### 8.7 Routine Universal Immunization of Physicians

As professionals committed to promoting the welfare of individual patients and the health of the public and to safeguarding their own and their colleagues' well-being, physicians have an ethical responsibility to encourage patients to accept immunization when the patient can do so safely, and to take appropriate measures in their own practice to prevent the spread of infectious disease in health care settings. Conscientious participation in routine infection control practices, such as hand washing and respiratory precautions is a basic expectation of the profession. In some situations, however, routine infection control is not sufficient to protect the interests of patients, the public, and fellow health care workers.

In the context of a highly transmissible disease that poses significant medical risk for vulnerable patients or colleagues, or threatens the availability of the health care workforce, particularly a disease that has potential to become epidemic or pandemic, and for which there is an available, safe, and effective vaccine, physicians have a responsibility to accept immunization absent a recognized medical contraindication or when a specific vaccine would pose a significant risk to the physician's patients.

Physicians who are not or cannot be immunized have a responsibility to voluntarily take appropriate action to protect patients, fellow health care workers and others. They must adjust their practice activities in keeping with decisions of the medical staff, institutional policy, or public health policy, including refraining from direct patient contact when appropriate.

Physician practices and health care institutions have a responsibility to proactively develop policies and procedures for responding to epidemic or pandemic disease with input from practicing physicians, institutional leadership, and appropriate specialists. Such policies and procedures should include robust infection control practices, provision and required use of appropriate protective equipment, and a process for making appropriate immunization readily available to staff. During outbreaks of vaccine-preventable disease for which there is a safe, effective vaccine, institutions' responsibility may extend to requiring immunization of staff. Physician practices and health care institutions have a further responsibility to limit patient and staff exposure to individuals who are not immunized, which may include requiring unimmunized individuals to refrain from direct patient contact.

#### AMA Principles of Medical Ethics: I,II

Background report(s):

CEJA Report 2-I-20 Amendment to Opinion 8.7, Routine universal immunization of physicians CEJA Report 5-I-10 Routine universal immunization of physicians

## REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS<sup>\*</sup>

CEJA Report 2, November 2020

Subject:Amendment to Opinion 8.7, "Routine Universal Immunization of Physicians"Presented by:Monique A. Spillman, MD, ChairReferred to:Reference Committee on Amendments to Constitution and Bylaws

1 Growing public skepticism about immunization, falling rates of immunization and the associated 2 resurgence of infectious childhood diseases, and the emergence of new zoonotic diseases that have 3 spread rapidly through human populations underscore the importance of physicians' 4 responsibilities to protect the welfare not only of individual patients, but also of communities. 5 Given heightened awareness of physicians' public health role, the Council on Ethical and Judicial 6 Affairs reviewed ethics guidance set out in Opinion 8.7, "Routine Universal Immunization of 7 Physicians." The following report summarizes the council's deliberations and clarifies its guidance 8 on physicians' responsibility to accept immunization when a safe, effective vaccine is available, 9 especially for a disease that has potential to become epidemic or pandemic. 10 11 VACCINATION OF HEALTH CARE WORKERS 12 13 Vaccination of health care workers, including physicians, is a logical measure to decrease 14 transmission of vaccine-preventable diseases during patient encounters. Yet despite extensive education on the benefit of vaccination, recommendations from the Society for Healthcare 15 16 Epidemiology of America [1,2], and strong efforts by health care institutions to promote this 17 preventive measure, rates of vaccination among health care workers can be surprisingly low, 18 especially for seasonal influenza [3]. 19 20 Requiring vaccination of health care workers does increase vaccination rates for seasonal influenza [3,4]. One multispecialty medical center achieved an influenza vaccination rate of approximately 21 22 98 percent among health care workers by requiring vaccination, with exemptions for medical and 23 religious reasons [3]. A study comparing medical centers with and without an influenza vaccine mandate showed a 30 percent difference in vaccination rate between the two groups [4]. The study 24 25 also found a decrease in days absent for symptomatic influenza-like illness (ILI) for the mandatory vaccination group. 26 27 28 However, the available evidence, most of which comes from observational studies, is mixed 29 regarding the extent to which mandated vaccination of physicians and other health care workers benefits patients [5,6,7]. One meta-analysis of studies from facilities that offered influenza 30 vaccination reported a reduction in all-cause mortality and ILI, but did not show changes in 31 hospitalizations and confirmed cases of influenza [8]. A Cochrane meta-analysis that focused on 32 33 assessing whether influenza vaccination for health care workers in long-term care institutions 34 similarly did not find significant effect of vaccination in decreasing hospitalizations or confirmed

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cases of influenza among residents [9]. There is a paucity of randomized controlled trials that 1

2 directly assess the effect of vaccination mandates or campaigns on patient health. One European

3 trial that assessed the impact of a multi-faceted influenza vaccination program for health care

- 4 workers did find a 5.8 percent reduction in nosocomial cases of influenza and/or pneumonia among
- 5 hospitalized patients [10].
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7 Critics have observed significant methodological flaws in these studies, including multiple sources 8 of bias and violation of the principle of dilution, casting doubt on the studies' validity [6,7]. This 9 has led proposals for alternatives to mandatory vaccination of health care workers, such as 10 strategies to reduce "presenteeism" (working while ill), which can drastically affect the

- transmission of influenza [6]. 11
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13 LAW & POLICY

14

15 Law and policy throughout the United States require immunizations or other documentation of 16 immunity as a condition of public school attendance and, in some cases, as a condition of 17 employment [11]. Historically, in decisions in Jacobson v. Massachusetts [12] and Zucht v. King 18 [13], the U.S. Supreme Court has held that states can mandate immunizations to protect public 19 health, but, if they do, they must also allow medical exemptions. Courts have further held that the 20 exemption process must not violate the individual's constitutional rights. Thus, most states must 21 also provide for non-medical exemptions to accommodate religious beliefs of some individuals 22 who oppose immunization [14]. Some states also provide non-medical exemptions for individuals 23 who oppose immunization for personal or philosophical reasons [14].

