

117TH CONGRESS
1ST SESSION

H. R. 3258

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

IN THE HOUSE OF REPRESENTATIVES

MAY 14, 2021

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

A BILL

To amend title XXVII of the Public Health Service Act to improve patient access to anti-cancer oral medications, 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 “Timely Access to Can-
5 cer Treatment Act of 2021” or the “TACT Act of 2021”.

6 **SEC. 2. PATIENT ACCESS TO ANTI-CANCER ORAL MEDICA-**
7 **TIONS.**

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

1 “(f) ACCESS TO ANTI-CANCER ORAL MEDICA-
2 TIONS.—

3 “(1) REQUIREMENTS FOR CONTRACTS BE-
4 TWEEN GROUP HEALTH PLANS OR HEALTH INSUR-
5 ANCE ISSUERS AND PHARMACIES.—If a group health
6 plan or a health insurance issuer offering group or
7 individual health insurance coverage covers or pro-
8 vides any benefits for anti-cancer oral medications
9 (as defined in paragraph (4)) and enters into a con-
10 tract with a pharmacy, whether directly or through
11 an agent of such plan or issuer (including a phar-
12 macy benefit manager), to dispense such medications
13 to participants, beneficiaries, or enrollees of the plan
14 or coverage, such plan or issuer shall require, as
15 conditions of such contract, such pharmacy to carry
16 out the procedures described in paragraph (2).

17 “(2) PROCEDURES DESCRIBED.—For purposes
18 of paragraph (1), the procedures described in this
19 paragraph with respect to a participant, beneficiary,
20 or enrollee of the plan or coverage and a health care
21 provider who submits to such pharmacy a prescrip-
22 tion for an anti-cancer oral medication for such par-
23 ticipant, beneficiary, or enrollee are the following (as
24 applicable):

1 “(A) PHARMACY CONFIRMATION OF ABIL-
2 ITY TO DISPENSE.—Not later than 24 hours
3 after receiving such prescription—

4 “(i) confirm to such health care pro-
5 vider that such pharmacy received such
6 prescription; and

7 “(ii) inform such health care provider,
8 as well as such plan or issuer, whether
9 such pharmacy will dispense such anti-can-
10 cer oral medication to such participant,
11 beneficiary, or enrollee by not later than
12 72 hours after receiving such prescription,
13 including any time for benefits verification,
14 prior authorization, or any other adminis-
15 trative procedure required by the agent of
16 such plan or issuer (including a pharmacy
17 benefit manager) prior to authorizing the
18 pharmacy to dispense the medication.

19 “(B) PHARMACY ABLE TO FILL PRESCRIP-
20 TION.—In the case that such pharmacy informs
21 such health care provider in writing under sub-
22 paragraph (A)(ii) that such pharmacy is able to
23 dispense such anti-cancer oral medication to
24 such participant, beneficiary, or enrollee by the
25 72-hour deadline described in such subpara-

1 graph, dispense such anti-cancer oral medica-
2 tion to such participant, beneficiary, or enrollee
3 by such deadline.

4 “(C) PHARMACY UNABLE TO FILL PRE-
5 SCRIPTION.—In the case that such pharmacy
6 informs such health care provider under sub-
7 paragraph (A)(ii) that such pharmacy is not
8 able to dispense such anti-cancer oral medica-
9 tion to such participant, beneficiary, or enrollee
10 by the 72-hour deadline described in such sub-
11 paragraph, immediately provide a written notice
12 to—

13 “(i) the prescribing physician or other
14 health care provider;

15 “(ii) the group health plan or a health
16 insurance issuer offering group or indi-
17 vidual health insurance coverage; and

18 “(iii) such participant, beneficiary, or
19 enrollee;

20 with a clear and understandable explanation of
21 such inability and of the option of such partici-
22 pant, beneficiary, or enrollee to be dispensed
23 such anti-cancer oral medication from any pro-
24 vider or pharmacy described in paragraph
25 (3)(C), in accordance with the cost-sharing re-

1 requirements described in subparagraphs (A) and
2 (B) of such paragraph.

3 “(D) PHARMACY FAILURE TO COMMU-
4 NICATE.—If the pharmacy does not commu-
5 nicate its ability to dispense as required by sub-
6 paragraph (A), or, after confirming that it will
7 dispense an anti-cancer oral medication under
8 such subparagraph, does not actually dispense
9 such medication by the 72-hour deadline de-
10 scribed in such paragraph, such pharmacy shall
11 be deemed to have confirmed that it is not able
12 to dispense such medication under subpara-
13 graph (C).

