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118TH CONGRESS
1ST SESSION

H. R. 4011

To amend title XXVII of the Public Health Service Act to improve patient access to oral medications, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 12, 2023

Mr. BILIRAKIS (for himself and Ms. SEWELL) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title XXVII of the Public Health Service Act to improve patient access to oral medications, 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 ''Timely Access to Clinical Treatment Act of 2023'' or the ''TACT Act of 2023''.

SEC. 2. PATIENT ACCESS TO ORAL MEDICATIONS.

(a) IN GENERAL.—Section 2719A of the Public Health Service Act (42 U.S.C. 300gg–19a) is amended by adding at the end the following new subsection:

''(f) ACCESS TO ORAL MEDICATIONS.—

''(1) REQUIREMENTS FOR CONTRACTS BETWEEN GROUP HEALTH PLANS OR HEALTH INSURANCE ISSUERS AND PHARMACIES.—If a group health plan or a health insurance issuer offering group or individual health insurance coverage covers or provides any benefits for oral medications (as defined in paragraph (4)) and enters into a contract with a pharmacy, whether directly or through an agent of such plan or issuer (including a pharmacy benefits manager) to dispense such medications to participants, beneficiaries, or enrollees of the plan or coverage, such plan or issuer shall require, as conditions of such contract, such pharmacy to carry out the procedures described in paragraph (2).

''(2) PROCEDURES DESCRIBED.—For purposes of paragraph (1), the procedures described in this paragraph with respect to a participant, beneficiary, or enrollee of the plan or coverage and a health care provider who submits to such pharmacy a prescription for an oral medication for such participant, beneficiary, or enrollee are the following (as applicable):

''(A) PHARMACY CONFIRMATION OF ABILITY TO DISPENSE.—Not later than 24 hours after receiving such prescription—

"(i) confirm to such health care provider that such pharmacy received such prescription; and

"(ii) inform such health care provider as well as such plan or issuer whether such pharmacy will dispense such oral medication to such participant, beneficiary, or enrollee by not later than 72 hours after receiving such prescription, including any time for benefits verification, prior authorization, or any other administrative procedure required by the agent of such plan or issuer (including a pharmacy benefits manager) prior to authorizing the pharmacy to dispense the medication.

"(B) PHARMACY ABLE TO FILL PRESCRIPTION.—In the case that such pharmacy informs such health care provider under subparagraph (A)(ii) that such pharmacy is able to dispense such oral medication to such participant, beneficiary, or enrollee by the 72-hour deadline described in such subparagraph, dispense such oral medication to such participant, beneficiary, or enrollee by such deadline.

"(C) PHARMACY UNABLE TO FILL PRESCRIPTION.—In the case that such pharmacy informs such health care provider under subparagraph (A)(ii) that such pharmacy is not able to dispense such oral medication to such participant, beneficiary, or enrollee by the 72-hour deadline described in such subparagraph, immediately provide a written notice to—

"(i) the prescribing physician or other health care provider;

"(ii) the group health plan or a health insurance issuer offering group or individual health insurance coverage; and

"(iii) such participant, beneficiary, or enrollee,

with a clear and understandable explanation of such inability and of the option of such participant, beneficiary, or enrollee to be dispensed such oral medication from any provider or pharmacy described in subparagraph (C) of paragraph (3), in accordance with the requirements described in subparagraphs (A) and (B) of such paragraph.

"(D) PHARMACY FAILURE TO COMMUNICATE.—If the pharmacy does not commu-

nicate its ability to dispense as required by subparagraph (A), or, after confirming that it will dispense an oral medication under such subparagraph, does not actually dispense such medication by the 72-hour deadline described in such paragraph, such pharmacy shall be deemed to have confirmed that it is not able to dispense such medication under subparagraph (C).

''(3) REQUIREMENTS FOR GROUP HEALTH PLANS AND HEALTH INSURANCE ISSUERS.—

''(A) PATIENT SELECTION OF ALTERNATE PROVIDER OR PHARMACY.—If a group health plan or a health insurance issuer offering group or individual health insurance coverage (or its agent, including a pharmacy benefits manager) described in paragraph (1) enters into a contract described in such paragraph, with a pharmacy and such pharmacy, with respect to a participant, beneficiary, or enrollee of the plan or coverage and a health care provider who submits to such pharmacy a prescription for an oral medication for such participant, beneficiary, or enrollee, informs such health care provider under subparagraph (A)(ii) of such

paragraph that such pharmacy will not dispense such oral medication to such participant, beneficiary, or enrollee by the 72-hour deadline described in such subparagraph (or in the case that the participant, beneficiary, or enrollee has not received the oral medication by the 72-hour deadline), the plan or issuer—

''(i) shall authorize such participant, beneficiary, or enrollee to select any provider or pharmacy described in subparagraph (C) to dispense such oral medication to such participant, beneficiary, or enrollee based on the written notice described in paragraph (2)(C) or a certification by a the prescribing physician or other health professional that the participant, beneficiary, or enrollee has not received the oral medication by the 72-hour deadline; and

''(ii) in the case that the provider or pharmacy selected under clause (i) does not have a contract with such plan or issuer to dispense such oral medication to such participant, group health plan or a health insurance issuer offering group or individual health insurance coverage de-

scribed in paragraph (1) shall cover the medication and pay the provider or pharmacy in accordance with the provisions of subparagraph (B).