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25 State laws mandating vaccination of health care workers vary across the country. For example, as of 2017, eight states require that a hospital "ensure" its health care personnel are vaccinated for 26 seasonal influenza; 11 others require only that hospitals "offer" a flu vaccine to their employees 27 28 [15]. States also vary with respect to whether they recognize exemptions and which exemptions— 29 medical, religious, philosophical—they allow [15].

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31 Employers of health care workers may implement their own mandatory vaccination programs 32 under contractual employment law, as hundreds of facilities around the country have done [16]. 33 Title VII of the Civil Rights Act prohibit religious discrimination and thus requires that employers 34 consider religious exemptions to vaccination and implement such exemptions so as to ensure that 35 any vaccine mandate is nondiscriminatory. Employers must also generally ensure that mandatory 36 vaccination programs allow appropriate medical exemptions for individuals with a disability that would be adversely affected by vaccination [17]. In requiring employers to keep the workplace free 37 38 of hazards, the Occupational Health and Safety Act may impose a duty on employers to encourage or mandate vaccination to prevent employees from contracting or spreading serious diseases in the 39 workplace [17].

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42 Policies of the AMA House of Delegates generally support physician immunization. H-225.959,

43 Staff Medical Testing, maintains that, when local statute and regulation do not provide for immunization of health care personnel, hospital medical staffs should determine which tests or 44 immunizations are to be required for members of the medical staff and "delineate under what 45

- 46 circumstances such tests or immunizations should be administered."
- 47

48 Policy also opposes non-medical exemptions, including non-medical exemptions from mandated

- 49 pediatric immunizations. H-440.970, Non-Medical Exemptions from Immunization, supports
- 50 eliminating non-medical exemptions from immunization and encourage physicians to grant 51 exemption requests "only when medical contraindications are present." AMA policy further

1 supports restricting the activity of medical staff who are not immunized. In the specific context of

2 Hepatitis B, for example, <u>H-440.949</u>, Immunity to Hepatitis B Virus, requires that medical staff

3 who do not have immunity from a natural infection or who have not been immunized, "either be

4 immunized or refrain from performing invasive procedures."

5 6 PHY

PHYSICIANS' ETHICAL RESPONSIBILITIES

- Physicians have well-recognized professional responsibilities to protect the health of their
  individual patients (<u>Principle VIII</u>, <u>Opinion 8.11</u>, "Health Promotion and Disease Prevention").
  They also have responsibilities to protect the health of the community at large (<u>Principle VII</u>,
  <u>Opinion 8.3</u>, "Physicians' Responsibilities in Disaster Response and Preparedness"). And they
  have an obligation to protect their own health and that of their colleagues and other members of the
  health care workforce (<u>Principle X</u>, <u>Opinion 9.3.1</u>, "Physician Health and Wellness"; Opinion 8.3;
  Opinion 8.4, "Ethical Use of Quarantine and Isolation").
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16 Responsibility to Protect

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18 In the context of a health care crisis—e.g., epidemic, disaster, or terrorism—physicians' ethical 19 obligation is to subordinate their personal interests to those of their patients. Their first duty, set out 20 in Opinion 8.3, is to "provide urgent medical care . . . even in the face of greater than usual risk to physicians' own safety, health or life." Opinion 8.3 recognizes that the physician workforce itself is 21 22 not an unlimited resource, however. Thus, physicians are expected to assess the risks of providing 23 care to individual patients in the moment against the ability to provide care in the future. Opinion 8.4 similarly requires physicians to "protect their own health to ensure that they remain able to 24 25 provide care."

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27 Taken together, these considerations argue strongly for a responsibility on the part of physicians to 28 accept immunization against vaccine-preventable diseases—unless there are compelling reasons for the individual not to receive a specific vaccine. Medical exemptions from vaccination are intended 29 30 to prevent harm to individuals who are at increased risk of adverse events from the vaccine because 31 of underlying conditions. Vaccines are medically contraindicated for individuals who have 32 histories of severe allergic reactions from prior doses of vaccine. Many underlying conditions also 33 place individuals at increased risk of complications from certain vaccines as well as from the 34 diseases they prevent. For example, individuals who are severely immunocompromised should not 35 be inoculated with vaccines containing live attenuated viruses, such as the varicella zoster (chicken 36 pox or shingles) or measles, mumps, and rubella (MMR) vaccines [18]. Individuals for whom vaccines are medically contraindicated are protected from exposure to vaccine-preventable diseases 37 38 through herd immunity by ensuring high rates of coverage among the rest of the population. 39

40 The relative strength of the responsibility to accept vaccination is conditioned on several factors, 41 including how readily a given disease is transmitted; what medical risk the disease represents for patients, colleagues, and society; the individual's risk of occupational exposure; the safety and 42 43 efficacy of available vaccine(s); the effectiveness and appropriateness of immunization relative to other strategies for preventing disease transmission; the medical value or possible contraindication 44 45 of immunization for the individual [19], and the prevalence of the disease. Unless medically contraindicated, the more readily transmissible the disease and the greater the risk to patients and 46 47 others with whom the physician comes into contact relative to risks of immunization to the 48 physician, the stronger the physician's duty to accept immunization. Physicians should not be 49 required to accept immunization with a novel agent until and unless there is a body of scientifically 50 well-regarded evidence of safety and efficacy.

1 It is not ethically problematic to exempt from vaccination an individual with medical 2 contraindications. Ethical concerns arise when individuals are allowed to decline vaccinations for 3 non-medical reasons. The rationale for non-medical exemptions must strike a prudent balance

4 among multiple interests and values, including the welfare of individuals, groups and communities;

5 respect for civil liberties and autonomy; and fairness.

