HHS Public Access

Author manuscript

J Law Med Ethics. Author manuscript; available in PMC 2018 March 01.

Published in final edited form as:

J Law Med Ethics. 2017 March ; 45(1 Suppl): 16–19. doi:10.1177/1073110517703307.

The Latest in Vaccine Policies: Selected Issues in School Vaccinations, Healthcare Worker Vaccinations, and Pharmacist Vaccination Authority Laws

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Introduction

Vaccine policies have played a vital role in protecting the public's health through disease prevention. The Centers for Disease Control and Prevention (CDC) lists vaccination as one of the "Ten Great Public Health Achievements in the 20th Century" because of its tremendous impact on morbidity and mortality in the United States.[1] Despite these successes, recent outbreaks of certain vaccine-preventable diseases have been on the rise.[2] While measles was declared eliminated in the United States in 2000, there were 23 measles outbreaks and a reported 668 cases of the disease in the U.S. in 2014.[3] Intentionally unvaccinated individuals comprised a substantial proportion of the recent U.S. cases of measles,[4] suggesting a continued role for vaccine policies to increase vaccination rates and reduce disease outbreaks.

This paper identifies select state vaccine policies across the U.S. First, the paper discusses state legal frameworks for mandatory vaccination in the context of school and healthcare worker vaccination and corresponding litigation. The paper then turns to one policy approach to expanding vaccine access — specifically, state laws allowing pharmacists the authority to vaccinate.

Mandatory Vaccinations

School Entrance

All 50 states require children to receive certain vaccinations before attending public school, and often these requirements extend to children attending day care or private schools.[5] State laws permit exemptions from school vaccination requirements for medical (in all 50 states), religious (in 47 states), or philosophical reasons (in 18 states).[6] From late 2014 through early

2015, one measles outbreak originating from exposures at a theme park in California resulted in a total of 125 cases and spread throughout eight states.[7] California residents accounted for 110 of the 125 cases.[8] Of the California measles patients, 45% were unvaccinated for measles, and 43% had unknown vaccination status, with other patients receiving varying doses of measles vaccine.[9] Among the unvaccinated patients, which included 18 children aged 18 years or younger who contracted measles during the outbreak, a majority (67%) of vaccine-eligible patients intentionally were unvaccinated because of personal beliefs.[10]

The 2014–2015 measles outbreak spurred policy discussions regarding vaccine requirements and exemptions. During the 2015 legislative session two states, Vermont and California, passed legislation that made it more difficult for parents to seek exemptions from mandatory vaccination requirements.[11] Vermont's legislation removed the state's philosophical exemption but retained its religious vaccination exemption.[12] California's legislation restricted vaccine exemptions only to those seeking it for medical reasons (joining Mississippi and West Virginia as the only states permitting only medical exemptions to vaccines).[13] The legislation in California (Senate Bill 277) removed the state's philosophical exemption and the religious exemption.[14] Students entering daycare or school for the first time or advancing to seventh grade, except for homeschooled students, must now receive all mandatory vaccinations in order to attend school in the state, unless they have a medical reason for not doing so.[15]

Healthcare Worker Vaccination

Healthcare facilities are an additional setting in which vaccination requirements have been established. These vaccination requirements can be found in state statutes and regulations or be established by healthcare facility policy. Healthcare worker vaccination laws vary across states but generally fall into four categories: (1) laws requiring healthcare facilities to assess the vaccination status of healthcare workers, known as assessment requirements;[16] (2) laws requiring healthcare facilities to offer vaccination to healthcare workers, known as administrative offer requirements;[17] (3) laws requiring that healthcare workers be vaccinated or have a valid medical or religious exemption or other declination statement, known as administrative ensure requirements;[18] and (4) laws requiring healthcare workers who have not been vaccinated for influenza to wear surgical masks while at the workplace.[19]

State healthcare worker vaccination laws include requirements for vaccination for various diseases, including hepatitis B, influenza, measles, mumps, pertussis, pneumonia, rubella, and varicella. However, the requirements vary by state and by applicable healthcare facility. For example, 18 states have established influenza vaccination laws for hospital healthcare workers; 8 of these states have assessment requirements, 10 have administrative offer requirements, 8 have administrative ensure requirements, and 3 have surgical mask requirements.[20]