''(B) COVERAGE REQUIREMENTS FOR PRESCRIPTIONS DISPENSED BY ALTERNATE PROVIDER OR PHARMACY.—For prescriptions dispensed by an alternate provider or pharmacy in accordance with subparagraph (A) that does not have a contract with a group health plan or a health insurance issuer offering group or individual health insurance coverage (or its agent, including a pharmacy benefits manager) described in paragraph (1) to dispense such oral medication to such participant, such group health plan or a health insurance issuer (or its agent, including a pharmacy benefits manager) shall cover the medication and pay the provider or pharmacy subject to the following requirements—

''(i) such medication will be provided without imposing any requirement under the plan for prior authorization of the medication or any limitation on coverage that is more restrictive than the require-

ments or limitations that apply to oral medications received from participating providers and pharmacies with respect to such plan;

''(ii) the cost-sharing requirement (expressed as a copayment amount or coinsurance rate) is not greater than the requirement that would apply if such services were provided by a participating provider or a participating pharmacy;

''(iii) such cost-sharing requirement is calculated as if the total amount that would have been charged for such services by such participating provider or participating pharmacy were equal to the recognized amount (as determined by the Secretary) for such oral medications, plan, and year;

''(iv) the group health plan pays to such provider or pharmacy, respectively, the amount by which the recognized amount for such services and year involved exceeds the cost-sharing amount for such services (as determined in accordance with clauses (ii) and (iii)) and year;

"(v) any cost-sharing payments made by the participant or beneficiary with respect to such oral medication so furnished shall be counted toward any in-network deductible or out-of-pocket maximums applied under the plan (and such in-network deductible and out-of-pocket maximums shall be applied) in the same manner as if such cost-sharing payments were made with respect to oral medication furnished by a participating provider or a participating pharmacy; and

"(vi) such medication will be provided without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2704 of this Act, including as incorporated pursuant to section 715 of the Employee Retirement Income Security Act of 1974 and section 9815 of this Act, and other than applicable cost-sharing).

"(C) PROVIDER OR PHARMACY DESCRIBED.—A provider or pharmacy described in this subparagraph, with respect to a partici-

pant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage described in paragraph (1) and a prescription for an oral medication for such participant, beneficiary or enrollee, is a provider or pharmacy that—

"(i) is licensed by the State in which such provider or pharmacy is located to dispense such oral medication, if such a license is required by the State;

"(ii) is either located within a reasonable distance (as determined by the Secretary) of the residence of such participant, beneficiary, or enrollee, or is able to deliver such oral medication to such participant, beneficiary, or enrollee at such residence; and

"(iii) is able to dispense (and if applicable, deliver), such oral medication to such participant, beneficiary, or enrollee within 48 hours of the date on which it receives the prescription.

For purposes of this section, a provider or pharmacy described in this subparagraph includes a physician or other health care practi-

tioner authorized to dispense oral medication to such participant, beneficiary, or enrollee pursuant to the law of the State in which the physician or other health care practitioner is located.

"(D) PRIOR AUTHORIZATION REQUIREMENTS.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that requires prior authorization for an oral medication to be dispensed to a participant, beneficiary, or enrollee of the plan or coverage, such plan or issuer (or its agent, including a pharmacy benefits manager) shall make a decision with respect to a request for such a prior authorization by not later than 72 hours after receiving such request. In the case that such plan or issuer (or its agent, including a pharmacy benefits manager) does not make a decision with respect to a request for prior authorization for an oral medication to be dispensed to a participant, beneficiary, or enrollee of the plan or coverage by the 72-hour deadline described in the previous sentence, such participant, beneficiary or enrollee may select any pharmacy described in subparagraph (C) to dispense such oral medica-

tion to such participant, beneficiary, or enrollee, in accordance with the cost-sharing requirements described in subparagraph (B).

''(E) USE OF RELEVANT QUALITY MEASURES UNDER INCENTIVE PAYMENT AND ADJUSTMENT SYSTEMS.—If a group health plan or a health insurance issuer offering group or individual health insurance coverage uses an incentive payment and adjustment system (as defined by the Secretary) in determining pharmacy reimbursement payments for oral medications, such system shall only use quality measures that are relevant to the performance of such pharmacy with respect to areas that the pharmacy can impact based on the oral medications dispensed and managed by the pharmacy.

''(4) ORAL MEDICATION DEFINED.—In this subsection, the term 'oral medication' means a drug or biological (as defined in section 1861(t) of the Social Security Act) that is used for a medically accepted indication that is dispensed as an outpatient and taken by mouth.''.

(b) CONFORMING AMENDMENT.—Section 2719A(e) of the Public Health Service Act (42 U.S.C. 300gg–

19a(e)) is amended by inserting ''(other than subsection (f))'' after ''The provisions of this section''.

(c) GAO REPORT AND RECOMMENDATIONS.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Chair and Ranking Member of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chair and Ranking Member of the Committee on Energy and Commerce of the House of Representatives a report on the effects of the implementation of subsection (f) of section 2719A of the Public Health Service Act (as added by subsection (a)) on the timely access of patients to oral medications (as defined in subsection (f)(4) of such section), together with such recommendations as the Comptroller General determines are appropriate.

(2) ITEMS INCLUDED.—The report submitted under paragraph (1) shall include—

(A) a comparison of the amount of time between the date on which a prescription is written and the date on which a patient receives an oral medication before and after the implementation of subsection (f) of section 2719A of the Public Health Service Act;

(B) an assessment of the effects on patient health outcomes, including morbidity and mortality;

(C) an evaluation of costs to patients, health insurance issuers, physicians, and other healthcare providers; and

(D) a risk assessment with mitigation recommendations on any actual or potential fraud, waste and abuse relating to the implementation of such subsection.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after January 1, 2024.

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