6

7 In general, society respects individuals' freedom to make health care decisions for themselves in 8 keeping with their religious commitments, and within limits, decisions based on personal beliefs 9 that are not encoded in specific religious doctrine per se. Ideally, those beliefs will comprise a 10 "substantive, coherent, and relatively stable set of values and principles" to which the individual is genuinely committed and that are reflected broadly in the individual's decisions and actions [20]. 11

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13 Individuals who have direct patient contact should rightly expect their autonomy to be respected when their personal health choices do not put others at risk of harm [21]. In certain circumstances 14 15 physicians should refrain from being immunized in order to protect the well-being of their patients: 16 for example, if receiving a live virus vaccine would put immune-compromised or never-immunized 17 patients at risk during the time the physician may transmit the attenuated virus.

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19 Aside from these limited circumstances, however, physicians and other health care workers who 20 decline to be vaccinated do put others at risk for vaccine-preventable disease. In deciding whether to decline vaccination, therefore, physicians have a responsibility to strike an ethically acceptable 21 22 balance between their personal commitments as moral individuals and their obligations as medical 23 professionals. Those who cannot or choose not to be immunized when a safe, effective, and well-24 tested vaccine is available must take other steps to protect themselves and those to whom they may 25 transmit a vaccine-preventable disease, which may include refraining from patient contact.

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27 Arguably, physicians' responsibility to protect patients' well-being extends to ensuring that all staff 28 in their own practices are vaccinated, absent medical contraindication; when they or their staff are 29 not immunized, physicians must protect themselves and patients in other ways. At a minimum, 30 physician-leaders in practices and health organizations should require that staff who come into 31 contact with high-risk patients take appropriate protective measures.

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Responsibility to Promote Shared Decision Making 33

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35 As trusted sources of information and guidance, physicians can play a significant role in shaping 36 their patients' perspectives about vaccines and the decisions patients make about immunizing 37 themselves and their families [22-27]. In keeping with practices recognized for increasing uptake of childhood immunizations, physicians have a responsibility to educate patients about the risks of 38 39 forgoing or delaying a recommended immunization [28]. Exploring with vaccine hesitant patients 40 their reasons for declining recommended immunizations is crucial. Vaccine hesitant patients 41 commonly misunderstand physicians' motivation for urging immunization, but when reminded that their physician is motivated first and foremost by their welfare instead of public health concerns are 42 43 more receptive to considering immunization [28]. Candor, willingness to listen, encouraging questions, and respectfully acknowledging patients'-or parents-concerns are essential elements 44 of conversations with vaccine-hesitant individuals [28]. 45

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47 Physicians also serve as role models for their patients, consciously or otherwise. Physicians who

48 adhere to immunization requirements and recommendations for themselves and their children can

49 be powerful motivators for patients, colleagues, and others in the community to pursue

50 immunization [2]. Physicians can take advantage of their power to motivate by communicating that they themselves have been immunized. By the same token, physicians who fail to follow their own advice risk compromising patients' trust and undermining their credibility as advisors.

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- **RESPONSIBILITIES OF HEALTH CARE INSTITUTIONS**
- Medicine is fundamentally a moral activity, and as sites in which that activity is carried out, health care institutions share the profession's "commitment to fidelity and service" [29]. They have obligations to the communities of patients the institution serves, to the physicians and other health care professionals who provide hands-on care, and to the other personnel who support those activities. <u>Opinion 11.2.6</u>, "Mergers of Secular and Religiously Affiliated Institutions," holds that "[p]rotecting the community that the institution serves as well as the integrity of the institution, the physicians and other professionals who practice in association with it" is an essential responsibility.
- 12 13

14 Health care institutions discharge this responsibility by proactively developing policies and 15 procedures for responding to epidemic or pandemic disease with input from practicing physicians, 16 institutional leadership, and appropriate specialists. Such policies and procedure should include 17 robust infection control practices, providing appropriate protective equipment, and a program for 18 making appropriate immunization readily available to staff. During outbreaks of vaccine-19 preventable disease for which there is a safe, effective vaccine, institutions' responsibility may 20 extend to requiring immunization of their staff. Health care institutions have a further responsibility 21 to limit patient and staff exposure to individuals who are not immunized, which may include 22 requiring unimmunized individuals to refrain from patient care activities or other direct patient 23 contact.

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## 25 RECOMMENDATION

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In light of these considerations, the Council on Ethical and Judicial Affairs recommends that
Opinion 8.7, "Routine Universal Immunization of Physicians," be amended by insertion and
deletion as follows and that the remainder of this report be filed:

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31 As professionals committed to promoting the welfare of individual patients and the health of the public and to safeguarding their own and their colleagues' well-being, physicians have an 32 33 ethical responsibility to encourage patients to accept immunization when the patient can do so 34 safely, and to take appropriate measures in their own practice to prevent the spread of 35 infectious disease in health care settings. Conscientious participation in routine infection 36 control practices, such as hand washing and respiratory precautions is a basic expectation of the profession. In some situations, however, routine infection control is not sufficient to protect 37 38 the interests of patients, the public, and fellow health care workers. 39

In the context of a highly transmissible disease that poses significant medical risk for
vulnerable patients or colleagues, or threatens the availability of the health care workforce,
particularly a disease that has potential to become epidemic or pandemic, and for which there is
an available, safe, and effective vaccine, physicians should:

Accept have a responsibility to accept immunization absent a recognized medical, religious, or
 philosophic reason to not be immunized contraindication or when a specific vaccine would
 pose a significant risk to the physician's patients.

