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# State law and influenza vaccination of health care personnel

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#### ABSTRACT

Nosocomial influenza outbreaks, attributed to the unvaccinated health care workforce, have contributed to patient complications or death, worker illness and absenteeism, and increased economic costs to the health care system. Since 1981, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) has recommended that all HCP receive an annual influenza vaccination.

Health care employers (HCE) have adopted various strategies to encourage health care personnel (HCP) to voluntarily receive influenza vaccination, including: sponsoring educational and promotional campaigns, increasing access to seasonal influenza vaccine, permitting the use of declination statements, and combining multiple approaches. However, these measures failed to significantly increase uptake among HCP. As a result, beginning in 2004, health care facilities and local health departments began to require certain HCP to receive influenza vaccination as a condition of employment and annually. Today, hundreds of facilities throughout the country have developed and implemented similar policies. Mandatory vaccination programs have been endorsed by professional and non-profit organizations, state health departments, and public health. These programs have been more effective at increasing coverage rates than any voluntary strategy, with some health systems reporting coverage rates up to 99.3%.

Several states have enacted laws requiring HCEs to implement vaccination programs for the workforce. These laws present an example of how states will respond to threats to the public's health and constrain personal choice in order to protect vulnerable populations.

This study analyzes laws in twenty states that address influenza vaccination requirements for HCP who practice in acute or long-term care facilities in the United States. The laws vary in the extent to which they incorporate the six elements of a mandatory HCP influenza vaccination program. Four of the twenty states have adopted a broad definition of HCP or HCE. While 16/20 of the laws require employers to "provide," "arrange for," "ensure," "require" or "offer" influenza vaccinations to HCP, only four states explicitly require HCEs to cover the cost of vaccination. Fifteen of the twenty laws allow HCP to decline the vaccination due to medical contraindication, religious or philosophical beliefs, or by signing a declination statement. Finally, three states address how to sanction noncompliant HCPs. The analysis also discusses the development of a model legal policy that legislators could use as they draft and revise influenza prevention guidelines in health care settings.

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Beginning in 1981, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommends all health care personnel (HCP) receive an annual influenza vaccination [1]. ACIP recommendations create the national standard of care for immunization practice. The 2011 recommendations [2] are reflected in the Healthy People 2020 objectives that set a goal of 90% coverage for this population [3] and guidance issued by the National Vaccine Program Office (NVPO), US Department of Health and Human Services (HHS) [4].

However, vaccination rates among HCP remain lower than national goals [5–7]. Between 2004 and 2008, approximately 40% of all HCP received the vaccine [8–11]. During the 2011–12 influenza season, uptake increased to approximately 66.9% [12]. Physicians and nurses (77.9%) reported the highest coverage levels [12]. Fiftytwo percent of long-term care facility staff were vaccinated.

Unvaccinated HCP contribute to nosocomial influenza outbreaks in health care settings. These outbreaks result in increased patient morbidity and mortality, worker illness and absenteeism, and increased economic costs to the health care system [13,14]. While research indicates that outbreaks are under-detected and under-reported [15–17], they have been documented across the United States and abroad.

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Eleven to 59% of exposed workers can be affected [18,19], but continue to work [20], transmitting infection to 3–50% of exposed patients [5,21–24]. Median patient mortality can range from 16% in a general ward setting to 33–60% in a transplant setting [18,19]. For example, an outbreak in February 2011 in a neonatal intensive care unit was attributed to low vaccination among the staff [25]. Sixty-three percent of medical staff, 15% of nurses, and 50% of auxiliary staff had been vaccinated [25]. Three patients became ill when 8 of 33 nurses developed symptoms [25].

#### 1. Methods

The purpose of our project was to determine the extent to which legislators will use state power to implement public health recommendations in the context of mandatory vaccination. We analyzed state laws that address influenza vaccination requirements for HCP who practice in acute or long-term care facilities in the United States

We identified the most effective strategies that health care facilities have implemented to increase uptake of influenza vaccine among HCP. The strategies were consolidated into six essential elements of a comprehensive mandatory vaccination program (Table 1). Using a standard legal database, we identified 20 state laws/regulations that address influenza vaccination of HCP. The statutory duties were identified, charted, and reviewed against the six elements.

