

1 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**
2 **STANDARDS FOR HOSPITALS AND HEALTH FACILITIES**
3 **CHAPTER II – GENERAL LICENSURE STANDARDS**
4 **6 CCR 1011-1 Chap 02**
5 **Part 10 – INFLUENZA IMMUNIZATION OF HEALTHCARE WORKERS**

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7 **STATUTORY AUTHORITY AND APPLICABILITY**

8 10.1 THE STATUTORY AUTHORITY FOR THE PROMULGATION OF THESE RULES IS SET FORTH IN
9 SECTIONS 25-1.5-102, 25-1.5-103 AND 25-3-103,C.R.S.

10 10.2 EACH HEALTHCARE ENTITY THAT IS LICENSED BY THE DEPARTMENT SHALL COMPLY WITH THIS
11 PART 10.

12 10.3 THE REQUIREMENTS OF THIS PART 10 SHALL BE OVERSEEN AND ENFORCED BY THE
13 DEPARTMENT IN A MANNER CONSISTENT WITH SECTIONS 2.11 AND 2.12 OF PART 2 OF THIS
14 CHAPTER.

15 **GENERAL PROVISIONS**

16 10.4 HEALTHCARE ENTITIES AND HEALTHCARE WORKERS HAVE A SHARED RESPONSIBILITY TO
17 PREVENT THE SPREAD OF INFECTION AND AVOID CAUSING HARM TO THEIR PATIENTS OR
18 RESIDENTS BY TAKING REASONABLE PRECAUTIONS TO PREVENT THE TRANSMISSION OF
19 VACCINE-PREVENTABLE DISEASES. VACCINE PROGRAMS ARE, THEREFORE, AN ESSENTIAL PART
20 OF INFECTION PREVENTION AND CONTROL FOR SLOWING OR STOPPING THE TRANSMISSION OF
21 SEASONAL INFLUENZA VIRUSES FROM ADVERSELY AFFECTING THOSE INDIVIDUALS WHO ARE
22 MOST SUSCEPTIBLE.

23 **DEFINITIONS**

24 10.5 FOR PURPOSES OF THIS PART 10, THE FOLLOWING DEFINITIONS SHALL APPLY:

25 (A) AMBULATORY SURGICAL CENTER MEANS A FACILITY THAT IS LICENSED AND REGULATED
26 PURSUANT TO 6 CCR 1011-1, CHAPTER XX, AMBULATORY SURGICAL CENTER.

27 (B) "DEPARTMENT" MEANS THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND
28 ENVIRONMENT.

29 (C) "EMPLOYEE" MEANS ANY PERSON WHO PERFORMS A SERVICE FOR WAGES OR OTHER
30 REMUNERATION FOR A LICENSED HEALTHCARE ENTITY. FOR PURPOSES OF THIS PART
31 10, THE DEFINITION OF EMPLOYEE INCLUDES STUDENTS, TRAINEES, PERSONS WHO
32 HAVE INDIVIDUAL CONTRACTS WITH THE HEALTHCARE ENTITY AND PHYSICIANS WITH
33 STAFF PRIVILEGES. THE DEFINITION OF EMPLOYEE DOES NOT INCLUDE VOLUNTEERS OR
34 PERSONS WHO PROVIDE SERVICES THROUGH A CONTRACTUAL ARRANGEMENT