- 49 (b) Accept a decision of the medical staff leadership or health care institution, or other
- 50 appropriate authority to adjust practice activities if not immunized (e.g., wear masks or refrain

1	from direct patient care). It may be appropriate in some circumstances to inform patients about
2	immunization status.
3	
4	Physicians who are not or cannot be immunized have a responsibility to voluntarily take
5	appropriate action to protect patients, fellow health care workers and others. They must adjust
6	their practice activities in keeping with decisions of the medical staff, institutional policy, or
7	public health policy, including refraining from direct patient contact when appropriate.
8	
9	Physician practices and health care institutions have a responsibility to proactively develop
10	policies and procedures for responding to epidemic or pandemic disease with input from
11	practicing physicians, institutional leadership, and appropriate specialists. Such policies and
12	procedures should include robust infection control practices, provision and required use of
13	appropriate protective equipment, and a process for making appropriate immunization readily
14	available to staff. During outbreaks of vaccine-preventable disease for which there is a safe,
15	effective vaccine, institutions' responsibility may extend to requiring immunization of staff.
16	Physician practices and health care institutions have a further responsibility to limit patient and
17	staff exposure to individuals who are not immunized, which may include requiring
18	unimmunized individuals to refrain from direct patient contact.
19	
20	(Modify HOD/CEJA Policy)

Fiscal Note: Less than \$500

## REFERENCES

- 1. Talbott TR, Bradley SF, Cosgrove SE, et al. Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. *Infect Control Hosp Epidemiol*. 2005;26(11):882-890.
- Talbott TR, Schaffner W. On Being the First: Virginia Mason Medical Center and Mandatory Influenza Vaccination of Healthcare Workers. *Infect Control Hosp Epidemiol*. 2010; 31(9): 889–891.
- 3. Rakita RM, Hagar BA, Crome P, Lammert JK. Mandatory influenza vaccination of healthcare workers: a 5-year study. *Infect Control Hosp Epidemiol*. 2010;31(9): 881-888.
- 4. Frederick J, Brown AC, Cummings DA, et al. Protecting healthcare personnel in outpatient settings: the influence of mandatory versus nonmandatory influenza vaccination policies on workplace absenteeism during multiple respiratory virus seasons. *Infect Control Hosp Epidemiol.* 2018;39:452–461.
- 5. Anikeeva O, Braunack-Mayer A, Rogers, W. Requiring influenza vaccination for health care workers. *Am J Public Health*. 2009;99:24–29.
- 6. Edmond MB. Mandatory flu vaccine for healthcare workers: not worthwhile. *Open Forum Infect Dis.* 2019; 6(4):ofy214.
- 7. De Serres G, Skowronski DM, Ward BJ, et al. Inuenza vaccination of healthcare workers: critical analysis of the evidence for patient benet underpinning policies of enforcement. *PLoS ONE*. 2017; 12(1): e0163586.
- Ahmed F, Lindley MC, Allred N, Weinbaum CM, Groshkopf L. Effect of Influenza Vaccination of Healthcare Personnel on Morbidity and Mortality Among Patients: Systematic review and grading of evidence. *Clin Infect Dis.* 2014; 58(1):50–57.
- 9. Thomas RE, Jefferson T, Lasserson TJ. Influenza vaccination for healthcare workers who care for people aged 60 or older living in long-term care institutions [review]. *Cochrane Database of Systematic Reviews*. 2016;6. Art. No.: CD005187.
- Riphagen-Dalhuisen J, Burgerhof JG, Frijstein G, et al. Hospital-based cluster randomised controlled trial to assess effects of a multi-faceted programme on influenza vaccine coverage among hospital healthcare workers and nosocomial influenza in the Netherlands, 2009 to 2011. *Euro Surveill*. 2013;18(26):pii=20512.
- 11. Cole JP, Swendiman KS. Mandatory Vaccinations: Precedent and Current Laws. *Congressional Research Service*, 7-5700, May 21, 2014.
- 12. Jacobson v. Massachusetts, 197 US 11 (1905).
- 13. Zucht vs. King, 260 US 174 (1922).
- 14. Novak A., The Religious and Philosophical Exemptions to State-Compelled Vaccination: Constitutional and Other Challenges. U. Pa. J. Const. L. 2005;7(4):1101-1130.
- Centers for Disease Control and Prevention. Public Health Law: Menu of State Hospital Influenza Vaccination Laws. Available at<u>https://www.cdc.gov/phlp/docs/menu-</u> shfluvacclaws.pdf. Last updated: October 2017. Accessed: May 26, 2020.
- 16. Stewart AM, Caplan A, Cox MA, Chang KHM. Mandatory vaccination of health-care personnel: good policy, law, and outcomes. *Jurimetrics*. 2013;53(3):341-360.
- 17. Baxter TD. Employer-Mandated Vaccination policies: different employers, new vaccines, and hidden risks. *Utah Law Review*. 2017;5:885-938.
- Kroger AT, Sumava CV, Pickering LK, Atkinson WL. General recommendations on immunization—recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2011;60(2):1-60.
- 19. American Medical Association Council on Ethical and Judicial Affairs. *Report 5-I-10: Routine Universal Immunization of Physicians for Vaccine-Preventable Disease*. Available at <a href="https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/about-">https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/about-</a>

ama/councils/Council Reports/council-on-ethics-and-judicial-affairs/i10-ceja-routineuniversal-immunization-physicians-vpd.pdf. Accessed September 9, 2020.

