

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.

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## 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

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## 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-

graph, dispense such anti-cancer 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 anti-cancer 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 anti-cancer oral medication from any provider or pharmacy described in paragraph (3)(C), in accordance with the cost-sharing re-

quirements described in subparagraphs (A) and (B) of such paragraph.

“(D) PHARMACY FAILURE TO COMMUNICATE.—If the pharmacy does not communicate its ability to dispense as required by subparagraph (A), or, after confirming that it will dispense an anti-cancer 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 health care provider who sub-

mits to such pharmacy a prescription for an anti-cancer 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 anti-cancer 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 anti-cancer 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 anti-cancer oral medication to such participant, beneficiary, or enrollee based on the written noticed described in paragraph (2)(C) or a certification by the prescribing physician or other health professional that the participant, beneficiary, or enrollee has not received the anti-cancer oral medication by 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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