Litigation

Laws aimed at changing the immunization requirements landscape have not been without legal challenges. As described above, California removed non-medical exemptions to

vaccine requirements for school entrance. As of early September 2016, at least two lawsuits had been filed to challenge the new California law. The first lawsuit, filed in April 2016, raises several challenges to the law, including that the plaintiffs' children have a right to education regardless of vaccination status, and is still pending review by state court.[21] The second lawsuit, filed on July 1, 2016, by parents of children in California, plus additional nonprofit organizations, sought to suspend the bill's implementation.[22] The complaint included assertions that plaintiffs' children have "a right to be free from potentially dangerous medical interventions," and plaintiffs have concerns, based on their religious beliefs, about vaccines.[23] The plaintiffs' motion for a preliminary injunction to temporarily stop the law was denied on August 26, 2016,[24] and the plaintiffs voluntarily withdrew the lawsuit shortly thereafter.[25]

Mandatory healthcare worker vaccination policies have also led to litigation, with healthcare workers challenging healthcare facility policies that mandate vaccination. Although healthcare facilities generally have the authority to establish such policies, the adoption, implementation, and enforcement of these policies can be subject to various areas of law.[26] Successful challenges to these policies have arisen under various legal theories.[27]

For example, in *Virginia Mason Hospital v. Washington State Nurses Association*, a labor union representing nurses in the state of Washington challenged a hospital's mandatory vaccination policy. The union argued that adoption of the policy should not have been unilateral but instead bargained for, as required by the collective bargaining agreement between the parties.[28] An arbitrator found that the hospital could not unilaterally implement a mandatory vaccination policy, a decision that was later affirmed in federal court.[29] As demonstrated by this and other cases, healthcare facilities interested in mandatory vaccination policies might consider the impact of labor laws, as well as other areas of law including employment law, when adopting mandatory healthcare worker vaccination policies.

Expanding Vaccine Access

Pharmacist Vaccination Authority

Vaccination mandates for students and healthcare workers are not the only vaccination policy levers states have used. Many patients understand the benefits of immunization but have insufficient access to vaccination services.[30] Consequently, implementing laws that expand scopes of practice is another approach used by states to potentially expand vaccine access. Laws that authorize pharmacists to administer vaccines are one example of this approach that have achieved widespread adoption despite resistance from some physician groups.[31]

Pharmacists in all states administer vaccines, but state laws vary considerably on the scope of vaccination authority. A 2016 assessment of pharmacist vaccination authority found more than 200 distinct legal variables in state laws across 51 jurisdictions.[32] This assessment revealed three types of legal provisions that can significantly impact pharmacists' roles in vaccinations.

First, patient age restrictions can affect access to vaccination in several ways. Laws with lower patient age restrictions effectively increase the pool of patients that pharmacists can vaccinate. Additionally, certain vaccines are only effective if they are administered *before* exposure to the pathogen.[33] For example, some states permit pharmacists to administer the human papillomavirus (HPV) vaccine to adult patients; however, many adolescents become sexually active and are exposed to the virus before they turn 18.[34] In those situations, high age restrictions might limit access to *effective* vaccination.

Next, state vaccine restrictions also impact vaccination access. Pharmacists cannot provide vaccinations if the state law does not authorize their administration. Yet, the introduction of recommendations for newly licensed vaccines and changes in recommendations for existing vaccines (e.g., expanded populations, changes in dosing) can make it difficult for state policy makers to keep pace. Some states have employed a way to dynamically adapt their laws to new evidence without changing the letter of the law: authorizing pharmacists to administer vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).[35] Pharmacists in these states are permitted to follow the most recent ACIP guidance without having to wait for statutory or regulatory amendments.[36]

Third-party authorization requirements are another factor that could significantly affect pharmacists' ability to improve vaccine access. In many states, pharmacists must have an authorization from a third party before administering a vaccine.[37] These third-party authorization requirements can be either patient-specific (i.e., a prescription covering a named patient),[38] or general (i.e., a standing order).[39] Other laws go further and authorize pharmacists to administer vaccines independently without a third-party authorization.[40] Laws granting pharmacists prescriptive vaccination authority could improve access by removing administrative hurdles for certain safe vaccinations.