- 20. Benjamin M. Splitting the Difference: Compromise and Integrity in Ethics and Politics. Lawrence, KS: University Press of Kansas, 1990.
- 21. Schwartz JL, Caplan AL. Vaccination refusal: ethics, individual rights, and the common good. *Prim Care Office Pract*. 2011;38:717-728.
- 22. Omer SA. Applying Kass's public health ethics framework to mandatory health care worker vaccination: the devil is in the details. *Am J Bioethics*. 2013;13(9):55-57.
- 23. Salmon DA, Moulton LH, Omer SB, et al. Factors associated with refusal of childhood vaccines among parents of school-aged children: a case-control study. *Arch Pediatr Adolesc Med*. 2005;159(5):470–476.
- 24. Gust DA, Darling N, Kennedy A, Schwartz B. Parents with doubts about vaccines: which vaccines and reasons why. *Pediatrics*. 2008; 122(4):718–725.
- 25. Smith PJ, Kennedy AM, Wooten K, et al. Association between health care providers' influence on parents who have concerns about vaccine safety and vaccination coverage. *Pediatrics*. 2006;118(5):e1287-e1292.
- 26. Levi BH. Addressing parents' concerns about childhood immunizations: a tutorial for primary care providers. *Pediatrics*. 2007;120(1):18–26.
- 27. Salmon DA, Pan WK, Omer SB, et al. Vaccine knowledge and practices of primary care providers of exempt vs vaccinated children. *Hum Vaccin*. 2008;4(4):286-291.
- 28. Diekema DS, American Academy of Pediatrics Committee on Bioethics. Responding to parental refusals of immunization of children. *Pediatrics*. 2005;115(5):1428–1431.
- 29. American Medical Association Council on Ethical and Judicial Affairs. *Report 1-A-11: Financial Relationships with Industry in Continuing Medical Education.* Available at https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/aboutama/councils/Council Reports/council-on-ethics-and-judicial-affairs/a11-ceja-financialrelationships-industry-cms.pdf. Accessed September 9, 2020.

#### REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS\*

CEJA Report 5-I-10

Subject:	Routine Universal Immunization of Physicians for Vaccine-Preventable Disease (Resolution 922-I-09, Resolution 928-I-09
Presented by:	John W. McMahon, Sr., MD, Chair
Referred to:	Reference Committee on Amendments to Constitution and Bylaws (Daniel B. Kimball, Jr., MD, Chair)

1 This report by the Council on Ethical and Judicial Affairs (CEJA) was developed in response to 2 Resolutions 922-I-09 and 928-I-09, which were both referred. Resolution 922-I-09, "Mandatory 3 H1N1 Vaccine for Health Care Workers," which was presented by the American Association of 4 Public Health Physicians, asks our CEJA and the Council on Science and Public Health jointly 5 study and issue guidance on mandatory H1N1 vaccination for health care workers. Resolution 6 928-I-09, "Mandatory Immunization of Health Care Workers Against Seasonal and 2009 7 H1N1 Influenza," which was presented by the Infectious Diseases Society of America, asks our 8 American Medical Association (AMA) to reaffirm its support for universal influenza vaccination 9 of health care workers and support universal immunization of health care workers against seasonal 10 and 2009 H1N1 influenza through mandatory vaccination programs except under certain defined 11 circumstances. The resolution further asked the AMA to support policies that require health care 12 workers who are not vaccinated to wear masks or be reassigned from direct patient care. 13 14 **INFECTIOUS DISEASE & PATIENT WELFARE** 15 Nosocomial infection is a major problem for patient safety.<sup>1</sup> Such infections result in prolonged 16 17 hospital stay, long-term disability, antimicrobial resistance, additional financial burden, high costs for patients and their families, and excess deaths.<sup>1</sup> Influenza outbreaks in particular can have 18

19 serious implications on patient morbidity and mortality. In the United States, an average season of 20 influenza results in tens of thousands of deaths and as many as 200,000 hospitalizations due to

influenza results in tens of thousands of deaths and as many as 200,000 hospitalizations due to
 influenza-related causes.<sup>2</sup> The burden of nosocomial infection is increased in high-risk patients
 such as the elderly, infants and children, pregnant women, those admitted to ICUs, and people who
 are chronically ill or immunocompromised.<sup>1,3</sup> Physicians and other health care workers play a role
 in both preventing and transmitting nosocomial infection.

25

26 Health care workers' constant contact with patients and infective material puts them at risk of

27 exposure to and possible transmission of disease, including vaccine-preventable disease.<sup>3-8</sup> Health

28 care workers are at no greater risk of infection than the general population for certain vaccine-

29 preventable diseases (such as tetanus, diphtheria, pneumococcal disease). Some diseases (such as

30 tuberculosis, hepatitis A, meningococcal disease, typhoid fever, vaccinia) put health care workers

31 at increased risk in certain circumstances (such as outbreaks or when worker has come in direct

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contact with disease). Still others (such as influenza, hepatitis B, measles, mumps, rubella, and 1 2 varicella) put health care workers at significant risk of acquiring and transmitting to their patient.<sup>5</sup> 3 4 For vaccine-preventable diseases, the most effective way to reduce transmission from health care 5 worker to patient is immunization.<sup>8</sup> Immunizing health care workers has the double benefit of directly protecting the health care worker and indirectly protecting the patients with whom they 6 7 come in contact.<sup>3,9</sup> For example, studies continue to show that immunizing health care workers for 8 influenza reduces patient morbidity and mortality in both acute and long-term care settings.<sup>8-12</sup> Immunization also creates herd immunity, protecting patient and health care workers who cannot 9 10 be vaccinated or for whom vaccine is unlikely to trigger a sufficient antibody response.<sup>9</sup> 11 Immunization helps to maintain the critical workforce during disease outbreaks, during which health care workers are the first line of defense.<sup>9</sup> In addition, by being vaccinated, physicians and 12 13 other health care workers set an example to their peers, patients, and the public concerning the importance of immunization.<sup>9</sup> 14 15 Most health care facilities require workers to be vaccinated against varicella, measles, mumps, and 16 rubella.<sup>9</sup> Health care workers are also expected to take part in comprehensive infection control 17 measures that reduce the risk of infectious disease transmission, including good hand hygiene and 18 respiratory control etiquette and the use of personal protective equipment.<sup>9</sup> 19 20 21 FUNDAMENTAL ELEMENTS OF IMMUNIZATION POLICIES 22 23 Despite documented benefits for patient safety and efforts by government agencies, regulatory groups, and such professional societies as the AMA to promote influenza vaccination among health 24 care workers, immunization rates remain low—around 40%,<sup>3,9,13</sup> although there is evidence that 25 immunization rates were higher during the 2009-2010 influenza season.<sup>14</sup> According to the Centers 26 for Disease Control (CDC), the ideal is "vaccination of 100% of employees who do not have 27 medical contraindications."<sup>15</sup> 28 29 30 A range of options is available to any institution contemplating a vaccine policy, including 31 voluntary immunization, routine universal immunization that permits exemptions on medical or 32 religious or philosophical grounds, or requiring health care workers to be immunized except when 33 that is medically contraindicated. While the CDC acknowledges that policies that work best to 34 achieve this coverage may vary among facilities, studies have demonstrated that coordinated 35 campaigns of education and outreach to address concerns and vaccination can lead to higher rates 36 of immunization among health care workers.<sup>15</sup> 37 38 Thus educational programs that center on a message of patient safety can be effective in dispelling 39 myths—for example, that health care workers are not at risk of influenza or that the influenza 40 vaccine is unsafe or ineffective-and increase immunization rates. During the 2009-2010 41 influenza season, Veterans Health Administration health care facilities vaccinated 64% of employees through the system-wide "Infection: Don't Pass it On" campaign.<sup>16</sup> Strong support 42 from senior medical staff and leaders at health care institutions is also associated with higher 43 acceptance of vaccination among health care workers,<sup>6,9,17</sup> and convenient access to vaccines 44 provided at no cost has been shown to substantially improve vaccine coverage.<sup>5,17,18</sup> At a 45 minimum, accredited health care institutions are required by Joint Commission standards to offer 46 influenza vaccination to staff.<sup>7,9,19</sup> 47