- 1 BETWEEN THE LICENSEE AND A SEPARATE ORGANIZATION, ASSOCIATION OR OTHER
2 HEALTHCARE ENTITY.
- 3 (D) "HEALTHCARE ENTITY" MEANS A HEALTH CARE FACILITY OR AGENCY THAT IS REQUIRED
4 TO OBTAIN A LICENSE FROM THE DEPARTMENT PURSUANT TO SECTION 25-3-101,
5 C.R.S. UNLESS OTHERWISE INDICATED, THE TERM "HEALTHCARE ENTITY" IS
6 SYNONYMOUS WITH THE TERMS "FACILITY" OR "AGENCY" AS USED ELSEWHERE IN 6
7 CCR 1011-1, STANDARDS FOR HOSPITALS AND HEALTH FACILITIES.
- 8 (E) "HEALTHCARE WORKER" MEANS ANY PERSON, PAID OR UNPAID, WORKING IN A
9 HEALTHCARE ENTITY WHO HAS THE POTENTIAL FOR EXPOSURE TO PATIENTS,
10 RESIDENTS, OR CONSUMERS OF THE HEALTHCARE ENTITY AND/OR TO INFECTIOUS
11 MATERIALS, INCLUDING BODY SUBSTANCES, CONTAMINATED MEDICAL SUPPLIES AND
12 EQUIPMENT, CONTAMINATED ENVIRONMENTAL SURFACES, OR CONTAMINATED AIR.
- 13 HEALTHCARE WORKER INCLUDES, BUT IS NOT LIMITED TO, PHYSICIANS, NURSES,
14 NURSING ASSISTANTS, THERAPISTS, TECHNICIANS, EMERGENCY MEDICAL SERVICE
15 PERSONNEL, DENTAL PERSONNEL, PHARMACISTS, LABORATORY PERSONNEL, AUTOPSY
16 PERSONNEL, STUDENTS AND TRAINEES, CONTRACTUAL PERSONNEL, HOME CARE
17 PERSONNEL, AND PERSONS NOT DIRECTLY INVOLVED IN PATIENT CARE (E.G., CLERICAL,
18 DIETARY, HOUSE-KEEPING, LAUNDRY, SECURITY, MAINTENANCE, BILLING AND
19 CHAPLAINS) BUT POTENTIALLY EXPOSED TO INFECTIOUS AGENTS THAT CAN BE
20 TRANSMITTED TO AND FROM THE HEALTHCARE WORKER AND PATIENTS, RESIDENTS OR
21 CONSUMERS OF THE HEALTHCARE ENTITY. THE DEFINITION OF HEALTHCARE WORKER
22 DOES NOT INCLUDE VOLUNTEERS.
- 23 (F) "HOSPITAL" MEANS A FACILITY THAT IS LICENSED AND REGULATED PURSUANT TO 6 CCR
24 1011-1, CHAPTER IV, GENERAL HOSPITALS.
- 25 (G) "HOSPITAL UNIT" MEANS A FACILITY THAT IS LICENSED AND REGULATED PURSUANT TO 6
26 CCR 1011-1, CHAPTER XIX, HOSPITAL UNITS.
- 27 (H) "INFLUENZA SEASON" MEANS NOVEMBER 1 THROUGH MARCH 31 OF THE FOLLOWING
28 YEAR, OR AS OTHERWISE DEFINED BY THE DEPARTMENT EPIDEMIOLOGY AND FLU
29 SURVEILLANCE TEAM.
- 30 (I) "INFLUENZA VACCINE" MEANS A CURRENTLY LICENSED FDA APPROVED VACCINE
31 PRODUCT.
- 32 (J) "LONG TERM CARE FACILITY" MEANS A FACILITY THAT IS LICENSED AND REGULATED
33 PURSUANT TO 6 CCR 1011-1, CHAPTER V, LONG TERM CARE FACILITIES.
- 34 (K) "PROOF OF IMMUNIZATION" MEANS A WRITTEN STATEMENT FROM A LICENSED
35 HEALTHCARE PROVIDER WHO HAS ADMINISTERED AN INFLUENZA VACCINE TO A
36 HEALTHCARE WORKER, SPECIFYING THE VACCINE ADMINISTERED AND THE DATE IT WAS
37 ADMINISTERED OR ELECTRONIC ENTRY IN THE COLORADO IMMUNIZATION INFORMATION
38 SYSTEM (CIIS).
- 39 (L) "VOLUNTEER" MEANS A PERSON WHO PROVIDES SERVICES WITHOUT WAGES OR OTHER
40 REMUNERATION.

1 **EXEMPTION FOR HEALTHCARE ENTITIES MEETING VACCINATION TARGETS**

2 10.6 IF A LICENSED HEALTHCARE ENTITY DEMONSTRATES THAT IT HAS VACCINATED A TARGETED
3 PERCENTAGE OF ITS EMPLOYEES IN A GIVEN YEAR, USING ITS OWN METHODOLOGY, IT SHALL BE
4 EXEMPT FROM THE REQUIREMENTS OF SECTIONS 10.7 THROUGH 10.12 OF THIS PART FOR THE
5 FOLLOWING YEAR AS LONG AS IT CONTINUES TO USE THE SAME OR MORE STRINGENT
6 METHODOLOGY.

7 (A) THE MINIMUM TARGETS REQUIRED FOR THIS EXEMPTION ARE:

- 8 (1) 60 PERCENT OF EMPLOYEES VACCINATED BY DECEMBER 31, 2012;
- 9 (2) 75 PERCENT OF EMPLOYEES VACCINATED BY DECEMBER 31, 2013; AND
- 10 (3) 90 PERCENT OF EMPLOYEES VACCINATED BY DECEMBER 31, 2014; AND BY
11 DECEMBER 31 OF EACH YEAR THEREAFTER.

