HEALTH CARE PERSONNEL VACCINATION: State Legal & Regulatory Environment

For

2014 National Council of State Boards of Nursing, Discipline Case Management Conference,

Park City, Utah

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June 6, 2014
## INFLUENZA IN THE UNITED STATES

Flu has greatest impact of all vaccine-preventable diseases

<table>
<thead>
<tr>
<th> </th>
<th>Annual Morbidity</th>
<th>Annual Mortality</th>
<th>Hospitalizations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children</strong></td>
<td>Children = 2 to 3X more likely to become ill than adults</td>
<td>5-20% of people in U.S.</td>
<td>381,000</td>
</tr>
<tr>
<td><strong>90%</strong></td>
<td>90% = Elderly 1 in 20 deaths</td>
<td>3,000 - 49,000</td>
<td><strong>Source:</strong> <a href="http://www.niaid.nih.gov/topics/Flu/understandingFlu/Pages/overview.aspx">http://www.niaid.nih.gov/topics/Flu/understandingFlu/Pages/overview.aspx</a></td>
</tr>
</tbody>
</table>
Over the last 30 years, flu outbreaks in health care settings attributed to HCP have been well-described

- During an average flu season, 23% of HCP are infected with the virus, show mild symptoms, and continue to work despite being infectious

**Nosocomial outbreaks of influenza can:**

- Last from 2 to 69 days
- Affect 3 to 50% of exposed patients
- Affect 11 to 59% of exposed workers
- Result in a median mortality range from 16% in a general ward setting to 33 to 60% in a transplant setting
- Contribute to patient complications or death & increased economic costs to the health care system

NOSOCOMIAL INFLUENZA

Influenza vaccination of HCP can:
• Reduce patient morbidity and mortality
• Reduce HCP absenteeism
• Protect HCP & their families from disease
• Reduce associated health care costs of influenza outbreaks
REDUCTION IN NOSOCOMIAL INFLUENZA IS CORRELATED WITH HIGHER HCP VACCINATION

PUBLIC HEALTH RECOMMENDATIONS
• CDC recommendation:
  – Since 1981

• Healthy People 2020:
  – 90% influenza vaccination coverage for HCP

• Supported by professional organizations:
  – American Academy of Pediatrics
  – American College of Physicians
  – American Medical Association
  – American Nurses Association
  – Association for Professionals in Infection Control and Epidemiology
  – National Foundation for Infectious Disease
  – Infectious Disease Society of America
ETHICS
Hippocratic Oath (Classic)
I will apply dietetic measures for the benefit of the sick according to my ability and judgment; **I will keep them from harm and injustice.**

Hippocratic Oath (Modern)
I will apply, for the benefit of the sick, all measures [that] are required, avoiding those twin traps of overtreatment and therapeutic nihilism.

**I will prevent disease whenever I can, for prevention is preferable to cure.**

“A physician must recognize responsibility to patients first and foremost.”

“A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.

“To preserve the quality of their performance, physicians have a responsibility to maintain their health and wellness… When health or wellness is compromised, so may the safety and effectiveness of the medical care provided.”

• “The nurse’s primary commitment is to the patient, whether an individual, family, group or community.”

• “The nurse promotes, advocates for, and strives to protect the health, safety, and rights of the patient.”

DEFINING THE HEALTH CARE WORKFORCE & HEALTH CARE EMPLOYER
The health care industry supports 14.3 million jobs:
-- Paid or unpaid
-- Occupational activities involve **direct or indirect contact** with patients or contaminated material

- Employee
- Staff
- Contractors
- Clinicians
- Volunteers
- Students
- Trainees
- Clergy
- Home health care providers
- Dietary staff
- Housekeeping staff

DEFINING THE HEALTH CARE EMPLOYER

There are ~600,000 health care establishments:

- Acute care hospitals
- Nursing homes
- Skilled nursing facilities
- Physician’s offices
- Urgent care centers
- Outpatient clinics
- Home health care
- Emergency medical services
- Schools
- Correctional facilities
- Rehabilitation centers
- Chronic care facilities
- Long-term care facilities
- Assisted living facilities
- Specialty care assisted living facilities
- Comprehensive care facilities
- Extended care facilities
- Adult day care facilities
VOLUNTARY METHODS TO ENCOURAGE HCP VACCINATION
Educational & promotional campaigns:
• To increase HCP knowledge about vaccination & respond to concerns

Increased immunization access:
• Offer vaccination free in the workplace at convenient times & locations

Declination statements:
• Form signed to indicate receipt/refusal of vaccination, informs HCP of the rationale for vaccination

Combination programs:
• Hybrid approach

Reporting & tracking of HCP vaccination rates:
• Record facility HCP vaccination rates & publically report rates
STRATEGIES TO IMPROVE HCP VACCINATION

Ensure commitment from top management
• Must have strong & visible administrative leadership

Use every possible means to deliver messages
• Visible vaccination of key leaders
• Encourage vaccination champions

Repeat campaign on an annual basis
• Provide adequate staff & resources
• Train-the-trainer programs that empower unit staff

Monitor progress
• Track individual & unit-based vaccination compliance
• Provide feedback
WHY HCP REFUSE VACCINATION

- Don’t want the vaccine
- Vaccine is unsafe & may cause adverse events
- The vaccine can cause flu
- They are not at risk for contracting flu
- Flu is not a serious disease
- Time & location of the vaccine is unsuitable
- Vaccine is not effective
- Fear or dislike of needles
- Employer apathy
- Are allergic to the vaccine
- Vaccination is a matter of personal choice

<table>
<thead>
<tr>
<th>WHY HCP CHOOSE TO BE VACCINATED</th>
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<tbody>
<tr>
<td>• Self-protection</td>
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<tr>
<td>• Employer requirement</td>
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<tr>
<td>• Protect patients</td>
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<tr>
<td>• Protect family</td>
</tr>
<tr>
<td>• Previous vaccination</td>
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<tr>
<td>• Perceived effectiveness</td>
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<tr>
<td>• Avoid missing work</td>
</tr>
<tr>
<td>• Peer recommendation</td>
</tr>
<tr>
<td>• Physician recommendation</td>
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<tr>
<td>• Employer recommendation</td>
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<tr>
<td>• Previously contracted influenza</td>
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<tr>
<td>• Vaccination is a professional responsibility</td>
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<tr>
<td>• Access to vaccination/coverage</td>
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<tr>
<td>• Vaccinations provided free</td>
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<tr>
<td>• Benefits outweigh the risks</td>
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COVERAGE LEVELS
### HCP INFLUENZA VACCINATION COVERAGE LEVELS

<table>
<thead>
<tr>
<th>2005 - 2013</th>
<th>Increased from 35.7% to 72%</th>
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#### HCP who receive flu vaccine

<table>
<thead>
<tr>
<th>HCP</th>
<th>Coverage Level</th>
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<tbody>
<tr>
<td>Pharmacists</td>
<td>90%</td>
</tr>
<tr>
<td>Physicians</td>
<td>84%</td>
</tr>
<tr>
<td>Nurses</td>
<td>79%</td>
</tr>
<tr>
<td>Nurse Practitioners/Physician Assistants</td>
<td>78%</td>
</tr>
<tr>
<td>Other Clinical Professionals</td>
<td>71%</td>
</tr>
<tr>
<td>Assistants/Aides</td>
<td>49%</td>
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<tr>
<td>Administrative/Non-Clinical support staff</td>
<td>54%</td>
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</table>

#### Setting where HCP receive flu vaccine

<table>
<thead>
<tr>
<th>Setting</th>
<th>Coverage Level</th>
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<tbody>
<tr>
<td>Hospitals</td>
<td>79%</td>
</tr>
<tr>
<td>Long term care facility</td>
<td>53%</td>
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#### Impact of employer requirement