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49 Though controversial, a highly effective approach to achieving high vaccination coverage among

50 health care workers is a mandatory vaccination policy, exempting only those with a medical

51 contraindication.<sup>9,14</sup> The CDC estimates that in 2009, employer requirements or recommendations

for vaccination were associated with an eightfold and fourfold greater likelihood of vaccination for 1 2 2009 H1N1, respectively.<sup>14</sup> Hospitals and health care systems that have required vaccination of health care workers often have achieved coverage rates of over 90%.<sup>9</sup> 3 4 5 Efforts to increase vaccination coverage among health care workers using mandatory vaccination 6 policies are supported by various national accrediting and professional organizations, including the 7 World Medical Association, American College of Physicians, Infectious Diseases Society of 8 America, Society for Healthcare Epidemiology of America, National Foundation for Infectious Diseases, National Patient Safety Foundation, and National Quality Forum.<sup>6,8,9,13,15,20-22</sup> All of these organizations allow exemptions for a medical contraindication, <sup>6,8,9,13,15,20-22</sup> while only some support 9 10 exemptions for religious or philosophical objections.<sup>6,7,9,21</sup> 11 12 13 Health care institutions and physician groups have begun to implement policies that require influenza vaccination as a condition of employment. For example, BJC Healthcare in St. Louis 14 15 (BJC) made influenza vaccination a condition of employment prior to the 2008-2009 season-and provided vaccines for free at multiple locations.<sup>9,23</sup> Those employees who were neither vaccinated 16 nor exempted for medical or religious objections by a certain date were suspended.<sup>9,23</sup> Those 17 employees who were granted an exemption were encouraged to wear an isolation mask while 18 providing patient care during the flu season.<sup>9,23</sup> BJC implemented the condition as part of an 19 aggressive patient safety initiative marketed through managers, educational materials, letters to 20 employees, articles on the institution's intranet site, and town hall meetings.<sup>9,23</sup> As a result, BJC's 21 influenza vaccination rate greatly increased, to 98.4% from less than 80% the previous year.<sup>9,23</sup> 22 23 24 Other institutions require immunization for influenza, but allow health care workers to opt out so 25 long as they justify their intent to refrain from vaccination—often in writing—to the institution. 26 Some institutions restrict the patient care activities of employees who have not been immunized for 27 influenza. Some, like Johns Hopkins Health System, have implemented both policies. The health 28 system requires all staff, students, volunteers, and personnel who have direct patient contact to 29 receive the influenza vaccine or complete an online questionnaire identifying their reasons for 30 declining vaccination.<sup>20</sup> Vaccinated staff wear a yellow ID badge clip, while nonvaccinated staff must wear a mask when they come within three feet of patients.<sup>20</sup> 31 32 Pursuant to their power to protect the public health, states have regulations that promote the 33 vaccination of health care workers against influenza.<sup>24</sup> The state's power to mandate vaccinations 34 in the interest of the public health has been established since 1905.<sup>26</sup> Many states simply require 35 36 hospitals to have a vaccination policy, some direct health care facilities to offer influenza 37 vaccination to their employees, while still other states require that health care workers receive influenza vaccination or indicate a religious, medical, or philosophic reason for not being 38 vaccinated.<sup>26</sup> California, for example, requires employees of general acute care hospitals to be

- vaccinated.<sup>26</sup> California, for example, requires employees of general acute care hospitals to be
   vaccinated annually against influenza or to sign a written declination explaining their refusal,<sup>26-28</sup>
- while Maine requires designated health facilities to adopt a policy that recommends and offers
   annual immunization to health care personnel who provide direct care for residents of the facility.<sup>26</sup>
- 42 annual infinitumization to hearth care personner who provide direct care for residents of the facility.
   43 Alabama requires hospitals to establish vaccination requirements for employees that are consistent
   44 with current CDC and OSHA recommendations.<sup>26</sup>
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# 46 ETHICAL CONSIDERATIONS

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48 Confronting the ethical challenges posed by infectious disease requires physicians to strike a

- 49 prudent balance among multiple interests and values. Patient welfare, respect for individual
- 50 liberties and decision-making autonomy, and fair implementation must all play a role in strategies
- 51 to prevent transmission of disease.