12 (B) TO TAKE ADVANTAGE OF THIS ANNUAL EXEMPTION, THE LICENSEE SHALL:

- 13 (1) HAVE DEFINED PROCEDURES TO PREVENT THE SPREAD OF INFLUENZA FROM
14 ITS UNVACCINATED HEALTHCARE WORKERS;
- 15 (2) MAINTAIN SUPPORTING DOCUMENTATION FOR A PERIOD OF THREE (3) YEARS
16 THAT MAY BE EXAMINED BY THE DEPARTMENT IN A RANDOM AUDIT PROCESS;
17 AND
- 18 (3) REPORT TO THE DEPARTMENT THAT THE QUALIFYING PERCENTAGE OF ITS
19 EMPLOYEES WAS APPROPRIATELY VACCINATED (ACCORDING TO THE ANNUAL
20 RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION
21 PRACTICES) AGAINST SEASONAL INFLUENZA BY DECEMBER 31ST OF THE YEAR
22 SPECIFIED. THIS REPORT SHALL BE SUBMITTED TO THE DEPARTMENT, IN THE
23 FORM AND MANNER SPECIFIED, NO LATER THAN MARCH 31ST OF THE
24 FOLLOWING YEAR.

25 **REQUIREMENTS FOR HOSPITALS, HOSPITAL UNITS, AMBULATORY SURGICAL CENTERS AND LONG-**
26 **TERM CARE FACILITIES**

27 10.7 EACH LICENSED HOSPITAL, HOSPITAL UNIT, AMBULATORY SURGICAL CENTER AND LONG-TERM
28 CARE FACILITY SHALL PROVIDE OR MAKE AVAILABLE AN ANNUAL INFLUENZA VACCINE FOR EACH
29 OF ITS HEALTHCARE WORKERS WHEN THE INFLUENZA VACCINE IS READILY AVAILABLE.

30 10.8 EACH LICENSED HOSPITAL, HOSPITAL UNIT, AMBULATORY SURGICAL CENTER AND LONG-TERM
31 CARE FACILITY SHALL HAVE A WRITTEN POLICY REGARDING THE ANNUAL INFLUENZA
32 IMMUNIZATION OF ITS HEALTHCARE WORKERS THAT, AT A MINIMUM, ADDRESSES THE FOLLOWING
33 CRITERIA:

34 (A) ENSURING THAT EACH OF ITS HEALTHCARE WORKERS HAS EITHER:

- 35 (1) PROOF OF IMMUNIZATION, OR

- 1 (2) A MEDICAL EXEMPTION SIGNED BY A PHYSICIAN, PHYSICIAN'S ASSISTANT,
2 ADVANCED PRACTICE NURSE OR NURSE MIDWIFE LICENSED IN THE STATE OF
3 COLORADO STATING THAT THE INFLUENZA VACCINATION FOR THAT INDIVIDUAL
4 IS MEDICALLY CONTRAINDICATED AS DESCRIBED IN THE PRODUCT LABELING
5 APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.
- 6 (B) ENSURING THAT EACH HEALTHCARE WORKER WHO DOES NOT HAVE PROOF OF
7 IMMUNIZATION WEARS A SURGICAL OR PROCEDURE MASK DURING INFLUENZA SEASON
8 WHEN IN DIRECT CONTACT WITH PATIENTS AND IN COMMON AREAS AS SPECIFIED BY THE
9 LICENSEE'S POLICY. SUCH MASKS SHALL BE IN ADDITION TO OTHER STANDARD
10 PERSONAL PROTECTIVE EQUIPMENT.
- 11 (C) ENSURING IT HAS ESTABLISHED A PROCEDURE TO:
- 12 (1) MAINTAIN PROOF OF ANNUAL IMMUNIZATION OR MEDICAL EXEMPTION FOR
13 EACH EMPLOYEE; AND
- 14 (2) INFORM OTHER HEALTHCARE WORKERS WHO PROVIDE SERVICES ON THE
15 LICENSEE'S PREMISES THAT:
- 16 (a) THE LICENSEE HAS A POLICY REGARDING THE ANNUAL INFLUENZA
17 IMMUNIZATION OF ITS HEALTHCARE WORKERS;
- 18 (b) THE LICENSEE REQUIRES EACH HEALTHCARE WORKER WHO HAS NOT
19 BEEN IMMUNIZED TO WEAR A MASK DURING INFLUENZA SEASON WHEN
20 IN DIRECT CONTACT WITH PATIENTS OR IN COMMON AREAS SPECIFIED
21 BY THE FACILITY; AND
- 22 (c) THE LICENSEE HAS MASKS AVAILABLE FOR THOSE HEALTHCARE
23 WORKERS WHO HAVE NOT BEEN IMMUNIZED.
- 24 10.9 EACH LICENSED HOSPITAL, HOSPITAL UNIT, AMBULATORY SURGICAL CENTER AND LONG- TERM
25 CARE FACILITY SHALL TRACK AND REPORT THE ANNUAL INFLUENZA VACCINATION RATE FOR ITS
26 EMPLOYEES THROUGH DECEMBER 31ST OF EACH YEAR. THIS REPORT SHALL BE SUBMITTED TO
27 THE DEPARTMENT, IN THE FORM AND MANNER SPECIFIED, NO LATER THAN MARCH 31ST OF THE
28 FOLLOWING YEAR.

