

**STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY FOR**

Amendments to Rules Pertaining to the Standards for Hospitals and Health Facilities
6 CCR 1011-1
Chapter II, General Licensure Standards
December 16, 2011

Basis and Purpose:

As the title indicates, Chapter II contains standards that pertain to all licensed health facilities. The proposed rule consists of a new part that requires all licensed healthcare entities to establish and maintain a policy regarding the annual influenza immunization of its healthcare workers.²

Influenza is a contagious respiratory disease that can cause mild to severe illness and may be fatal, particularly in high-risk groups such as the elderly, young children, immune-suppressed persons and persons with chronic illnesses. The Centers for Disease Control and Prevention (CDC) estimates that influenza causes more than 200,000 hospitalizations and 3,000 to 49,000 deaths annually in the U.S.

In healthcare settings, influenza can be transmitted from healthcare personnel to patients or residents. The CDC has recommended annual influenza vaccination for healthcare workers (HCWs) with direct patient contact since 1984 and for all HCWs since 1993 because it reduces the chance that HCWs serve as vectors for healthcare-associated influenza due to their close contact with high-risk patients and enhances both healthcare personnel and patient safety. Influenza vaccination of HCWs is particularly important since adults shed the infectious influenza virus at least one day *before* they experience any symptoms. Although approximately 50 percent of healthy adults who have influenza may not experience any symptoms themselves, they are still contagious and continue to spread the virus for up to 10 days.¹

The Centers for Medicare and Medicaid Services (CMS) requires certified long term care facilities to offer seasonal influenza immunization annually to its residents. However, because older people with weaker immune systems often have a lower protective immune response to the influenza vaccine; CMS recommends that all healthcare personnel should be vaccinated against influenza annually. The importance of offering the influenza vaccine to healthcare workers as well as long term care residents has been documented by a study conducted in partnership with the New Mexico Department of Health and featured in a recent issue of *Infection Control and Hospital Epidemiology*.²

At least a dozen national healthcare associations and the United States Department of Defense have policies supporting mandatory influenza vaccination of HCWs. The American Medical Directors Association, dedicated to long-term care medicine, supports a mandatory annual influenza vaccination for every long term care HCW. The Society for Healthcare Epidemiology of America (SHEA) and the

¹ Influenza Vaccination of Health-Care Personnel, Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP) *MMWR* 55, pp.1-16 (2006). http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm?s_cid=rr5502a1_e%A0

² The Importance of Employee Vaccination against Influenza in Preventing Cases in Long-Term Care Facilities, *Infection Control and Hospital Epidemiology*, Vol. 32, October 2011, pp. 990-997. <http://www.jstor.org/stable/10.1086/661916>

American Academy of Pediatrics (AAP) recommend mandatory vaccination of all healthcare personnel working in all healthcare settings, regardless of whether they come into contact with patients and whether they are directly employed by the facility. The recommendation extends to students, volunteers, and contract workers. The Association for Professionals in Infection Control and Epidemiology, Inc. (APIC) recommends that acute care hospitals, long term care, and other facilities that employ healthcare personnel require annual influenza immunization as a condition of employment unless there are compelling medical contraindications. In addition, the Joint Commission on Accreditation of Healthcare Organizations has issued a standard requiring critical access hospitals, hospitals and long-term care facilities to offer influenza vaccine to staff and licensed independent practitioners. Despite these policies and recommendations, voluntary immunization programs have failed to significantly increase HCW vaccination rates.

Recognizing the insufficiency of voluntary immunization programs, the Colorado Hospital Association endorsed a resolution in May 2011 recommending that all Colorado hospitals and health systems require all healthcare personnel to be annually vaccinated against influenza unless they have a medical contraindication, in which case they should be masked while on healthcare premises. CMS has also recognized the importance of HCW immunization and adopted new rules that will require certified hospitals and ambulatory surgical centers (ASCs) to annually report certain details about the influenza vaccination of their healthcare workers. CMS will use the data regarding a facility's HCW vaccination coverage from October 2013 through March 2014 as part of its payment determination for cost year 2015. The Department's proposed rules will become effective in September 2012, and will therefore assist hospitals and ASCs in ramping up to meet the CMS reporting criteria.

