Union Calendar No. 561

115TH CONGRESS
2D 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicaid Pharmaceutical Home Act of 2018''.

SEC. 2. DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.

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

''SEC. 1927A. DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.

''(a) IN GENERAL.—Beginning January 1, 2020, a State shall operate a qualified drug management program under which a State may enroll certain at-risk beneficiaries identified by the State under the program.

''(b) QUALIFIED DRUG MANAGEMENT PROGRAM.—For purposes of this section, the term 'qualified drug management program' means, with respect to a State, a program carried out by the State (including through a contract with a pharmacy benefit manager) that provides at least for the following:

''(1) IDENTIFICATION OF AT-RISK INDIVIDUALS.—Under the program, the State identifies, in accordance with subsection (c), individuals enrolled

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

''(2) ELEMENTS OF PROGRAM.—

''(A) IN GENERAL.—Under the program, the State, with respect to each individual identified under paragraph (1) and enrolled under the program under paragraph (5)—

''(i) subject to subparagraphs (B) and (C), selects at least one, but not more than three, health care providers and at least one, but not more than three, pharmacies for each such individual for purposes of clause (ii), in accordance with a selection process that takes into account reasonable factors such as the individual's previous utilization of items and services from health care providers and pharmacies, geographic proximity of the individual to such health care providers and pharmacies, access of the individual to health care, reasonable travel time, information regarding housing status, and any known preference of the individual for a certain health care provider or pharmacy; and

"(ii) requires that any controlled substance furnished to such individual during the period for which such individual is enrolled under the program be prescribed by a health care provider selected under clause (i) for such individual and dispensed by a pharmacy selected under clause (i) for such individual in order for such controlled substance to be covered under the State plan (or waiver).

"(B) BENEFICIARY PREFERENCE.—In the case of an individual receiving a notice under paragraph (3)(A) of being identified as potentially being an at-risk beneficiary described in such paragraph, such individual may submit, during the 30-day period following receipt of such notice, preferences for which health care providers and pharmacies the individual would prefer the State to select under subparagraph (A). The State shall select or change the selection of health care providers and pharmacies under subparagraph (A) for the individuals based on such preferences, except that in the case that State determines that such selection (or change of selection) of a health care pro-

vider or pharmacy under subparagraph (A) is contributing or would contribute to prescription drug abuse or drug diversion by the individual, the State may select or change the selection of health care provider or pharmacy for the individual without regard to the preferences of the individual described in this subparagraph. If the State selects or changes the selection pursuant to the preceding sentence without regard to the preferences of the individual, the State shall provide the individual with at least 30 days written notice of the selection or change of selection and a rationale for the selection or change.

''(C) TREATMENT OF PHARMACY WITH MULTIPLE LOCATIONS.—For purposes of subparagraph (A)(i), in the case of a pharmacy that has multiple locations that share real-time electronic prescription data and the same chain identification number, all such locations of the pharmacy shall collectively be treated as one pharmacy.

''(D) TREATMENT OF EXISTING FFS DRUG MANAGEMENT PROGRAMS.—In the case of a patient review and restriction program (as identi-

fied in the annual report submitted to the Secretary under section 1927(g)(3)(D)) operated by a State pursuant to section 1915(a)(2) before the date of the enactment of this section, such program shall be treated as a qualified drug management program.

''(E) REASONABLE ACCESS.—The program shall ensure, including through waiver of elements of the program (including under subparagraph (A)(ii)), reasonable access to health care (including access to health care providers and pharmacies with respect to prescription drugs described in subparagraph (A)) in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services (as defined for purposes of section 1860D–4(c)(5)(D)(ii)(II)).

''(3) NOTIFICATION TO IDENTIFIED INDIVIDUALS.—Under the program, the State provides each individual who is identified under paragraph (1), prior to enrolling such individual under the program, at least one notification of each of the following:

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

beneficiary for abuse or misuse of a controlled substance.

"(B) The name, address, and contact information of each health care provider and pharmacy that may be selected for the individual under paragraph (2)(A).

"(C) Information describing all State and Federal public health resources that are designed to address such abuse or misuse to which the individual has access, including mental health services and other counseling services.

"(D) Notice of, and information about, the right of the individual to—

"(i) submit preferences of the individual for health care providers and pharmacies to be selected under paragraph (2)(A), including as described in paragraph (2)(B);

"(ii) appeal under paragraph (4)—

"(I) such identification described in subparagraph (A); and

"(II) the selection of health care providers and pharmacies under paragraph (2)(A).

''(E) An explanation of the meaning and consequences of the identification of the individual as potentially being an at-risk beneficiary for abuse or misuse of a controlled substance, including an explanation of the program.

''(F) Information, including a contact list and clear instructions, that explain how the individual can contact the appropriate entities administering the program in order to submit preferences described in paragraph (2)(B) and any other communications relating to the program.

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

''(A) such individual may appeal—

''(i) such identification; and

''(ii) the selection of a health care provider or pharmacy under paragraph (2)(A);

''(B) in the case of an appeal described in subparagraph (A)(ii), the State shall accommodate the health care provider or pharmacy preferred by the individual for selection for purposes of paragraph (2)(A), unless the State de-

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

''(C) such individual is provided a period of not less than 30 days following the date of receipt of the notice described in paragraph (3) to submit such appeal; and

''(D) the State must make a determination with respect to an appeal described in subparagraph (A), and notify the individual of such determination, prior to enrollment of such individual in the program.