14 “(3) REQUIREMENTS FOR GROUP HEALTH
15 PLANS AND HEALTH INSURANCE ISSUERS.—

16 “(A) PATIENT SELECTION OF ALTERNATE
17 PROVIDER OR PHARMACY.—If a group health
18 plan or a health insurance issuer offering group
19 or individual health insurance coverage (or its
20 agent, including a pharmacy benefits manager)
21 described in paragraph (1) enters into a con-
22 tract described in such paragraph, with a phar-
23 macy and such pharmacy, with respect to a
24 participant, beneficiary, or enrollee of the plan
25 or coverage and health care provider who sub-

1 mits to such pharmacy a prescription for an
2 anti-cancer oral medication for such partici-
3 pant, beneficiary, or enrollee, informs such
4 health care provider under subparagraph (A)(ii)
5 of such paragraph that such pharmacy will not
6 dispense such anti-cancer oral medication to
7 such participant, beneficiary, or enrollee by the
8 72-hour deadline described in such subpara-
9 graph (or in the case that the participant, bene-
10 ficiary, or enrollee has not received the anti-
11 cancer oral medication by the 72-hour dead-
12 line), the plan or issuer—

13 “(i) shall authorize such participant,
14 beneficiary, or enrollee to select any pro-
15 vider or pharmacy described in subpara-
16 graph (C) to dispense such anti-cancer oral
17 medication to such participant, beneficiary,
18 or enrollee based on the written noticed de-
19 scribed in paragraph (2)(C) or a certifi-
20 cation by the prescribing physician or
21 other health professional that the partici-
22 pant, beneficiary, or enrollee has not re-
23 ceived the anti-cancer oral medication by
24 the 72-hour deadline; and

1 “(ii) in the case the provider or phar-
2 macy selected under clause (i) does not
3 have a contract with such plan or issuer to
4 dispense such anti-cancer oral medication
5 to such participant, group health plan or
6 health insurance issuer offering group or
7 individual health insurance coverage de-
8 scribed in paragraph (1) shall cover the
9 medication and pay the provider or phar-
10 macy in accordance with the provisions of
11 subparagraph (B).

12 “(B) COVERAGE REQUIREMENTS FOR PRE-
13 SCRIPTIONS DISPENSED BY ALTERNATE PRO-
14 VIDER OR PHARMACY.—For prescriptions dis-
15 pensed by an alternate provider or pharmacy in
16 accordance with subparagraph (A) that does
17 not have a contract with a group health plan or
18 a health insurance issuer offering group or indi-
19 vidual health insurance coverage (or its agent,
20 including a pharmacy benefits manager) de-
21 scribed in paragraph (1) to dispense such anti-
22 cancer oral medication to such participant, such
23 group health plan or a health insurance issuer
24 (or its agent, including a pharmacy benefits
25 manager) shall cover the medication and pay

1 the provider or pharmacy subject the following
2 requirements—

3 “(i) such medication will be provider
4 without imposing any requirement under
5 the plan for prior authorization of the
6 medication or any limitation on coverage
7 that is more restrictive than the require-
8 ments or limitations that apply to anti-can-
9 cer oral medications received from partici-
10 pating providers and pharmacies with re-
11 spect to such plan;

12 “(ii) the cost-sharing requirement (ex-
13 pressed as a copayment amount or coinsur-
14 ance rate) is not greater than the require-
15 ment that would apply if such services
16 were provided by a participating provider
17 or a participating pharmacy;

18 “(iii) such cost-sharing requirement is
19 calculated as if the total amount that
20 would have been charged for such services
21 by such participating provider or partici-
22 pating pharmacy were equal to the recog-
23 nized amount (as determined by the Sec-
24 retary) for such anti-cancer oral medica-
25 tions, plan, and year;

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

8 “(v) any cost-sharing payments made
9 by the participant or beneficiary with re-
10 spect to such anti-cancer oral medication
11 so furnished shall be counted toward any
12 in-network deductible or out-of-pocket
13 maximums applied under the plan (and
14 such in-network deductible and out-of-
15 pocket maximums shall be applied) in the
16 same manner as if such cost-sharing pay-
17 ments were made with respect to anti-can-
18 cer oral medication furnished by a partici-
19 pating provider or a participating phar-
20 macy; and

21 “(vi) such medication will be provided
22 without regard to any other term or condi-
23 tion of such coverage (other than exclusion
24 or coordination of benefits, or an affiliation
25 or waiting period, permitted under section

1 2704 of this Act, including as incorporated
2 pursuant to section 715 of the Employee
3 Retirement Income Security Act of 1974
4 and section 9815 of this Act, and other
5 than applicable cost-sharing).