**Table 1**Six Elements of a Comprehensive Influenza Vaccination Program for HCP.

Element	Description								
Broad definition of affected HCP	All persons, paid or unpaid, including but not limited to employees, staff, contractors, clinicians, emergency medical technicians, ambulance drivers, volunteers, students, trainees, clergy, home health care providers, dietary and housekeeping staff, and others whose occupational activities involve direct or indirect contact with patients or contaminated material in a health care, home health care, or clinical laboratory setting.								
Expansive definition of the affected HCE	"Employer" means a person or entity that has control over the wages, hours and working conditions of Health Care Personnel in settings that include, but are not limited to acute care hospitals, adult day programs or facilities, ambulatory surgical facilities, child day care facilities, correctional facilities, home health care agencies, hospices, intermediate care facilities, long-term care facilities, nursing homes, outpatient clinics, physicians' offices, rehabilitation centers, residential health care facilities, skilled nursing facilities, urgent care centers, dialysis centers, and occupational health centers.								
HCE obligations	(1) Providing the influenza vaccine to HCP, (2) choosing appropriate timing for administration, (3) providing education regarding influenza vaccine, (4) providing the influenza vaccine at no cost to HCP, (5) documentation requirements, (6) reporting requirements, (7) managing non-compliance.								
Exemption policy	<ul><li>(1) Medical contraindication, (2) religious belief,</li><li>(3) philosophical belief, (4) declination statement.</li></ul>								
HCP obligations	(1) Receiving the vaccination, (2) choosing site of administration, (3) Providing appropriate documentation.								
Evidence-based standard of care	Latest recommendations of the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).								

We drafted the *Uniform Act on Influenza Vaccination of Health Care Workers*, a model law incorporating the six elements [26]. The provisions serve as an accessible reference that policy makers could use as they draft new and modify existing policies to improve influenza vaccine uptake in health care settings.

#### 2. Results

### 2.1. Analysis of state laws

Twenty of 51 (20/51) states have enacted laws requiring certain health care employers (HCEs) to develop and implement influenza vaccination programs for identified categories of HCP [26]. We categorize the District of Columbia as a state (Table 2).

## 2.2. Defining affected health care personnel

States have adopted three approaches when identifying the HCP who will be required to comply with the policy (Table 2). Most states (16/20) include all facility employees and/or those who have occupational exposure in a public health setting (AL, AR, CA, DC, KY, ME, MD, NH, NY, NC, OK, PA, RI, TX, UT, VA). Four states incorporate a wide range of personnel categories (IL, MA, SC, TN). Six states include unpaid, student, volunteer, or other workers (DC, IL, MD, MA, RI, SC). For example, Illinois identifies other categories of workers, including technicians, therapists, emergency medical services staff, clerical, dietary, and housekeeping.

### 2.3. Defining the affected employer

Five of 20 states regulate both residential care facilities and acute care hospitals (IL, ME, MD, NH, RI) (Table 2). These states include a wide range of facilities including ambulatory surgical treatment centers, assisted, community living, and life care facilities, long-term care freestanding emergency centers, home health, services, or nursing agencies, hospice care programs and hospitals. Half of the 20 states under review regulate only long-term care or nursing facilities, or home health agencies (AL, AR, CA, IL, NY, NC, PA, SC, TN, TX).

# 2.4. Defining employer obligations

Sixteen of the 20 existing laws require employers to "provide," "arrange for," "ensure," "require," or "offer" influenza vaccinations to HCP (AL, AR, CA, DC, IL, KY, ME, MD, MA, NH, NY, NC, OK, PA, RI, TN) (Table 2). In 10 of the 16 states, HCEs must "provide" or "offer" the vaccine to HCP (AL, CA, IL, MD, ME, NC, NH, NY, OK, TN).

Four states explicitly require employers to cover the cost of the vaccination (CA, MA, OK, RI) (Table 2). However, these states fail to address how an employer should manage the cost of vaccine purchase, administration, and record keeping requirements.

Two states protect HCEs from absorbing the cost of the HCP vaccination program (KY, UT) (Table 2). In Utah, the individual HCP is expected to obtain the vaccination either through their personal health plan, or to purchase the vaccination out-of-pocket. In Kentucky, HCEs may charge a third party or the employee for the cost of vaccine and its administration.

Four states indicate that HCP may obtain the vaccine from a source other than the employer (DC, ME, OK, PA) (Table 2). For example, under Oklahoma's law, HCP must demonstrate that they have received the vaccine from another provider.

