Law and the Public's Health

This installment of *Law and the Public's Health* examines the issue of compulsory vaccination of health-care workers, an issue that has received considerable attention as a result of the H1N1 influenza pandemic. Following an overview of the health safety issues raised by unimmunized health-care workers, the column considers recent legal developments in the field.

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VACCINATING THE HEALTH-CARE WORKFORCE: STATE LAW VS. INSTITUTIONAL REQUIREMENTS

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Health-care workers (HCWs) who have direct contact with patients present the primary source of infectious disease outbreaks in health-care facilities.[1] Direct contact refers to people who, if they were infected with influenza, could transmit the disease to a patient, either through sharing a 6-foot space with a patient (person-to-person contact) or through touching a surface that comes in contact with a patient (equipment-to-patient contact).[2] While studies show that maintaining high levels of staff vaccination protects patients, HCWs, and their families from the complications of seasonal influenza,[3] mandatory vaccination of HCWs remains highly controversial. This installment of *Law and the Public's Health* examines legal issues surrounding immunization of people working in health-care settings.

BACKGROUND

The 15 million to 60 million cases of influenza that occur annually in the U.S. result in more than 200,000 hospitalizations and 36,000 deaths on average.[4] Vaccination against seasonal influenza can reduce morbidity by 70% to 90%, making it the most effective method to prevent transmission of the virus.[4]

Seasonal influenza outbreaks in health-care settings can have a significant impact on patients, HCWs, and the health-care system. Patients are at increased risk for disease when they are treated by HCWs who have been exposed to influenza. During an average season, 23% of HCWs are infected with the virus, show mild symptoms, and continue to work despite being infectious.[5]

Public health experts,[6] provider organizations,[4] and patient advocates[7] agree that HCWs who provide direct care to patients should receive an annual influenza vaccination. As a result, health-care facilities have employed various strategies to increase the voluntary receipt of immunization services, including workforce vaccination campaigns, accessible services, declination statements that permit the employee to refuse vaccination while certifying that he or she received information about the risks and benefits of influenza vaccine, education programs, and the possible use of financial incentives to boost vaccination rates.[8] Despite these efforts, the coverage rate among HCWs remains unacceptably low at approximately 40%.[3]

MANDATORY VACCINATION

Some facilities have instituted mandatory employee influenza vaccination programs,[9] and one state has promulgated regulations making seasonal and H1N1 influenza vaccination mandatory.[10] HCWs who oppose these requirements filed unsuccessful civil actions seeking to overturn them.[11] The *Virginia Mason Hospital* case, discussed in this article, presented the question of the legality of a unilateral job requirement imposed by a health-care facility in the context of a collective bargaining agreement.

Institutional requirements

In 2005, Bronson Methodist Hospital in Kalamazoo, Michigan, and Virginia Mason Medical Center in Seattle, Washington, became the first two health-care facilities in the nation to implement mandatory influenza vaccination programs for their staff.[12] By 2009, at least 25 other institutions in 17 states (California, Colorado, District of Columbia, Florida, Idaho, Illinois, Maryland, Michigan, Missouri, Nebraska, New York, Ohio, Pennsylvania, Virginia, Washington, West Virginia, and Wisconsin) had developed similar requirements. Some

policies permit HCWs to refuse the vaccination based upon religious beliefs. However, these unvaccinated workers are subject to additional precautions, including the use of masks or respirators during the influenza season, opting for a leave of absence, accepting reassignment to non-patient-care areas, and the potential risk of job termination.[12]

While most institutional programs have been successful, challenges remain. Recently, the Charleston Area Medical Center in Charleston, West Virginia, fired two people out of a more than 6,000-person workforce over their refusal to comply with the hospital's influenza vaccination requirement.[13]

Virginia Mason Hospital v Washington State Nurses Association

In *Virginia Mason Hospital v Washington State Nurses Association,* reviewed at greater length in a previous issue of *Public Health Reports*,[14] a hospital sought to establish a compulsory influenza vaccination program when its voluntary effort proved to be ineffective. The unionized Washington State Nurses Association (WSNA) opposed the mandate and filed a labor grievance. Following an arbitration ruling favoring the nurses, the hospital appealed. The basis for the arbitrator's ruling was that the requirement amounted to one that "directly affected conditions of employment."[9] As such, the program involved an impermissible alteration of employment rules without collective bargaining rather than a patient safety and infection control measure. The ruling was upheld by the U.S. Court of Appeals for the 9th Circuit, which held that workers and employers were free to collectively bargain over immunization status, as neither state public health laws nor federal Medicare hospital conditions of participation explicitly required HCW immunization as a condition of employment.

