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Expert Analysis

Court Upholds Mandatory Face Masks for Health Care Workers

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In recent years, there has been considerable controversy over whether the state's interest in protecting the health of patients in hospitals and nursing homes trumps the right of the physicians, nurses and other individuals providing services in those facilities to determine for themselves whether they will be inoculated with anti-influenza (flu) vaccine. Some states, including New York, have compromised by requiring that those who refuse to be inoculated wear face masks when interacting with patients. However, that too has been unacceptable to some health care workers. Two court decisions, including a recent one from the Appellate Division, have dismissed a challenge to the face mask alternative, and offer solid legal analyses of this issue.

Background

Patients in hospitals, elderly residents of nursing homes, and those receiving home care services often have compromised immune systems, and as such are especially vulnerable to contracting the flu (and other contagious diseases) from people with whom they come into contact. While the flu can make a healthy person very sick, it can debilitate or even be fatal to sick or elderly individuals.

Many hospitals, nursing homes, home health agencies, and other health care facilities in New York have long required that any health care provider or employee who is exposed to patients be vaccinated against influenza. Depending upon the facility, however, this requirement was sometimes enforced and sometimes not.

In August 2009, in advance of what was anticipated to be a flu epidemic, the State Hospital Review and Planning Council[1] of New York's Department of Health (DOH) adopted an emergency regulation[2] requiring health care workers to be vaccinated against the flu by Nov. 9, 2009 (unless the vaccine was medically inappropriate for an individual) or be terminated from employment. This regulation was immediately challenged in court by two unions, the New York State Public Employees Federation, and the United Federation of Teachers, and four registered nurses. The Supreme Court, Albany County, issued a temporary restraining order against enforcement of the emergency regulation. In the face of a severe shortage of flu vaccines, the DOH later suspended the vaccine mandate, and the emergency regulation was allowed to expire 90 days after it was issued.

In 2013, the DOH's Public Health and Health Planning Council amended the State Sanitary Code to require hospitals, nursing homes, diagnostic and treatment centers, ambulatory surgery centers, hospices, home health agencies and other licensed health care facilities to document the flu vaccination status of all personnel.[3] The term "personnel" is broadly defined in this regulation to include:

> …all persons employed or affiliated with a health care or residential facility or agency, whether paid or unpaid, including but not limited to employees, members of the medical and nursing staff, contract staff, students, and volunteers, who engaged in activities such that if they were infected with influenza, they could potentially expose patients or residents to the disease.[4]

The regulation requires the facilities to ensure that all personnel who are not vaccinated against current flu strains wear a surgical or procedure mask where patients or residents are typically present.[5] A later amendment created an exception to the face mask requirement for speech therapists, and added that covered facilities and agencies are free to adopt policies that are more stringent than the regulation.[6]

This regulation was challenged again by the Public Employees Federation and four registered nurses represented by

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that union, in *In re Application of Kent v. Nirav R. Shah*. They claimed that, in promulgating the regulation, the DOH acted in an arbitrary, capricious and irrational manner. They also alleged that:

- there is no sufficient scientific evidence establishing that mask wear by asymptomatic unvaccinated health care workers prevents the spread of influenza;
- the regulation is a de facto mandatory flu vaccination requirement because compliance with the masking is so onerous, it forces workers to be vaccinated;
- federal health agencies have not recommended the use of masks for this purpose;
- the influenza vaccine is only 20-80 percent effective in reducing the likelihood that the person receiving the vaccine will choose not to visit a doctor to have their flu symptoms treated;
- vaccination does not prevent the spread of influenza from a vaccinated individual to another individual;
- vaccinated asymptomatic health care providers are capable of spreading the influenza virus to patients but are not required to wear masks;
- non-vaccinated visitors and patients do not have to wear face masks;
- mask-wearing may increase the likelihood of respiratory infections for mask wearers;
- wearing the mask impedes communication between health care providers and patients, particularly elderly patients who could be hearing impaired;
- the mask may frighten a patient, particularly one suffering from mental illness;
- the regulations do not contain any exemptions from mask wear for religious or medical reasons.

The petitioners also argued that the regulation violates the separation of powers doctrine because DOH exceeded its authority in issuing the regulation.

In its response, the DOH countered that:

- the Public Health Law (PHL) authorizes the DOH to issue the regulation as part of DOH's power to enact the State Sanitary Code (PHL §225(5)(a));
- the adoption of the regulation was done in a deliberative process pursuant to the PHL and State Administrative Procedure Act;
- the PHL authorizes the DOH Commissioner to investigate the causes of disease and epidemics and the effect of employment on the public health (PHL §206(d));
- despite efforts to increase the voluntary vaccination rates, hospitals in 2011-12 reported only a 48.4 percent health care personnel vaccination rate;
- a study showed that in New York, during 2012-13, there were 112 influenza outbreaks in hospitals and 453 outbreaks in nursing homes; and that study showed that the transmission was from health care workers to patients and residents;
- influenza, like bacteria, is spread through droplets, splashes, sprays or splatter that reach the mouth or nose of the other person, and face masks may block these;
- health care professionals already must demonstrate their immunity to measles/rubella and must undergo regular tests for tuberculosis.

In her decision, Albany County Supreme Court Justice Judith A. Hard rejected the petitioners' claims and upheld the regulation.[7] Quoting PHL §225(5)(a), she stated that the Sanitary Code as enacted by DOH may "deal with any matters affecting the security of life or health or the preservation or improvement of the public health in the state of New York." She noted that under PHL §225(5)(a), the DOH may establish regulations for the maintenance of hospitals for communicable diseases, and under PHL §225(5)(h) may designate the communicable diseases which are dangerous to public health. As such:

> …the masking requirement appears reasonable given the Commissioner is charged with protecting the health of the inhabitants of this State.