Conclusion

Recent outbreaks of vaccine-preventable diseases continue to keep state vaccine policy in the forefront of public health policy debates. States have implemented various vaccine policies in order to prevent these outbreaks. For example, in 2015, two states passed legislation making it more difficult for children to be exempt from mandatory childhood vaccines. Similarly, while some healthcare facilities have implemented mandatory vaccination policies for healthcare workers,[41] some states have opted to establish statutory or regulatory mandates for healthcare worker vaccination assessment, as well as offer and ensure requirements in an effort to increase vaccination rates for healthcare workers. Apart from vaccination mandates, states are expanding access to vaccination services by increasing the scope of practice for healthcare professionals, such as pharmacists. State laws show sustained expansion for pharmacist vaccination authority.[42] Many states have expanded pharmacists' prescriptive authority, the patient age-groups pharmacists may vaccinate, and the vaccines pharmacists may administer.[43] Vaccination's recognition as one of the Ten Great Public Health Achievements in the 20th Century is in part due to the state laws and policies that promote vaccination coverage and access. States have continued to deploy law and policy tools to support vaccination in the settings of school vaccination, healthcare worker vaccination, and pharmacist vaccination authority.

Acknowledgments

Disclaimer

The findings and conclusions in this article are those of the authors and do not necessarily represent the official positions of the Centers for Disease Control and Prevention.

Biographies

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References

1. Centers for Disease Control and Prevention. Ten Great Public Health Achievements in the 20th Century. *available at* <http://www.cdc.gov/about/history/tengpha.htm> (last visited January 5, 2017)
2. Phadke VK, Bednarczyk RA, Salmon DA, Omer SB. Association Between Vaccine Refusal and Vaccine-Preventable Diseases in the United States: A Review of Measles and Pertussis. Journal of the American Medical Association. 2016; 315(11):1149–1158. at 1150–1151, 1155. [PubMed: 26978210]
3. *Id.*
4. *Id.*
5. National Conference of State Legislatures. States with Religious and Philosophical Exemptions From School Immunization Requirements. *available at* <http://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx> (last visited January 5, 2016)
6. *Id.*
7. Zipprich J, Winter K, Hacker J, Xia D, Watt J, Harriman K. Measles Outbreak — California, December 2014–February 2015. Morbidity and Mortality Weekly Report. 2015; 64(6):153–154. at 153. [PubMed: 25695321]
8. *Id.*
9. *Id.*
10. *Id.*