Sixteen states require HCEs to maintain up-to-date records describing the vaccination status of each HCP (AL, AR, CA, DC, IL, KY, ME, MD, MA, NY, NC, OK, PA, RI, SC, UT). However, 6 of 20 states require HCEs to report vaccination status to a designated public health agency (AR, CA, MA, ME, NH, RI).

 Table 2

 How state laws address the elements of comprehensive influenza vaccination program for HCP.

	SIX ELEMENTS OF MANDATORY HCP INFLUENZA VACCINATION POLICY																		
	AFFECTED HCP	AFFECTED HCE		HCE OBLIGATIONS						EXEMPTIONS				HCP OBLIGATIONS			STANDARD		
STATE		LTC, Nursing, & Home Health	Acute Care Hospital	Vaccine Provision	Timing of Administration	Education	Cost	Documentation	Reporting	Non-Compliance	Medical	Religious	Philosophical	Declinations	Choice of site administration	Receive vaccination	Documentation	CDC/ACIP	Other
AL	•	٠		٠	•	•		•			٠	•		•				٠	•
AK	•	•		•				•	•	•	•	•		•		•			
CA	•		•	•			•	•						•		•	•	•	
DC	•	•		•	•			•						•	•	•	•	•	
IL	•	•	•	•	•	•		•			•	•		•			•		
KY	•	•		•	•	•	•	•						•	9			•	
ME	•	•	•	•				•		•	•	•	•		•	•	•		
MD	•	•	•	•	•	•		•			•	•		•				•	
MA	•		•	•	•	•	•	•	•		•	•		•			•		•
NH	•	•	•	•	•						•	•	•				•	•	
NY	•	•		•	•	•		•			•	•		•		•	•	•	
NC	•	•		٠	•			•			•	•		•		•	•		•
ок	•		•	•		•	•	•			•			•	•	•	•	•	
PA	•	•		•				•			•	•		•	•	•	•	•	
RI	-	٠	•		•	•	•	•	•	•	٠	•		•		•	•	٠	
sc	•	٠			•			•			٠			•		•			
TN			•	٠		٠					٠			•			•		
TX	•	٠														•			•
UT	•	٠		٠			•	•			٠			•		•			
VA	•		•																
TOTAL	20/20	15/20	10/20	16/20	11/20	9/20	6/20	16/20	3/20	3/20	15/20	11/20 LAW, F	2/20	16/20	4/20	12/20	12/20	10/20	4/20

Source: GWU/SPHHS, DEVELOPING A MODEL STATE LAW, FALL 2012

Only three states outline how HCEs should address non-compliant HCP (AR, ME, RI). In Arkansas, the Office of Long-Term Care will enforce the law and sanction *employers* that fail to comply with the vaccination requirements. Maine allows public health officials to exclude an HCP if it is determined that the worker poses a "clear danger to the health of others." In these instances, the employer is not required to continue to pay an excluded worker, unless "otherwise provided for by law, contract, or collective bargaining agreement [27]." Further, when public health officials determine the existence of a public health threat, HCP who were granted an exemption may be immunized or tested for serological evidence of immunity. Individuals without immunity "*must* be excluded from the work site during one incubation period [27]."

Rhode Island requires HCP who are exempt from the vaccination requirement to wear a surgical face mask when the Department of Health declares influenza is widespread and when the HCP is engaged in direct contact with patients. HCP who refuse to comply are subject to a \$100 fine for each act. The HCP may be disciplined by the licensing board for unprofessional conduct.

# 2.5. Exemption policy

Fifteen of the 20 state laws include exemption possibilities (AL, AR, IL, ME, MD, MA, NH, NY, NC, OK, PA, RI, SC, TN, UT). All fifteen states allow exemptions based on medical contraindication

while 14/20 states permit HCP to submit a completed declination statement that indicates receipt of education related to the vaccine (AL, AR, CA, IL, MD, MA, NY, NC, OK, PA, RI, SC, TN, UT). Less frequently, HCP are permitted to claim exemptions due to religious or philosophical belief. Eleven states recognize religious exemptions (AL, AR, IL, ME, MD, MA, NH, NY, NC, PA, RI). Two states accept philosophical exemptions (ME, NH).