Fifteen other states require some or all of its licensed healthcare facilities to have policies or procedures regarding influenza immunization of their healthcare workers. Alabama requires each hospital to establish vaccination requirements for employees that are consistent with the current recommendations of the Centers for Diseases Control and Prevention and the Occupational Safety and Health Administration that, at a minimum, require annual influenza vaccinations. Massachusetts requires seasonal influenza vaccinations for all hospital, clinic and long-term care personnel along with annual reporting of those vaccination rates to the Massachusetts Department of Health.

The Department has determined that the preventing the spread of seasonal influenza from HCWs to healthcare patients, residents and consumers is an important public health issue that has not been adequately addressed through voluntary programs. Therefore, the proposed rule will require all acute care and long-term nursing care facilities to annually vaccinate personnel against influenza. All other licensed healthcare entities must assess their own clients, staff and services and develop a written policy regarding influenza vaccination of its HCWs. All licensed healthcare entities will be required to annually report their influenza vaccination rates to the Department. The Department will continue working with stakeholders regarding the reporting process to ensure that it will align as seamlessly as possible with any federal reporting requirements and not be administratively burdensome.

These rules are promulgated pursuant to the following statutes:

Section 25-1.5-103, C.R.S. (2011).

Section 25-3-101, *et seq.*, C.R.S. (2011).

Section 25-27-101, *et seq.*, C.R.S. (2011).

Section 25-27.5-101, *et seq.*, C.R.S. (2011).

Major Factual and Policy Issues Encountered:

There were four major factual and policy issues encountered:

1. Whether to have the regulation apply to all licensed healthcare entities or just select ones. This issue was resolved by crafting different requirements for different types of healthcare entities.
2. Whether the administrative and financial burden on facilities to provide the annual influenza vaccination (or masks) for its workers outweighed the health benefit to the patients, residents and other healthcare consumers. The scientific studies and policy statements of the various professional organizations on this point weigh heavily in favor of the public health benefit.
3. Whether to allow healthcare workers in acute and long-term care facilities to decline the vaccine for any reason, or to require that an exemption from vaccination only be allowed for religious and/or medical reasons. Because no conventional religion has forbidden influenza immunization as contrary to its beliefs and the American Medical Association opposes religious exemptions on the grounds that they endanger health not only for the unvaccinated individual but also for neighbors and the community at large;³ the proposed rule recognizes only medical exemptions. The right of a state to limit exemption from mandatory vaccination to medical reasons only has been litigated and upheld by the U.S. Court of Appeals.⁴
4. Whether to narrow the definition of healthcare worker for tracking and reporting purposes so that it was not overly burdensome for the licensed healthcare entities. This was accomplished by defining “employee” and “volunteer” and “healthcare worker” and specifying that the tracking and reporting requirements apply only to employees and volunteers.

The group of healthcare professionals and stakeholders that composed the workgroup assembled to address these issues ultimately determined that the Department should adopt a two-prong approach that would take into consideration the diversity of the healthcare facilities we license. Therefore, the regulation requires that facilities providing acute or long-term nursing care should ensure that its healthcare workers receive an annual influenza vaccination or wear a mask when in direct contact with patients during flu season. For all other healthcare facilities, the regulations require that each facility perform an assessment of their particular circumstances and adopt a written policy regarding influenza vaccination of its healthcare workers.

Alternative rules considered:

In developing these rules, the Department considered many different possibilities for halting the transmission of the seasonal influenza virus from healthcare workers to healthcare patients, residents and consumers. The Department has been working with stakeholders on this project since March of 2011. More than a dozen different versions of this rule were considered before arriving at the version presented here.

³ ["Health and Ethics Policies of the AMA House of Delegates"](#) pp. 460–461. American Medical Association (2009).

⁴ [Workman v. Mingo County Bd. of Education](#), 419 Fed. Appx. 348(4th Cir. 2011), *cert. denied*, 80 USLW 3221(Nov. 14, 2011).