<table>
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<tr>
<th>Requirement</th>
<th>Coverage Level</th>
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<tbody>
<tr>
<td>Existing vaccination requirement</td>
<td>89%</td>
</tr>
<tr>
<td>No existing vaccination requirement</td>
<td>44%</td>
</tr>
</tbody>
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Health Care Personnel and Flu Vaccination, Internet Panel Survey, United States, November 2013. Centers for Disease Control and Prevention
MANDATORY INSTITUTIONAL VACCINATION PROGRAMS
MANDATORY VACCINATION PROGRAMS

2004

• Virginia Mason Hospital, Seattle, WA
• 1st facility to implement HCP influenza vaccination as a condition of employment

2004 - Present

• 100s of facilities across the U.S. have implemented similar policies

• These facilities have achieved levels of HCP influenza vaccination up to 99.3%

EMPLOYEE VACCINATION MANDATES—REACTIONS

Elmer Smith: At CHOP, no flu shot, no job. No sense?

by Elmer Smith
Philadelphia Daily News

RODNEY BOND never expected a gold watch or a plaque commemorating his 31 years of service to Children's Hospital of Philadelphia.

He expected what he always got, a day's pay for a day's work.

"This job served me well," Bond said. "I got married young, three years out of high school. I needed a job. Some may say I was complacent.

"But I've been able to raise my family. I've always been happy for what this job has done for me.

"I'm disappointed about what's happening to me. But I'm not a disgruntled employee."

As of tomorrow, he won't be an employee at all. Bond, 51, who works in environmental services keeping the hospital clean and at least eight others are being fired for refusing to take a seasonal flu shot.

Children's Hospital, in a laudable attempt to protect its patients, has required all its employees to be inoculated for seasonal flu this year for the first time in its history.

Hospitals around the city, indeed all over the country, are adopting similar measures. But the requirement at CHOP exceeds the guidelines offered by the Centers for Disease Control and is far more harsh than policies at other area hospitals.

Typically, hospitals have required their workers to either get a flu shot or wear surgical masks when they are near patients. At CHOP, they have rejected the masks as a possible alternative.

Even hospitals with similar policies have not fired employees for failure to comply. CHOP is also distinct in its uneven application of the policy.

CHOP healthcare workers allege unfair firings

by Meg Bevilacqua | Sunday, December 13, 2009 at 7:55 pm

Nine employees at the Children's Hospital of Philadelphia were fired Dec. 4 allegedly for refusing to be vaccinated against influenza.

CHOP officials issued a statement the day the workers were fired, citing high rates of influenza among hospitalized children and children's weaker immune systems as the reason for CHOP's strict standards, which prompted the firings.

"Of 9,400 healthcare workers in patient buildings at CHOP, nine healthcare workers made the choice to not be vaccinated," CHOP officials wrote. "We are saddened they came to the decision to leave CHOP. We offered opportunity to apply for medical and religious exemptions but did not offer exemptions based on personally held beliefs."

In previous years, CHOP had made seasonal influenza vaccinations available but not a condition of employment. According to the statement, last year 500-800 employees refused seasonal influenza vaccination.

STATE POWER TO REQUIRE VACCINATION
U.S. Constitution: 10th AMENDMENT “POLICE POWER”

- A state may issue regulations to protect the public health & public safety
- Restraints may be placed upon individuals for the common good
- A community has the right to protect itself against an epidemic of disease which threatens the safety of its members

Jacobson v. Massachusetts, 197 US 11 (1905)
TYPES OF VACCINE REQUIREMENTS

- School-entry requirements (States/cities)
- Military personnel (Federal)
- Select populations in public health emergencies (States)
- Immigrants (Federal)
- Health care personnel (Employers/states)

SCHOOL ENTRY REQUIREMENTS

PRECEDENT FOR MANDATORY VACCINATION OF HCP

• Convert immunization recommendations into legally enforceable obligations

• Students must demonstrate receipt of certain vaccines as a condition of attendance

• Have proven to be the most effective tool ever devised
  – Increase coverage rates among the target population
  – Reduce disease transmission
  – 95% of children receive all recommended vaccines

SOURCE: -Hodge JG Jr., Gostin LO. School vaccination requirements: historical, social, and legal perspectives: a state of the art assessment of law and policy, Baltimore: Center for Law and the Public's Health at Johns Hopkins and Georgetown Universities; 2002.
The laws have evolved. The 2 most recent regulations address the primary barriers to a successful program.

