

**Second Regular Session  
Seventy-third General Assembly  
STATE OF COLORADO**

**REENGROSSED**

*This Version Includes All Amendments  
Adopted in the House of Introduction*

LLS NO. 22-0786.01 Christy Chase x2008

**HOUSE BILL 22-1264**

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**A BILL FOR AN ACT**

101 **CONCERNING UPDATING REFERENCES TO THE FEDERAL FOOD AND**  
102 **DRUG ADMINISTRATION IN THE HEALTH INSURANCE LAW.**

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**Bill Summary**

*(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <http://leg.colorado.gov/>.)*

**Statutory Revision Committee.** The bill strikes references to the federal food and drug administration in the health insurance code and replaces the references with the term "FDA", which is defined for the entire code to mean the federal food and drug administration.

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Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.  
*Capital letters or bold & italic numbers indicate new material to be added to existing statute.*  
*Dashes through the words indicate deletions from existing statute.*

HOUSE  
3rd Reading Unamended  
March 17, 2022

HOUSE  
2nd Reading Unamended  
March 16, 2022

1 *Be it enacted by the General Assembly of the State of Colorado:*

2 **SECTION 1.** In Colorado Revised Statutes, 10-16-104, **amend**  
3 (5.5)(a)(III)(B) and (21)(a) as follows:

4 **10-16-104. Mandatory coverage provisions - definitions -**  
5 **rules. (5.5) Behavioral, mental health, and substance use disorders**  
6 **- rules. (a) (III) (B)** A health benefit plan subject to this subsection (5.5)  
7 must provide coverage without prior authorization for a five-day supply  
8 of at least one of the ~~federal food and drug administration-approved~~  
9 FDA-APPROVED drugs for the treatment of opioid dependence; except that  
10 this requirement is limited to a first request within a twelve-month period.

11 **(21) Oral anticancer medication.** (a) Any health benefit plan  
12 that provides coverage for cancer chemotherapy treatment shall provide  
13 coverage for prescribed, orally administered anticancer medication that  
14 has been approved by the ~~federal food and drug administration~~ FDA and  
15 is used to kill or slow the growth of cancerous cells. The orally  
16 administered medication shall be provided at a cost to the covered person  
17 not to exceed the coinsurance percentage or the copayment amount as is  
18 applied to an intravenously administered or an injected cancer medication  
19 prescribed for the same purpose. A medication provided pursuant to this  
20 subsection (21) shall be prescribed only upon a finding that it is medically  
21 necessary by the treating physician for the purpose of killing or slowing  
22 the growth of cancerous cells in a manner that is in accordance with  
23 nationally accepted standards of medical practice, clinically appropriate  
24 in terms of type, frequency, extent site, and duration, and not primarily for  
25 the convenience of the patient, physician, or other health-care provider.  
26 This subsection (21) does not require the use of orally administered  
27 medications as a replacement for other cancer medications. Nothing in

1 this subsection (21) prohibits coverage for oral generic medications in a  
2 health benefit plan. Nothing in this subsection (21) prohibits a carrier  
3 from applying an appropriate formulary or other clinical management to  
4 any medication described in this subsection (21). For the purposes of this  
5 subsection (21), the treating physician for a patient covered under a health  
6 maintenance organization's health benefit plan shall be a physician who  
7 is designated by and affiliated with the health maintenance organization.

8 **SECTION 2.** In Colorado Revised Statutes, 10-16-104.6, **amend**  
9 (1) introductory portion as follows:

10 **10-16-104.6. Off-label use of cancer drugs.** (1) A health benefit  
11 plan that provides coverage for prescription drugs shall not limit or  
12 exclude coverage for any drug approved by the ~~United States food and~~  
13 ~~drug administration~~ FDA for use in the treatment of cancer on the basis  
14 that the drug has not been approved by the ~~United States food and drug~~  
15 ~~administration~~ FDA for the treatment of the specific type of cancer for  
16 which the drug is prescribed if:

17 **SECTION 3.** In Colorado Revised Statutes, 10-16-112.5, **amend**  
18 (7)(c)(I) as follows:

19 **10-16-112.5. Prior authorization for health-care services -**  
20 **disclosures and notice - determination deadlines - criteria - limits and**  
21 **exceptions - definitions - rules.** (7) **Definitions.** As used in this section:

22 (c) "Medical necessity" means a determination by the carrier that  
23 a prudent provider would provide a particular covered health-care service  
24 to a patient for the purpose of preventing, diagnosing, or treating an  
25 illness, injury, disease, or symptom in a manner that is:

26 (I) In accordance with generally accepted standards of medical  
27 practice and approved by the ~~federal food and drug administration~~ FDA

1 or other required agency;

2 **SECTION 4.** In Colorado Revised Statutes, 10-16-124.7, **amend**  
3 (3)(a) as follows:

4 **10-16-124.7. Opioid analgesics with abuse-deterrent**  
5 **properties - study - definitions.** (3) As used in this section:

6 (a) "Abuse-deterrent opioid analgesic drug product" means a  
7 brand or generic opioid analgesic drug product approved by the ~~United~~  
8 ~~States food and drug administration~~ FDA with abuse-deterrence labeling  
9 claims that indicate that the drug product is expected to result in a  
10 meaningful reduction in abuse.

11 **SECTION 5.** In Colorado Revised Statutes, 10-16-148, **repeal** (2)  
12 as follows:

13 **10-16-148. Medication-assisted treatment - limitations on**  
14 **carriers - rules.** (2) ~~As used in this section, "FDA" means the food and~~  
15 ~~drug administration in the United States department of health and human~~  
16 ~~services.~~

17 **SECTION 6. Act subject to petition - effective date.** This act  
18 takes effect at 12:01 a.m. on the day following the expiration of the  
19 ninety-day period after final adjournment of the general assembly; except  
20 that, if a referendum petition is filed pursuant to section 1 (3) of article V  
21 of the state constitution against this act or an item, section, or part of this  
22 act within such period, then the act, item, section, or part will not take  
23 effect unless approved by the people at the general election to be held in  
24 November 2022 and, in such case, will take effect on the date of the  
25 official declaration of the vote thereon by the governor.