11. Yang YT, Barraza L, Weidenaar K. Measles Outbreak as a Catalyst for Stricter Vaccine Exemption Legislation. Journal of the American Medical Association. 2015; 314(12):1229–1230. [PubMed: 26214397]
12. *Id.*
13. *Id.*
14. Lindley MC, Horlick GA, Shefer AM, Shaw FE, Gorji M. Assessing State Immunization Requirements for Healthcare Workers and Patients. American Journal of Preventive Medicine. 2007; 32(6):459–465. at 460. [PubMed: 17533060]
15. 6 Colo. Code Regs. 1011-1:II-10; 10 N.Y. Comp. Codes R. & Regs. 2.59; 31 R.I. Code R. 1–22:5.0.
16. See Lindley, *supra* note 14.
17. *Id.*
18. *Id.*
19. See *supra* note 15.
20. Hoss, A., Pepin, DA. Menu of State Hospital Influenza Vaccination Laws. CDC Public Health Law Program. Nov 25. 2015 updated 2016, *available at* <http://www.cdc.gov/phlp/docs/menu-shfluvacclaws.pdf> (last visited January 5 2016)
21. *Tamara Buck v. State of California*, First Amended Compl., Superior Court of the State of California, County of Los Angeles, Case No: BC 617766 (June 28, 2016); *Tamara Buck et al. v. Karen Smith*, Civil Docket, United States District Court, Central District of California (Western Division – Los Angeles), Case No. 2:16-cv-05111-GHK-MRW.
22. *Ana Whitlow v. State of California*, Compl., United States District Court, Southern District of California, Case No. 16-cv-1715 DMS (July 1, 2016).
23. *Id.*
24. *Ana Whitlow v. State of California*, Order Den. Pl.'s Mot. Prelim. Inj., United States District Court, Southern District of California, Case No. 16-cv-1715 DMS (August 26, 2016).
25. *Ana Whitlow v. State of California*, Notice of Voluntary Dismissal, United States District Court, Southern District of California, Case No. 16-cv-1715 DMS (August 31, 2016).
26. Najera RF, Reiss DR. First Do No Harm: Protecting Patients Through Immunizing Health Care Workers. Health Matrix. 2016; 26:363–402. at 380. [PubMed: 27263256]
27. *Id.*
28. *Virginia Mason Hospital v. Washington State Nurses Assoc.*, 2006 WL 27203, (D.W.A. 2006), aff'd, 511 F. 3d 908 (9th Cir. 2007).
29. *Id.*
30. Rimer, B., Harper, H., Witte, O. Accelerating HPV Vaccine Uptake: Urgency for Action to Prevent Cancer: A Report to the President of the United States from the President's Cancer Panel. National Cancer Institute; Feb. 2014 *available at* <http://deainfo.nci.nih.gov/advisory/pcp/annualReports/HPV/PDF/PCP_Annual_Report_2012-2013.pdf> (last visited January 5, 2017)
31. Hogue MD, Grabenstein JD, Foster SL, Rothholz MC. Pharmacist Involvement with Immunizations: A Decade of Professional Advancement. Journal of the American Pharmacy Association. 2005; 46(2):168–179. at 170. Hurley LP, Bridges CB, Harpaz R, et al. US Physicians' Perspective of Adult Vaccine Delivery. Annals Internal Medicine. 2014; 160(3):161–170. at 166.
32. Schmit, C., Reddick, A. Pharmacist Vaccination Laws. LawAtlas.org, Centers for Disease Control and Prevention; 2017. *available at* <http://lawatlas.org/datasets/pharmacist-vaccination> (last visited March 7, 2017)
33. See Rimer et al., *supra* note 15.
34. *Id.*
35. ARIZ. REV. STAT. ANN. § 32-1974; CAL. BUS. & PROF. CODE § 4052.8; CONN. GEN. STAT. ANN. § 20-633; IDAHO ADMIN. CODE r. 27.01.01.330; IOWA CODE ANN. § 155A.44(4); LA. STAT. ANN. § 37:1218.1; ME. REV. STAT. ANN. tit. 32, § 13831; MD. CODE ANN., HEALTH OCC. § 12-508; OHIO REV. CODE ANN. § 4729.41; S.C. CODE ANN. § 40-43-190(A)(2).
36. Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices. *available at* <https://www.cdc.gov/vaccines/acip/> (last accessed January 5, 2017)

37. See *supra* note 32.
38. ARIZ. ADMIN. CODE § R9-6-1301; IND. CODE ANN. § 25–26–13–31.2; LA. ADMIN. CODE tit. 46, pt. LIII, § 521; ME. REV. STAT. ANN. tit. 32, § 13831; N.C. GEN. STAT. ANN. § 90-85.15B; WY. R. & REGS. AI PHAR. CH. 16 s 3.
39. D.C. CODE ANN. § 3–1201.02(11)(A); FLA. STAT. ANN. § 465.189; KY. REV. STAT. ANN. § 315.010(19); OR. ADMIN. R. 855-019-0270; VT. ADMIN. CODE 20–4–1400:10.35; WIS. STAT. ANN. § 450.01(16)(k).
40. ARIZ. REV. STAT. ANN. § 32-1974; CAL. BUS. & PROF. CODE § 4052.8; IDAHO CODE ANN. § 54–1704; LA. STAT. ANN. § 37:1218; ME. REV. STAT. ANN. tit. 32, § 13831; WYO. STAT. ANN. § 33–24–157(a).
41. See Najera and Reiss, *supra* note 26.
42. See *supra* note 32.
43. *Id.*