#### 2.6. Standard of care

Thirteen of the 20 states identify the standard under which the policy will operate (AL, CA, DC, KY, MD, MA, NH, NY, NC, OK, PA, RI, TX). Ten of the 13 states have adopted the ACIP recommendations (AL, CA, DC, KY, MD, NH, NY, OK, PA, RI). Alabama references the Federal Occupational Safety and Health Administration (OSHA) while Massachusetts and North Carolina comply with directives issued by the Commissioner of Public Health. Texas refers to guidelines consistent with the Texas Board of Human Services.

# 3. Discussion

# 3.1. Employer-based vaccination policies

Health care employers have adopted various strategies to encourage HCP to voluntarily receive influenza vaccination [28–32]. However, these measures have failed to achieve 90% coverage levels. As a result, beginning in 2004, medical care facilities and local health departments began to require designated HCP to receive influenza vaccination as a condition of employment [41].

Today, hundreds of facilities throughout the country have developed and implemented similar policies [33]. Mandatory vaccination programs have been endorsed by professional and non-profit, state health, and public health entities. These programs have been more effective at increasing coverage levels than any voluntary strategy, with some health systems reporting coverage levels up to 99.3% [34–38].

Employer-based mandatory vaccination policies must address operational barriers before all HCP are vaccinated. First, facility administrators in approximately 600,000 health care establishments across the United States would be required to simultaneously develop identical programs [39]. Without this unified approach, reliable uptake of the vaccine will be confined to HCP who are associated with the comparatively few facilities that have established programs.

Variability in program design is another limitation associated with employer-based vaccination policies. While HCEs develop programs with consistent goals, each program's requirements may be different, creating further barriers to uptake. For example, program rules related to exemption policies, sanctions, and the categories of HCP governed may be too limited to promote 90% uptake, creating the opportunity for gaps in coverage.

Finally, under current interpretations of labor law, HCEs have been prohibited from applying HCP vaccination requirements to workers who are represented by unions. Unions have successfully claimed that it is an unfair labor practice for HCEs to develop and implement mandatory influenza vaccination programs. They argue that management must negotiate any change in working conditions with the union [40]. As a result, HCEs that wish to institute mandatory programs are subject to the usual collective bargaining process [40].

Because the Board's rulings do not apply to non-union workers, those HCEs that wish to establish mandatory programs may be required to negotiate and manage different standards for union workers. In these instances, optimal coverage rates may not be achieved.

# 3.2. State-based vaccination policies

State-based vaccination requirements are the more efficient method to increase vaccine uptake among all HCP when compared to employer-based requirements. The twenty state laws that address influenza vaccination for HCP reflect how each state incorporates vaccination of the health care workforce as part of a comprehensive infection control program in different settings.

These laws create a uniform policy applicable to all HCEs and HCP authorized to practice in the state. Statewide policies also mitigate the need for individual facilities to expend limited resources to develop, implement, and defend management decisions related to mandatory programs.

States may require vaccination of HCP using the "police powers" granted by the US Constitution's Tenth Amendment. State governments use police powers to authorize public health departments and other administrative authorities to enact a broad array of legislative, regulatory, and administrative measures in order to protect the public's health. For example, states regulate medical and health professionals to ensure that the public is protected against unsafe medical care.

Some HCP have argued that government-sponsored mandatory vaccination is unconstitutional and violates their civil rights. They claim that requiring HCP to receive a vaccine infringes on their right to practice religion, enter into contracts, and is an invasion

of privacy and compromises bodily autonomy. They maintain that health care decisions are personal and should not be controlled by their employers or the state [41].

However, the US Supreme Court has consistently supported mandatory vaccination as an appropriate intervention designed to protect the public health and safety. The Court has affirmed that states may require individuals to receive a vaccination [42,43]. Additionally, the right of an individual to enter into contracts for economic gain may be limited to protect the public's health [44,45]. Religious exemptions to vaccination requirements are not constitutionally required [46]. Finally, individual autonomy can be restricted when the interests of the public outweigh any inconvenience to, or intrusion on an individual's freedom [47].

#### 3.3. Model law

The proposed model law provides a blueprint for legislators in states that choose to revise current or draft new laws. The model incorporate all activities that have proven successful to achieve national vaccination goals in health care facilities and addresses obstacles to influenza vaccine acceptance that HCP have frequently cited. These concerns include safety, effectiveness, and necessity of the vaccine. Other barriers include the inability to be vaccinated during working hours, on the worksite, or the requirement to remain responsible for the cost of the vaccination [48,49]. If states adopt the proposed model, comprehensive immunization programs would be available statewide.