Alabama, Arkansas, California, D.C., Illinois, Kentucky, Maine, Maryland, Massachusetts, N. Hampshire, N. York, N. Carolina, Oklahoma, Pennsylvania, Rhode Island, S. Carolina, Tennessee, Texas, Utah, Virginia

Colorado (03/30/12), Rhode Island (10/12)

SOURCE: GWU/SPHHS, Developing a Model State Law, Summer 2011, Updated 12/12
### STATE LAW ANALYSIS

<table>
<thead>
<tr>
<th>AFFECTED HCP</th>
<th>MOST STATES</th>
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<tbody>
<tr>
<td>- Have adopted a narrow definition of HCP, (compensated employees)</td>
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<table>
<thead>
<tr>
<th>AFFECTED HCE</th>
<th>MOST STATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Address various types of residential care &amp; acute care hospitals</td>
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<table>
<thead>
<tr>
<th>EMPLOYER OBLIGATIONS</th>
<th>MOST STATES REQUIRE HEALTH CARE EMPLOYERS TO</th>
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<tbody>
<tr>
<td>- “Provide” “arrange for” “ensure” or “offer” flu vaccine</td>
<td></td>
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<tr>
<td>- Require HCP to receive the vaccine during a specified time period</td>
<td></td>
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<tr>
<td>- Require HCEs to provide education regarding the vaccine</td>
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<tr>
<td>- Require HCEs to document HCP immunization status</td>
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<thead>
<tr>
<th>FEW STATES</th>
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<tbody>
<tr>
<td>- Permit HCP to choose the provider &amp; admin. location of their choice</td>
</tr>
<tr>
<td>- Address how HCEs should manage cost compliance (vaccine purchase, admin, record keeping)</td>
</tr>
<tr>
<td>- Address how HCEs should sanction non-compliant HCWs</td>
</tr>
<tr>
<td>- Require HCEs to report vaccination rates to state public health</td>
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## STATE LAW ANALYSIS

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<thead>
<tr>
<th>HCP OBLIGATIONS</th>
<th>MOST STATES REQUIRE HCP TO</th>
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<tbody>
<tr>
<td></td>
<td>- Receive vaccination &amp; Present documentation</td>
</tr>
<tr>
<td></td>
<td>- Comply with exemption policy</td>
</tr>
<tr>
<td>FEW STATES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Expressly permit HCP to receive the vaccine at a provider and location of his/her choice</td>
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<tr>
<th>EXEMPTION POLICY</th>
<th>MOST STATES PERMIT</th>
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<tbody>
<tr>
<td></td>
<td>1) Medical Contraindication  2) Religious  3) Declination Statement</td>
</tr>
<tr>
<td>FEW STATES PERMIT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Philosophical/Personal Belief</td>
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<table>
<thead>
<tr>
<th>STANDARD OF CARE</th>
<th>MOST STATES ADOPT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Advisory Committee on Immunization Practices (ACIP) of the CDC</td>
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<tr>
<td>FEW STATES ADOPT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Occupational, Safety and Health Administration (OSHA)</td>
</tr>
<tr>
<td></td>
<td>- State Board of Health</td>
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<tr>
<td>EMPLOYER OBLIGATIONS</td>
<td>RHODE ISLAND &amp; COLORADO</td>
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<td>----------------------</td>
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</tr>
<tr>
<td><strong>COLORADO:</strong></td>
<td>1) Develop written policy 2) Inform all HCP of requirement 3) Provide vaccine when it is readily available 4) Enforce policy &amp; <strong>provide masks for unvaccinated HCP</strong> 5) Maintain documentation of vaccination status 6) Track &amp; report vaccination rates annually for Health Dept.</td>
</tr>
<tr>
<td><strong>Other HCEs not listed shall:</strong></td>
<td>1) Conduct an assessment to develop a flu vx policy 2) develop a written policy that offers flu vx, documents status, educates HCP, tracks &amp; reports vaccination rate annually for Health Dept.</td>
</tr>
<tr>
<td><strong>Excludes:</strong></td>
<td>HCEs that have vaccinated a targeted % of HCP (60% by 12/31/12 75%/2013 90%/2014)</td>
</tr>
<tr>
<td><strong>RHODE ISLAND:</strong></td>
<td>1) Require vaccination 2) Provide free vaccine 3) Track &amp; record vaccination levels for the Dept. of Health <strong>4) Require unvaccinated HCP to wear surgical masks during direct patient contact, when flu is widespread</strong> 5) Provide free masks 6) Pay $100 fine for each breach</td>
</tr>
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## RHODE ISLAND & COLORADO