29 **REQUIREMENTS FOR ALL OTHER LICENSED HEALTHCARE ENTITIES**

- 30 10.10 EACH LICENSED HEALTHCARE ENTITY, OTHER THAN THOSE IDENTIFIED IN SECTIONS 10.7
31 THROUGH 10.9, SHALL PERFORM AN INITIAL ASSESSMENT OF THEIR FACILITY OR AGENCY TO
32 ASSIST IN THE DEVELOPMENT OF A WRITTEN POLICY REGARDING INFLUENZA TRANSMISSION
33 FROM ITS HEALTHCARE WORKERS TO ITS PATIENTS, RESIDENTS OR CONSUMERS. THE
34 ASSESSMENT SHALL, AT A MINIMUM, CONSIDER THE FOLLOWING CRITERIA:
- 35 (A) THE NUMBER OF HEALTHCARE WORKERS AT THE HEALTHCARE ENTITY;
- 36 (B) THE NUMBER OF PATIENTS, RESIDENTS OR CONSUMERS SERVED BY THE HEALTHCARE
37 ENTITY;

- 1 (C) WHETHER THE HEALTHCARE ENTITY HAS AN ONGOING EMPLOYEE WELLNESS PROGRAM
2 THAT OFFERS ANNUAL INFLUENZA VACCINATIONS;
- 3 (D) WHETHER INFLUENZA TRANSMISSION FROM HEALTHCARE WORKERS IS ADDRESSED IN
4 THE HEALTHCARE ENTITY'S INFECTION CONTROL POLICY;
- 5 (E) WHAT PRECAUTIONS ARE TAKEN TO PREVENT THE TRANSMISSION OF INFLUENZA FROM
6 UNVACCINATED HEALTHCARE WORKERS; AND
- 7 (F) WHAT TYPE OF EDUCATIONAL MATERIAL IS UTILIZED BY THE HEALTHCARE ENTITY TO
8 PROMOTE INFLUENZA IMMUNIZATION FOR ITS HEALTHCARE WORKERS.
- 9 10.11 EACH LICENSED HEALTHCARE ENTITY, OTHER THAN THOSE IDENTIFIED IN SECTIONS 10.7
10 THROUGH 10.9, SHALL HAVE A WRITTEN POLICY REGARDING THE ANNUAL INFLUENZA
11 IMMUNIZATION OF ITS HEALTHCARE WORKERS THAT IS BASED ON THAT LICENSEE'S ATTRIBUTES
12 AND RESOURCES. THE POLICY SHALL, AT A MINIMUM, ADDRESS THE FOLLOWING CRITERIA:
- 13 (A) ENSURING THAT EACH EMPLOYEE IS OFFERED THE OPPORTUNITY TO RECEIVE AN
14 ANNUAL INFLUENZA IMMUNIZATION;
- 15 (B) MAINTAINING RECORDS OF EACH EMPLOYEE'S ANNUAL IMMUNIZATION, DECLINATION OR
16 EXEMPTION FROM IMMUNIZATION; AND
- 17 (C) ENSURING THAT ALL OF THE LICENSEE'S EMPLOYEES ARE PROVIDED INFORMATION
18 REGARDING:
- 19 (1) THE BENEFITS AND RISKS OF INFLUENZA IMMUNIZATION;
- 20 (2) THE AVAILABILITY OF INFLUENZA IMMUNIZATION; AND
- 21 (3) THE IMPORTANCE OF ADHERING TO STANDARD PRECAUTIONS.
- 22 10.12 EACH LICENSED HEALTH CARE ENTITY, OTHER THAN THOSE IDENTIFIED IN SECTIONS 10.7
23 THROUGH 10.9, SHALL TRACK AND REPORT THE ANNUAL INFLUENZA VACCINATION RATE FOR ITS
24 EMPLOYEES THROUGH DECEMBER 31ST OF EACH YEAR. THIS REPORT SHALL BE SUBMITTED TO
25 THE DEPARTMENT, IN THE FORM AND MANNER SPECIFIED, NO LATER THAN MARCH 31ST OF THE
26 FOLLOWING YEAR.