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1 Primacy of patient interests is one of the cornerstones of medical ethics. As the preamble to the

2 Principles of Medical Ethics notes, as members of the medical profession, physicians "must

recognize responsibility to patients first and foremost...." It is also well established that physicians must not place their patients at undue risk of harm,<sup>15,29</sup> including risk of infectious disease (E-9.13, 3

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5 Physicians and Infectious Diseases [AMA Policy Database]). Physicians' ethical obligation to

6 subordinate their personal interests to those of patients is even greater in times of health crises,

7 such as epidemic or pandemic (E-9.067, Physician Obligation in Disaster Preparedness and 8 Response).

9

10 Physicians also have well-recognized responsibilities to the community, including the ethical

11 obligation to promote the health of the public (Preamble; Principle VII; E-2.25, The Use of

12 Quarantine and Isolation as Public Health Interventions; E-9.067). Finally, physicians have a

13 responsibility to protect their own health and well-being, grounded in their professional commitment to ensure adequate availability of care<sup>13</sup> (Principle X; E-9.067). 14

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16 These considerations support a professional ethical obligation on the part of physicians to take all 17 reasonable actions to prevent the transmission of disease, including accepting immunization for 18 vaccine-preventable diseases. A variety of factors influence the relative strength of that obligation,

19 such as how readily a given disease is transmitted; the medical risk the disease represents for

20 patients, professional colleagues, and the intimates of all parties; risk of occupational exposure; the

21 safety and efficacy of available vaccine(s); appropriateness and effectiveness of immunization

22 relative to alternative strategies for disease prevention; medical value of vaccination to the

23 individual; and potential contraindications to vaccination for the individual physician or health care 24 worker.

25

At the same time, physicians have a right to expect that their personal liberties and autonomy as 26 27 decision makers will be respected and that they will be treated fairly. For example, the Code of 28 *Medical Ethics* recognizes that—within certain limits—physicians may choose whom they will 29 treat and in what environments they will practice medicine. (Principle VI: E-10.05, Potential 30 Patients). Thus physicians should be able to expect that they will not be put at undue or 31 unnecessary risk by being required to accept immunization that is medically contraindicated in 32 their individual circumstances. They should also be able to expect that strongly held personal 33 values will be respected when they decline in good faith to be vaccinated on religious or 34 philosophical grounds.

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36 But like the responsibility to accept immunization, physicians' autonomy as individuals is not 37 unlimited. Arguably, in entering the profession of medicine physicians accept certain constraints 38 on their behavior and decisions as individuals in exchange for the privileges of professional status 39 (E-9.067)<sup>30</sup> For example, physicians are expected to accept some level of personal risk in 40 providing care for patients (E-9.067; E-9.131, HIV-Infected Patients and Physicians). In the 41 context of preventing the transmission of infectious disease, it is reasonable to require that 42 physicians who decline to be vaccinated take other precautions to protect patients, such as wearing 43 a mask or refraining from close patient contact. Such requirements carry particular weight in the 44 context of highly infective diseases that carry the risk of becoming epidemic or pandemic or that 45 pose significant medical risk to vulnerable populations with whom the physician comes in contact. 46

47 As respected professionals and leaders in health care institutions, physicians are in a position to be 48 role models for the public, their patients, and their colleagues and fellow employees by setting the

49 example of being immunized for vaccine-preventable diseases. Within their institutions, physician-

50 leaders can also take responsibility for promoting immunization policies that are scientifically well

51 grounded, balanced, and procedurally fair. When it has been determined that vaccination will be

1 required absent medical contraindications or religious/philosophical objections, leaders of the 2 medical staff must ensure that there is an appropriate process in place to review an individual 3 physician's justification for declining vaccination and to communicate the individual's decision to 4 colleagues. As we have seen, experience to date indicates that the programs that are most 5 successful in promoting immunization among physicians and other health care workers combine 6 vigorous efforts to educate staff and address concerns and possible misconceptions, strongly 7 promote acceptance of immunization and make it easy for individuals to be vaccinated, and set 8 clear expectations for how unvaccinated individuals will interact with patients. The most 9 successful programs also set meaningful consequences for those who decline to be vaccinated and 10 communicate them clearly. 11 12 As professionals committed to promoting the welfare of individual patients and the health of the 13 public and to safeguarding their own and their colleagues' well-being, physicians have an ethical responsibility to take appropriate measures to prevent the spread of infectious disease. In the 14 15 context of vaccine-preventable diseases, this includes the obligation to accept immunization, absent contraindication, against highly transmissible diseases that pose significant medical risk to patients, 16 17 the public, and fellow health care workers. They should expect that when the policies of health care institutions do not recognize refusals of immunization on religious or philosophical grounds, 18 19 those policies will be transparent and will be communicated to physicians and other staff in 20 advance. 21 22 RECOMMENDATION 23 24 The Council on Ethical and Judicial Affairs recommends that the following be adopted in lieu of 25 Resolution 922-I-09 and Resolution 928-I-09, and that the remainder of this report be filed: 26 27 As professionals committed to promoting the welfare of individual patients and the health of 28 the public and to safeguarding their own and their colleagues' well-being, physicians have an ethical responsibility to take appropriate measures to prevent the spread of infectious disease in 29 30 health care settings. Conscientious participation in routine infection control practices, such as 31 hand washing and respiratory precautions is a basic expectation of the profession. In some situations, however, routine infection control is not sufficient to protect the interests of patients, 32 33 the public, and fellow health care workers. 34 35 In the context of a highly transmissible disease that poses significant medical risk for 36 vulnerable patients or colleagues, or threatens the availability of the health care workforce, 37 particularly a disease that has potential to become epidemic or pandemic, and for which there is 38 an available, safe, and effective vaccine, physicians have an obligation to: 39 40 (a) Accept immunization absent a recognized medical, religious, or philosophic reason to not 41 be immunized. 42 43 (b) Accept a decision of the medical staff leadership or health care institution, or other 44 appropriate authority to adjust practice activities if not immunized (e.g., wear masks or 45 refrain from direct patient care). It may be appropriate in some circumstances to inform 46 patients about immunization status. 47 48 (New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than \$500 to implement.

