

Second Regular Session  
Seventy-third General Assembly  
STATE OF COLORADO

INTRODUCED

LLS NO. 22-0049.01 Kristen Forrestal x4217

HOUSE BILL 22-1201

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HOUSE SPONSORSHIP

Van Beber, Holtorf, Lynch, Pelton, Pico, Ransom, Rich, Van Winkle, Will

SENATE SPONSORSHIP

(None),

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House Committees  
Business Affairs & Labor

Senate Committees

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A BILL FOR AN ACT

101 CONCERNING STANDARDS FOR IMMUNIZATION REQUIREMENTS.

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>.)*

The bill allows individuals who are required to receive an immunization for any purpose to claim an exemption from the requirement if the:

- Immunization has not been approved by the federal food and drug administration (FDA);
- Immunization has only received emergency use authorization;
- Immunization manufacturer is not liable for injury or death

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.

- caused by the immunization; or
- Pivotal clinical trial the FDA relied on to approve the immunization did not evaluate the immunization's safety, for at least one year after the immunization was first administered, against a control group.

The bill requires the department of public health and environment to post on its website:

- The criteria that must be met for an individual to claim an exemption from an immunization requirement; and
- For each immunization required:
  - The injuries or diseases caused by the immunization and the rate at which each injury or disease occurs; and
  - Whether the risk of permanent disability or death from the required immunization has been proven to be less than the risk of permanent disability or death from the infection or disease the immunization is intended to prevent.

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

2 **SECTION 1.** In Colorado Revised Statutes, **add** part 26 to article  
3 4 of title 25 as follows:

4 **PART 26**

5 **STANDARDS FOR IMMUNIZATION REQUIREMENTS**

6 **25-4-2601. Legislative declaration.** (1) THE GENERAL ASSEMBLY  
7 FINDS AND DECLARES THAT:

8 (a) IN ORDER TO INCREASE PUBLIC CONFIDENCE IN  
9 IMMUNIZATIONS, THE DEPARTMENT SHALL PUBLICIZE THAT EACH  
10 IMMUNIZATION MUST MEET SPECIFIC STANDARDS IN ORDER FOR ANY  
11 ENTITY TO REQUIRE THE IMMUNIZATION FOR ANY PURPOSE; AND

12 (b) AN INDIVIDUAL MAY CLAIM AN EXEMPTION FROM AN  
13 IMMUNIZATION ON BEHALF OF THE INDIVIDUAL OR THE INDIVIDUAL'S  
14 DEPENDENTS IF THE STANDARDS ARE NOT MET.

15 (2) IT IS THE INTENT OF THE GENERAL ASSEMBLY TO SET FORTH

1 MINIMUM STANDARDS THAT ALL REQUIRED IMMUNIZATIONS MUST MEET.

2 **25-4-2602. Definitions.** AS USED IN THIS PART 26, UNLESS THE  
3 CONTEXT OTHERWISE REQUIRES:

4 (1) "DEPARTMENT" MEANS THE DEPARTMENT OF PUBLIC HEALTH  
5 AND ENVIRONMENT.

6 (2) "FDA" MEANS THE FOOD AND DRUG ADMINISTRATION IN THE  
7 UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, OR ANY  
8 SUCCESSOR ENTITY.

9 (3) "PIVOTAL CLINICAL TRIAL" MEANS A HUMAN CLINICAL TRIAL  
10 OF AN IMMUNIZATION THAT IS INTENDED TO:

11 (a) PROVIDE EVIDENCE FOR OBTAINING REGULATORY APPROVAL  
12 FROM THE FDA AFTER THE END OF PHASE II OF THE TRIAL; AND

13 (b) ESTABLISH THE SAFETY AND EFFICACY OF THE IMMUNIZATION  
14 IN PATIENTS.

15 **25-4-2603. Standards for immunization requirements -**  
16 **exemption - department to post information.** (1) NOTWITHSTANDING  
17 ANY OTHER LAW TO THE CONTRARY, AN INDIVIDUAL WHO IS REQUIRED BY  
18 A PERSON TO RECEIVE AN IMMUNIZATION FOR ANY PURPOSE, INCLUDING  
19 AS A CONDITION OF EMPLOYMENT, SCHOOL ATTENDANCE, OR OBTAINING  
20 A LICENSE, CERTIFICATION, REGISTRATION, OR DEGREE, MAY CLAIM AN  
21 EXEMPTION FROM THE IMMUNIZATION REQUIREMENT IF:

22 (a) THE IMMUNIZATION HAS NOT BEEN APPROVED BY THE FDA;

23 (b) THE IMMUNIZATION HAS ONLY RECEIVED EMERGENCY USE  
24 AUTHORIZATION FROM THE FDA;

25 (c) THE MANUFACTURER OF THE IMMUNIZATION IS NOT SUBJECT TO  
26 LIABILITY FOR DEATH OR INJURY CAUSED BY THE IMMUNIZATION; OR

27 (d) THE PIVOTAL CLINICAL TRIAL THE FDA RELIED ON TO APPROVE

1 THE IMMUNIZATION DID NOT EVALUATE THE IMMUNIZATION'S SAFETY, FOR  
2 AT LEAST ONE YEAR AFTER THE IMMUNIZATION WAS FIRST ADMINISTERED,  
3 AGAINST A CONTROL GROUP THAT RECEIVED:

4 (I) A PLACEBO; OR

5 (II) A DIFFERENT IMMUNIZATION AUTHORIZED BY THE FDA, BASED  
6 ON A PIVOTAL CLINICAL TRIAL THAT EVALUATED THE SAFETY OF THE  
7 IMMUNIZATION AGAINST A CONTROL GROUP THAT RECEIVED A PLACEBO.

8 (2) THE DEPARTMENT SHALL POST ON ITS WEBSITE:

9 (a) THAT AN INDIVIDUAL MAY CLAIM AN EXEMPTION FROM AN  
10 IMMUNIZATION REQUIREMENT PURSUANT TO SUBSECTION (1) OF THIS  
11 SECTION;

12 (b) FOR EACH IMMUNIZATION REQUIRED BY THE STATE, AN  
13 AGENCY OR DEPARTMENT OF THE STATE, EXECUTIVE ORDER OF THE  
14 GOVERNOR, OR ANY OTHER ENTITY WITH AUTHORITY TO REQUIRE AN  
15 IMMUNIZATION:

16 (I) THE INJURIES OR DISEASES CAUSED BY THE IMMUNIZATION AND  
17 THE RATE AT WHICH EACH INJURY OR DISEASE OCCURS; AND

18 (II) WHETHER THE RISK OF PERMANENT DISABILITY OR DEATH  
19 FROM THE IMMUNIZATION HAS BEEN PROVEN TO BE LESS THAN THE RISK  
20 OF PERMANENT DISABILITY OR DEATH FROM THE INFECTION OR DISEASE  
21 THAT THE IMMUNIZATION IS INTENDED TO PREVENT.

22 **SECTION 2. Safety clause.** The general assembly hereby finds,  
23 determines, and declares that this act is necessary for the immediate  
24 preservation of the public peace, health, or safety.