Turning to petitioners' argument that the regulation violated the separation of powers doctrine, the court analyzed the four factors set forth by the Court of Appeals in *Boreali v. Axelrod*[8] for determining the validity of regulations and whether the government agency issuing them acted within its statutory authority. The court summarized the Boreali factors:

1) whether the exceptions to the regulations are based solely upon economic and social concerns without foundation in public health;
2) whether the agency merely filled in the details of broad legislation (interstitial rule-making) rather than creating its own comprehensive set of rules without legislative guidance;
3) whether the agency acted in an area that the Legislature repeatedly tried but failed to reach agreement on an issue; and
4) whether no special expertise or technical competence in the field of health was involved in the development of the regulation.

With respect to the first factor, Justice Hard found that the regulation's exceptions to mask-wearing for vaccinated health care personnel and speech therapists both had foundations in public health, and did not amount to "an overhaul to behavior that affects the public at large or the economy." As to the second Boreali factor, Justice Hard found that PHL §§206(1)(d) and 2800 gave the DOH authority to require masks for unvaccinated health personnel as a measure of the quality and fitness of hospitals, and for alleviating the transmission of influenza to patients and the public.

Justice Hard found that the introduction in the Legislature of one unsuccessful bill to mandate influenza vaccine for health care workers did not meet the third Boreali factor of repetitive attempts to legislate. Lastly, she found that the fourth Boreali factor had been met since the DOH had the requisite special expertise

in health required to formulate the health policy set forth in the regulation.

Appeal

Petitioners appealed, and on Feb. 25, 2016, a three-judge panel of the Appellate Division, Third Department, in Spence v. Shah, unanimously upheld the Supreme Court's decision.[9] In its opinion, the court also reviewed the four "coalescing circumstances" in the Boreali decision. The court found that the Legislature had enacted numerous provisions of the PHL that delegated broad authority to the DOH to consider and implement regulations regarding the preservation and improvement of public health, and to establish standards in licensed health care facilities to foster the prevention and treatment of diseases.

In this case, the court noted, the DOH conducted an extensive study and analysis regarding the transmission of flu in health care facilities and effective ways to address this serious health issue. It concluded that requiring vaccination or the wearing of a mask as a way of minimizing the risk of flu transmission "falls comfortably within the intent of the underlying legislation." It found that this choice afforded the workers options "while advancing the closely tailored goal of attempting to minimize an unwarranted and unnecessary public health risk from the spread of influenza." Accordingly, the court held that, in promulgating this regulation, the DOH had not crossed into the purview of the Legislature.

The court next reviewed the petitioners' argument that the regulation was arbitrary, capricious, irrational and contrary to law. It found that there was sufficient scientific and factual evidence in the record to support the regulation, and that the DOH had reviewed information that included studies and recommendations from the federal Centers for Disease Control and Prevention, the Food and Drug Administration, the Infectious Disease Society of America, and various journal articles written by infectious disease experts. The court noted that a DOH physician who is an expert in infectious disease had submitted an affidavit discussing in detail the issues considered by DOH when formulating the regulation, including:

- the serious and potentially widespread health risk posed by influenza in health care facilities;
- data and studies relevant to the spread of influenza;
- various approaches to the problem considered by experts in the field;
- potential concerns and consequences implicated by assorted methods of attempting to minimize the influenza risks; and
- the reasons for the approach recommended and ultimately taken by the DOH in the regulation.

Accordingly, the court found that the petitioners had not met the heavy burden of showing that the regulation is unreasonable and unsupported by any evidence.

Conclusion

There will continue to be debate about the merits of requiring all health care workers who are exposed to patients either to be vaccinated against the flu or to wear a face mask. When the DOH promulgated the regulation with the vaccine or face mask option, medical ethicist Arthur L. Caplan, Ph.D., supported the requirement and commented:

> …every doctor, nurse and [health care worker] knows that they are supposed to put patient interests ahead of their own interests. Whatever you think about flu shots, it is good for patients that their health care providers are vaccinated against the flu, particularly among patients who cannot themselves be vaccinated, such as some of the elderly, babies, people with immune diseases, and people who just received transplants or are getting cancer treatment. Vaccination does not help them. They are all immunosuppressed.[10]

Others have pointed out that wearing a face mask is no more burdensome than the universal precautions (e.g., washing hands, wearing non-porous medical gloves, goggles and face shields) that health care workers are required to follow when coming into contact with patients or bodily fluids.

It thus appears abundantly clear—from an epidemiological, legal and ethical point of view—that the DOH was correct in requiring health care workers who refuse to get vaccinated against influenza to wear a face mask when providing care to patients. Two courts have now agreed.

Endnotes:

1. The Hospital Review and Planning Council was subsequently merged into the Public Health Council, and is now known as the Public Health and Health Planning Council.

2. 10 NYCRR §66-3, Aug. 13, 2009.

3. 10 NYCRR §2.59(c).

4. Id. §2.59(a)(1).

5. Id. §2.59(d).

6. Id. §2.59(h).

7. *In re Application of Kent v. Nirav R. Shah*, Index No. 6454-13 (Supreme Court, Albany County, June 10, 2014).

8. 71 NY2d 1 (1987). For an analysis of the Boreali case, see Serbaroli, "'Boreali v. Axelrod': The Limits of Agency Power" NYLJ, Jan. 22, 2013, p.3.

9. *Spence v. Shah*, Index No. 520977, New York Law Journal 1202750750858 (3d Dept. Feb. 25, 2016).

10. http://www.nbcnews.com/id/33210502/ns/health-health_care/t/health-workers-must-get-flu-shot-or-quit/#.VuBwuk1OXcs.