6 “(C) PROVIDER OR PHARMACY DE-
7 SCRIBED.—A provider or pharmacy described in
8 this subparagraph, with respect to a partici-
9 pant, beneficiary, or enrollee of a group health
10 plan or group or individual health insurance
11 coverage described in paragraph (1) and a pre-
12 scription for an anticancer oral medication for
13 such participant, beneficiary or enrollee, is a
14 provider or pharmacy that—

15 “(i) is licensed by the State in which
16 such provider or pharmacy is located to
17 dispense such anti-cancer oral medication,
18 if such a license is required by the State;

19 “(ii) is either located within a reason-
20 able distance (as determined by the Sec-
21 retary) of the residence of such partici-
22 pant, beneficiary, or enrollee, or is able to
23 deliver such anti-cancer oral medication to
24 such participant, beneficiary, or enrollee at
25 such residence; and

1 “(iii) is able to dispense (and if appli-
2 cable, deliver), such anti-cancer oral medi-
3 cation to such participant, beneficiary, or
4 enrollee within 48 hours of the date on
5 which it receives the prescription.

6 For purposes of this section, a provider or
7 pharmacy described in this subparagraph in-
8 cludes a physician or other health care practi-
9 tioner authorized to dispense anti-cancer oral
10 medication to such participant, beneficiary, or
11 enrollee pursuant to the law of the State in
12 which the physician or other health care practi-
13 tioner is located.

14 “(D) PRIOR AUTHORIZATION REQUIRE-
15 MENTS.—In the case of a group health plan or
16 a health insurance issuer offering group or indi-
17 vidual health insurance coverage that requires
18 prior authorization for an anti-cancer oral
19 medication to be dispensed to a participant,
20 beneficiary, or enrollee of the plan or coverage,
21 such plan or issuer (or its agent , including a
22 pharmacy benefits manager) shall make a deci-
23 sion with respect to a request for such a prior
24 authorization by not later than 72 hours after
25 receiving such request. In the case that such

1 plan or issuer (or its agent, including a phar-
2 macy benefits manager) does not make a deci-
3 sion with respect to a request for prior author-
4 ization for an anticancer oral medication to be
5 dispensed to a participant, beneficiary, or en-
6 rollee of the plan or coverage by the 72-hour
7 deadline described in the previous sentence,
8 such participant, beneficiary or enrollee may se-
9 lect any pharmacy described in subparagraph
10 (C) to dispense such anticancer oral medication
11 to such participant, beneficiary, or enrollee, in
12 accordance with the cost-sharing requirements
13 described in subparagraph (B) but only if the
14 prescription for such anti-cancer oral medica-
15 tion meets the clinical guidelines set forth by
16 the National Comprehensive Cancer Network.

17 “(4) ANTI-CANCER ORAL MEDICATION DE-
18 FINED.—In this subsection, the term ‘anti-cancer
19 oral medication’ means a drug or biological (as de-
20 fined in section 1861(t) of the Social Security Act)
21 that is used in an anti-cancer chemotherapeutic regi-
22 men for a medically accepted indication, including
23 any related supportive care drugs and biologicals
24 that are dispensed as an outpatient and taken by the
25 mouth.”.

1 (b) EFFECTIVE DATE.—The amendments made by
2 this section shall apply with respect to plan years begin-
3 ning on or after January 1, 2022.

4 (c) GAO REPORT AND RECOMMENDATIONS.—

5 (1) IN GENERAL.—Not later than 2 years after
6 the date of enactment of this Act, the Comptroller
7 General of the United States shall submit to the
8 Chair and Ranking Member of the Committee on
9 Health, Education, Labor and Pensions of the Sen-
10 ate and the Chair and Ranking Member of the Com-
11 mittee on Energy and Commerce of the House of
12 Representatives a report on the effects of the imple-
13 mentation of subsection (f) of section 2719A of the
14 Public Health Service Act (as added by subsection
15 (a)) on the timely access of patients to anti-cancer
16 oral medications (as defined in subsection (f)(4) of
17 such section), together with such recommendations
18 as the Comptroller General determines are appro-
19 priate.

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

22 (A) a comparison of the amount of time
23 between the date on which a prescription is
24 written and the date on which a patient receives
25 an anti-cancer oral medication before and after

1 the implementation of subsection (f) of section
2 2719A of the Public Health Service Act;

3 (B) an assessment of the effects on patient
4 health outcomes, including morbidity and mor-
5 tality;

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

9 (D) a risk assessment with mitigation rec-
10 ommendations on any actual or potential fraud,
11 waste and abuse relating to the implementation
12 of such subsection.

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