## REFERENCES

- 1. Centers for Disease Control. Guideline for Hand Hygiene on Health Care Settings. <u>Morbidity</u> <u>and Mortality Weekly Report</u>. 2002;51(RR-16).
- 2. Centers for Disease Control. Estimates of Deaths Associated with Seasonal Influenza United States, 1976-2007. Morbidity and Mortality Weekly Report. 2010;59(3):1057-1089.
- Douville LE, Myers A, Jackson MA, Lantos JD. Health Care Worker Knowledge, Attitudes, and Beliefs Regarding Mandatory Influenza Vaccination. <u>Arch Pediatr Adolesc Med</u>. 2010;164(1):33-37.
- 4. For a list of current vaccine-preventable diseases, go to http://www.cdc.gov/vaccines/vpd-vac/vpd-list.htm.
- Centers for Disease Control. Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). <u>Morbidity and Mortality Weekly Report</u>. 1997;46(RR-18):1-42.
- Talbot TR, Bradley SF, Cosgrove SE, Ruef C, Siegel JD, Weber DJ. SHEA Position Paper: Influenza Vaccination of Healthcare Workers and Vaccine Allocation for Healthcare Workers During Vaccine Shortages. <u>Infect Control & Epidemiol</u>. 2005;26(11):882-890.
- 7. American College of Physicians. Policy on Influenza Vaccination of Health Care Workers. http://www.acponline.org/clinical\_information/resources/adult\_immunization/flu\_hcw.pdf.
- 8. National Foundation for Infectious Diseases. Improving Influenza Vaccination Rates in Health Care Workers. 2004. http://www.nfid.org/pdf/publications/hcwmonograph.pdf.
- Talbot TR, Babcock H, Caplan AL, Cotton D, Maragakis LL, Poland GA, et al. Revised SHEA Position Paper: Influenza Vaccination of Healthcare Personnel. <u>Infect Control & Epidemiol</u>. 2010;31(10).
- Lugo NR. Will Carrots or Sticks Raise Influenza Immunization Rates of Health Care Personnel? <u>Am J Infect Control</u>. 2007;35(1):1-6.
- 11. Potter J, et al. Influenza Vaccination of Healthcare Workers in Long Term Care Hospitals Reduced the Mortality of Elderly Patients. J Infect Dis. 1997;165:1-6.
- Carman WF, Elder AG, Wallace LA, et al. Effects of Influenza Vaccination of Health-care Workers on Mortality of Elderly People in Long-term Care: A Randomised Controlled Trial. <u>Lancet</u>. 2000;355(9198):93-97.
- 13. Wynia MK. Mandating Vaccination: What Counts as a "Mandate" in Public Health and When Should They Be Used? <u>Am J Bioethics</u>. 2007;7(12)2-6.
- Centers for Disease Control. Interim Results: Influenza A (H1N1) 2009 Monovalent and Seasonal Influenza Vaccination Coverage Among Health-Care Personnel — United States, August 2009–January 2010. <u>Morbidity and Mortality Weekly Report</u>. 2010;59(12):357-383.
- 15. Centers for Disease Control. Prevention and Control of Influenza with Vaccines (Early Release). <u>Morbidity and Mortality Weekly Report</u>. 2010;59:1-62.
- 16. Department of Veterans Affairs. VA Influenza Manual 2009/2010. Available at http://www.publichealth.va.gov/docs/flu/VA influenza manual09-10.pdf.
- 17. Centers for Disease Control. Influenza Vaccination of Health-Care Personnel. <u>Morbidity and</u> <u>Mortality Weekly Report</u>. 2006;55(RR-2).
- 18. Rea E, Upshur R. Semmelweis Revisited: The Ethics of Infection Prevention Among Health Care Workers. <u>Can Med J</u>. 2001;164(10).
- 19. Joint Commission Standard IC.4.15 (effective July 1, 2007). Joint Commission Perspectives. 2006;26(6):10-11.
- 20. Immunization Action Coalition. Honor Roll for Patient Safety: Mandatory Influenza Vaccination Policies for Healthcare Workers. www.immunize.org/laws/influenzahcw.asp.
- 21. Infectious Diseases Society of America. IDSA Policy on Mandatory Immunization of Health Care Workers Against Seasonal and 2009 H1N1 Influenza. September 30, 2009.

- 22. World Medical Association. WMA Statement on Avian and Pandemic Influenza. Adopted by the WMA General Assembly, Pilanesberg, South Africa, October 2006.
- 23. Babcock HM, Gemeinhart N, Jones M, Dunagan WC, Woeltje KF. Mandatory Influenza Vaccination of Health Care Workers. <u>Clin Infect Dis</u>. 2010;50:459-464.
- 24. Swendiman KS. Mandatory Vaccinations: Precedent and Current Laws. CRS Report for Congress (Order Code RS21414). January 7, 2008.
- 25. Jacobson v. Commonwealth of Massachusetts, 197 U.S. 11 (1905).
- 26. Centers for Disease Control. Immunization Administration Requirements for Influenza. http://www2a.cdc.gov/nip/stateVaccApp/StateVaccsApp/AdministrationbyVaccine.asp?Vaccin etmp=Influenza#21. (last accessed August 2, 2010).
- 27. Parmet JE. Pandemic Vaccines The Legal Landscape. <u>N Engl J Med. 2010</u>;362(21):1949-1952.
- 28. Cal. Health & Safety Code § 1288.7 (2007).
- 29. Van Delden JJM, Ashcroft R, Dawson A, Marckmann G, Upshur R, Verweij MF. The Ethics of Mandatory Vaccination Against Influenza for Health Care Workers. <u>Vaccine</u>. 2008;26:5562-5566.
- 30. Daniels N. Duty to Treat or Right to Refuse? Hastings Center Report. 1991; 21:2:36-46.