The model incorporates all categories of staff who may have direct or indirect contact with a patient, including volunteers, students, administrative, security, housekeeping, and food service personnel. These HCP work in a broad range of settings cited in the model. The wide scope of setting and personnel definitions ensure that an HCP is not excluded from immunization requirements.

Health care employers must require HCP to receive the vaccination as a precondition of employment and annually thereafter. Employers must also notify HCP of the vaccination requirement, conduct educational programs to increase knowledge among HCP about influenza vaccination, respond to concerns regarding vaccine safety and efficacy, and educate facility management about common reasons HCP refuse influenza vaccination.

Further, HCEs must either provide or arrange for the vaccination at the worksite and at no cost to the HCP. The HCP has the option to receive the vaccination from the provider of his or her choice. Other duties outlined in the proposed model require the HCE to document HCP vaccination status and report HCP vaccination status to designated public health officials.

The mandatory vaccination program requires that vaccines are administered according to standards developed by the CDC's ACIP. As the only entity in the federal government that develops recommendations regarding the safe and effective use of vaccines in the civilian population, HCP may be confident that the vaccination policy is based on the most current evidence-based guidelines available. Adoption of the ACIP standard eliminates the need to revise the requirement should administration guidelines change.

While a large portion of the model law outlines the responsibilities of employers, HCP also share responsibility for complying with the requirement. Designing a process that HCP must follow creates clear expectations regarding required performance and reduces the likelihood that HCP will remain unvaccinated. HCEs may also remain unaware of workforces' vaccination statuses.

HCP are required to receive the vaccination annually and submit a completed, signed "Certificate of Immunization" to the HCE by an identified date or comply with exemptions. Any HCP is authorized to receive the vaccination either at the workplace or at an alternate location chosen by the HCP. Without clarity regarding provider choice, HCP may be discouraged from seeking the vaccine.

Exemption policies are one of the most frequently debated components of a mandatory vaccination program. The most effective law would permit HCP to refuse vaccination only if a medical contraindication is documented by a licensed health care provider. However, state legislators could experience opposition from some HCP. The model law includes provisions for five exemption opportunities for legislators to choose when drafting their policy, based on: medical contraindication, religious belief, philosophical belief, declination statement, or vaccine shortage.

Permitting multiple opportunities to refuse the vaccination may diminish the impact of a mandatory policy. However, the availability of exemptions is an established practice, as demonstrated by state school entry immunization requirements. Despite the availability of exemptions, school entry requirements remain the driving force for optimal vaccination rates among school children [50].

Finally, HCEs will determine how to manage those HCP who do not comply with the policy. Clearly defined sanctions strengthen the effectiveness of the vaccination requirement and permit employers to adequately enforce the policy. The model law supports maximum employer flexibility to develop the enforcement policy that is best suited to their circumstances. Sanctions could range from suspending the HCP without pay until he or she is in compliance with the requirement, up to and including, termination.

# 4. Conclusion

The consequences of influenza outbreaks in health care settings have received increased attention from state and federal policy makers, HCEs, patient advocates, and the health workforce. Yet, vaccination rates have not met public health goals. The evidence shows that state-level mandatory influenza vaccination policies are the most reliable and effective method to ensure optimal coverage rates among HCP.

While state policy makers in nearly half of the United States have demonstrated their willingness to enact influenza vaccination laws for certain HCP in some settings, the laws vary in the extent to which they incorporate the six elements of a comprehensive program. Mandatory vaccination policies must be carefully calibrated to properly balance the risks and benefits of influenza vaccination on workers *and* patients. These differences could contribute to gaps in coverage rates and allow HCP to remain unvaccinated.

To correct these deficits, laws should be enacted that: (1) require every HCE operating in the state to participate in mandatory immunization, (2) identify strategies to assist HCE purchase and distribution of influenza vaccine for HCP, (3) draft exemption policies permitting HCP to opt-out only for a medical contraindication, and (4) establish clear policies and procedures to address appropriate sanctions for noncompliant HCP. State laws will provide the impetus to vaccinate all HCP as appropriate.

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