<table>
<thead>
<tr>
<th>HCP OBLIGATIONS</th>
<th>COLORADO: Comply with policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>RHODE ISLAND:</td>
<td>Comply with policy regardless of any provision in any Collective bargaining agreement or other contract or policy Section 5.7</td>
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<table>
<thead>
<tr>
<th>EXEMPTION POLICY</th>
<th>COLORADO: Medical</th>
</tr>
</thead>
<tbody>
<tr>
<td>RHODE ISLAND:</td>
<td>1) Medical 2) Signed Declination Form including agreement to wear mask &amp; pay $100 fine for each breach = unprofessional conduct</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>STANDARD OF CARE</th>
<th>COLORADO: None identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>RHODE ISLAND:</td>
<td>ACIP</td>
</tr>
</tbody>
</table>
CASE STUDY
LEGAL ARGUMENTS ADDRESSING MANDATORY VACCINATION
Supreme Court:

- Deprivation of personal rights without appropriate legal process
- Limiting freedom of religion
- Rights of a competent adult to refuse medical treatment
- Freedom to enter into private employment contracts

Supreme Court:

- Smallpox vaccination requirement
- School entry requirement

- Individuals do not have an absolute right to be, at all times and in all circumstances, wholly freed from restraint.

- There are manifold restraints to which every person is necessarily subject for the common good.

Supreme Court:

• Balanced an individual’s right to religious expression against important societal interests.

• Held that religious exemptions to immunization requirements are not constitutionally required.

Prince v. Massachusetts, 321 U.S. 158 (1944)
Supreme Court:

- Right to bodily autonomy (*Refuse Treatment*) is not absolute

- Weigh extent of bodily invasion against the effectiveness of the intervention & interests of the public

VIOLATION OF FREEDOM OF CONTRACT UNDER 5TH AND 14TH AMENDMENTS

Supreme Court:

• The Contract Clause permits employees & employers to enter into contracts as they see fit

  HOWEVER

• Public welfare trumps economic liberty

• States may limit & regulate contract rights to protect community health or vulnerable populations

Williamson v. Lee Optical Co., 348 U.S. 483 (1955); West Coast Hotel, Co. v. Parrish, 300 U.S. 379 (1937); Muller v. Oregon, 208 U.S. 412 (1908)
OBSERVATIONS
STATE LAW & MANDATORY VACCINATION

• State law is an effective & reliable method to increase HCP vaccination when compared to individual facility-based policies:
  – Law has broad application across state
  – Establish uniform requirements
  – Incorporates all workers & all employers
  – State regulatory framework governing HCE responsibilities is already established
HOW COURTS WILL DECIDE

1. It is impossible to predict with absolute certainty how a court will decide any case.

2. However, courts must rely on previous relevant decisions.

3. HCP have the same rights as other individuals.

4. In the final analysis, courts will prioritize the rights of the community as a whole when considering the case of mandatory vaccination of HCP.