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

''(A) in the case of such an individual who does not submit an appeal under paragraph (4) within the period applied by the State pursuant to subparagraph (C) of such paragraph, beginning on the day after the last day of such period; and

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

"(6) NOTIFICATION OF HEALTH CARE PROVIDERS AND PHARMACIES.—Under the program, the State provides to each health care provider and pharmacy selected for an individual under paragraph (2)—

"(A) notification that the individual is an at-risk beneficiary enrolled under the program and that the provider or pharmacy has been selected for the individual under paragraph (2);

"(B) information on such program and the role of being so selected; and

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

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

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

''(i) assess, in accordance with publicly available evidence-based guidelines, whether or not such individual should continue to be enrolled under the program; and

''(ii) notify such individual of the results of the assessment under clause (i);

''(B) continue, subject to subparagraph (C), enrollment of such individual if such assessment recommends such continuation; and

''(C) appeal the continuation of enrollment in accordance with the appeals process described in paragraph (4).

''(c) AT-RISK BENEFICIARY.—

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

''(A) is identified as such an at-risk beneficiary through the use of publicly available evi-

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

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

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

''(A) is receiving—

''(i) hospice or palliative care; or

''(ii) treatment for cancer;

''(B) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

''(C) the State elects to treat as an exempted individual for purposes of paragraph (1).

''(d) APPLICATION OF PRIVACY RULES CLARIFICATION.—The Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), related to the sharing of data under subsection (b)(6) in the same manner as the Secretary is required under subparagraph (J) of section 1860D–4(c)(5) to clarify privacy requirements related to the sharing of data described in such subparagraph.

''(e) REPORTS.—

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

''(A) The number of individuals enrolled under the State plan (or waiver of the State plan) who are enrolled under the program and the percentage of individuals enrolled under the State plan (or waiver) who are enrolled under such program.

''(B) The number of prescriptions for controlled substances that were dispensed per month during each such year per individual en-

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

"(C) The number of pharmacies filling prescriptions for controlled substances for individuals enrolled under such program.

"(D) The number of health care providers writing prescriptions for controlled substances (other than prescriptions for a refill) for individuals enrolled under such program.

"(E) Any other data that the Secretary may require.

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

For each such report for a year after 2021, the information described in this paragraph shall be provided in a manner that compares such information with respect to the prior calendar year to such information with respect to the second prior calendar year.

"(2) MACPAC REPORTS AND REVIEW.—Not later than two years after the date of the enactment of this section, the Medicaid and CHIP Payment and Access Commission (in this section referred to as 'MACPAC'), in consultation with the National

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

"(A) best practices for operating drug management programs, based on a review of a representative sample of States administering such a program;

"(B) a summary of the experience of the appeals process under drug management programs operated by several States, such as the frequency at which individuals appealed the identification of being an at-risk individual, the frequency at which individuals appealed the selection of a health care provider or pharmacy under such a program, the timeframes for such appeals, a summary of the reasons for such appeals, and the design of such appeals processes;

"(C) a summary of trends and the effectiveness of qualified drug management programs operated under this section; and

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

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

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

''(A) who are enrolled under the program; or

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

''(f) APPLICABILITY TO MANAGED CARE ENTITIES.—

''(1) IN GENERAL.—With respect to any contract that a State enters into on or after January 1, 2020, with a managed care entity (as defined in

section 1932(a)(1)(B)) pursuant to section 1903(m), the State shall, as a condition of the contract, require the managed care entity—

"(A) to operate a qualified drug management program (as defined in subsection (b)) for at-risk beneficiaries who are enrolled with such entity and identified by the managed care entity by means of application of paragraph (2);

"(B) to submit to the State an annual report on the matters described in subparagraphs (A) through (E) of subsection (e)(1); and

"(C) to submit to the State a list (and as necessary update such list) of individuals enrolled with such entity under the qualified drug management program operated by such entity under subparagraph (A) for purposes of allowing State plans for which medical assistance is paid on a fee-for-service basis to have access to such information.

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

"(A) under paragraph (1)(A)—

"(i) the definition of the term 'qualified drug management program' under

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

"(ii) the provisions of paragraphs (1) and (2) of subsection (c); and

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

each reference in such subsection (b) and paragraphs of subsection (c) to 'a State' or 'the State' (other than to 'a State plan' or 'the State plan') shall be deemed a reference to the managed care entity, each reference under such subsection, paragraphs, or subparagraphs to individuals enrolled under the State plan (or waiver of the State plan) shall be deemed a reference to individuals enrolled with such entity, and each reference under such subsection, paragraphs, or subparagraphs to individuals enrolled under the qualified drug management program operated by the State shall be deemed a reference to individuals enrolled under the qualified drug management program operated by the managed care entity.

"(g) CONTROLLED SUBSTANCE DEFINED.—For purposes of this section, the term 'controlled substance' means a drug that is included in schedule II, III, or IV

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

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

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

(2) for transitioning, as applicable, such individuals from receiving medical assistance under such title through a managed care entity (as defined in section 1932(a)(1)(B) of the Social Security Act) with a contract that with the State pursuant to section 1903(m) of such Act (and such a program oper-

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

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

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

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

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

(C) best practices for transitioning such individuals to such a plan; and

(D) best practices for coordination between the qualified drug management program (as described in section 1927A(b) of the Social Secu-

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

(2) TRANSITIONING INDIVIDUALS.—For purposes of paragraph (1), a transitioning individual is an individual who, with respect to a month—

(A) is enrolled under the State plan (or waiver of the State plan) and under the qualified drug management program (as described in section 1927A(b) of the Social Security Act, as added by subsection (a)) carried out by the State; and

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

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