu-
22 rity Act, as added by subsection (a)) carried out
23 by the State and a drug management program
24 carried out under such a plan pursuant to sec-

1 tion 1860D-4(c)(5) of the Social Security Act
2 (42 U.S.C. 1395w-10(c)(5)).

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

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

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