The New York State regulations

The New York State rules can be seen as a follow-on response to *Virginia Mason,* adopting for the state's health-care system the type of explicit immunization requirement lacking in Washington State. In August 2009, the New York State Health Commissioner promulgated regulations[10] that, as a precondition of employment, and annually thereafter, would require immunization against seasonal and H1N1 influenza for HCWs and volunteers who have direct contact with patients or who may expose patients to disease.[15] Under the rule, health-care facilities must "provide or arrange for influenza vaccinations at no cost to personnel, either at the facility or elsewhere depending on personal choice."[16] Exempted staff are those who can show that they have a medical contraindication recognized in national guidelines. Each facility would have the discretion to determine how to reduce health risks created by unvaccinated HCWs.[17] The rule also would permit the state to suspend the requirements in cases in which the vaccine is in limited supply.[18]

Several provider groups sued to prevent enforcement of the regulation.[11] On October 16, 2009, a state trial court issued a temporary restraining order that prevented the regulation from becoming effective.[19] On October 22, 2009, the Governor of New York announced the suspension of the regulation as a result of an insufficient supply of vaccine and the need to ensure that priority groups—including pregnant women, and children and young adults between the ages of six months and 24 years—received all available supplies.[20] On February 19, 2010, the Supreme Court of the State of New York dismissed the providers' claims because the "regulation . . . had been withdrawn subsequent to the commencement of [the case]."[21]

In the New York cases, the HCWs argued that the regulations amounted to a constitutional violation of their 14th Amendment due process rights, their right to the "free exercise" of religion under the First Amendment, their right to "freedom of contract" between employer and employee under the Fifth and 14th Amendments, and their right to privacy and bodily autonomy as a matter of substantive due process under the 14th Amendment. How well these arguments will fare depends on judicial precedent surrounding compulsory public health statutes that limit individual autonomy and freedoms in favor of broader public health protections.

A considerable body of case law suggests that under certain circumstances, the government may restrict personal liberty to protect the public's health. Beginning with the landmark U.S. Supreme Court decision in *Jacobson v Massachusetts*,[22] courts have ruled that states have the authority to exercise their 10th Amendment "police powers" to require immunizations[23] and that public health considerations related to the threats posed by transmissible disease trump individual autonomy to refuse health care. These decisions remain equally relevant today, given that the dangers of vaccine-preventable diseases and the means to prevent transmission have "a real and substantial relation to the protection of the public health and the public safety."[24,25]

Similarly relevant are judicial precedents that balance religious freedoms against public health and safety. These cases suggest that while it is a bedrock of U.S. society that individuals remain free to practice their religious beliefs without government interference,

the "free exercise clause" nonetheless does not insulate this freedom against the counterweight of important societal interests. Indeed, courts have ruled that religious exemptions to vaccination requirements in other contexts are not constitutionally required.[26]

Also relevant are prior rulings related to the meaning of the Contract Clause. Although the Constitution protects the right of individuals to enter into agreements with others without government interference, courts have ruled that states may also limit and regulate contracts in the interest of the public's welfare,[27–29] and essentially to place protection of the public against individual economic interest.

Finally, competent individuals have the right to refuse medical treatment. But, as with other cases, courts have ruled that patient autonomy can be restricted when government can demonstrate that the interests of the public exceed the extent of individual intrusion.[30]

IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

The U.S. Constitution recognizes the right of individuals to refuse medical treatment, and U.S. labor laws recognize the right of individuals to form unions and collectively bargain over the terms and conditions of employment in the absence of overarching public policies that limit bargaining discretion. New York's public health law requiring the immunization of HCWs is in essence a response to this basic legal framework. In setting immunization requirements for the health-care workforce, the regulations represent an attempt to balance the autonomy of individuals and the right to collectively bargain conditions of employment against the need to protect the public—in this case, patients in health-care facilities—from illness and death. The basis for the rules can be found in the statistics on immunization rates among the health-care workforce, as well as evidence of transmission from workers to patients. Given this evidence, as well as the means to intervene to protect the public's health, the state of New York essentially has sought to temper economic and personal autonomy in the name of public safety. Whether the state regulations ultimately are upheld remains to be seen, but judicial precedent suggests that the regulation rests on a viable legal platform.

Of equally great importance is the role of the federal government. It is the case that the direct regulation of the public's health is a traditional state function under the 10th Amendment. At the same time, the federal government has enormous powers under the Commerce Clause and the Spending Clause to both attach conditions of participation to federally funded programs as well as to regulate economic activity,[31] of which health care is viewed as a preeminent example. To this end, federal conditions of participation for the Medicare and Medicaid programs, which currently do not address the immunization status of the health-care workforce, offer another potential basis for establishing minimum safeguards against the transmission of disease in health-care settings, in particular settings in which sick patients reside, such as nursing homes and hospitals.

The judicial course of the New York State law, as well as efforts to reframe federal policy in the area of health-care quality and safety, will be important issues to watch as the nation attempts to grapple with balancing public health safety against individual and economic freedom.

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