

## EXECUTIVE SUMMARY

### THE EPIDEMIOLOGY OF U.S. IMMUNIZATION LAW: MANDATED COVERAGE OF IMMUNIZATIONS UNDER STATE HEALTH INSURANCE LAWS

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#### Introduction

This analysis provides an in-depth examination of state insurance mandates related to immunization coverage for children and adults. The analysis, carried out under a cooperative agreement funded by the National Immunization Program (NIP) of the Centers for Disease Control and Prevention (CDC), is the first in a series of nationwide studies of the “legal epidemiology” of immunization coverage under both public and private health insurance. It is designed to provide federal and state policy makers as well as other interested persons with information on the nature and extent of immunization coverage standards under U.S. law. The sources of law surveyed under this project span both federal and state law, as well as contracts of coverage between public and private sponsors of group health plans and health insurers and managed care organizations.

#### Background and Methodology

Immunizations are both basic clinical care as well as an essential public health activity with population-wide health implications. Many private health insurers include some level of immunization coverage for certain enrollees, although the extent to which the industry builds coverage into coverage design is unknown. Medicaid and the State Children’s Health Insurance Plan (SCHIP) establish comprehensive, “first dollar” coverage standards linked to CDC recommendations, and Medicare covers certain biologicals for program beneficiaries. There is no comprehensive source of information on the level of coverage established as a matter of law.

For a number of reasons, the focus on national immunization policy has intensified in recent years: increased concern regarding the achievement of national preventable disease goals; concerns about public health protection as a matter of national security; and a sustained interest in how health resources can be invested preventively to reduce long term health costs.

State legislatures play a primary role under U.S. law in regulating health insurance,<sup>1</sup> and their decisions regarding policy content affect the approximately 100 million non-elderly persons covered

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<sup>1</sup> Rand Rosenblatt, Sylvia Law, and Sara Rosenbaum, *Law and the American Health Care System* (Foundation Press, NY, NY, 1997) Ch. 2

by state-regulated health insurance plans. In the case of insurance plans subject to state law,<sup>2</sup> state mandates effectively establish a “coverage floor” below which coverage cannot fall. Thus, reviewing the extent of state immunization health insurance mandates is essential in examining the overall adequacy of health insurance financing for immunization services.

Most individual and group health insurance products sold in the U.S. today and regulated by state law are “defined benefit” in nature. “Defined benefit” refers to an insurance product that specifies coverage of particular services, benefits, and treatment procedures that are classified as falling within the scope of the insurance contract. When these services and benefits are medically necessary and not otherwise excluded in a particular case, an insurer or health plan will make payment on an enrollee’s behalf. In the absence of express statutory coverage standards, health insurers retain discretion over benefit design and content. Furthermore, unless statutes or contract provisions specify otherwise, health insurers and plan administrators preserve considerable discretion to interpret and apply the terms of their coverage arrangements and to determine precisely what level of coverage will be made available.<sup>3</sup> Thus, even where a law might ostensibly address a benefit, it may be drafted so broadly and ambiguously that insurers retain considerable flexibility to limit or minimize their risk exposure even where coverage was intended.

This retention of broad discretion even in the face of seemingly clear coverage “mandates” is relatively poorly understood; as a result, it is easy to think of a benefit as “mandated,” when in fact the coverage standards established under a law may be so vague as to not constitute a meaningful standard from a legal perspective. An example of such ambiguity would be a state law that mandates “appropriate” immunization coverage and yet remains silent on the meaning of the term “appropriate.” In such a case, insurers would retain the flexibility to ascribe their own meaning to the term: they could interpret “appropriate” in accordance with objective, evidence-based standards, or they may elect to define “appropriate” from their own vantage point. In sum, a law may appear to mandate coverage, yet may fail to address the most crucial legal issues in coverage, including the standard of coverage, the permissibility of patient cost sharing, the age groups of the enrollees for whom the coverage is recommended, the amount an insurer must pay for the coverage, or the circumstances under which out-of-network coverage must be provided in the case of network-style health insurance arrangements (the predominant insurance today).

In conducting this analysis, we compared state insurance mandates in effect as of 2003 against what is undoubtedly the “gold standard” in immunization practice, namely the recommendations of the Advisory Committee on Immunization Practices (ACIP). The ACIP is an official advisory body to the CDC; its charge is to provide the federal government with scientific advice on immunization practice. The ACIP issues formal practice recommendations as vaccine technology evolves and also makes recommendations concerning actual immunization practice in the context of both preventive care and the use of vaccines to treat disease. Thus, immunizations may be recommended either as a primary preventive service or as a form of secondary prevention (i.e., treatment).<sup>4</sup>

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<sup>2</sup> Self insured employee health benefit plans governed by ERISA would be exempt from such laws, as would be other federally regulated plans.

<sup>3</sup> Id.

<sup>4</sup> A primary preventive service would be made available to all individuals within a particular subgroup for whom a vaccination is recommended without regard to condition or diagnosis (e.g., children, elderly adults, or sexually active adolescents). A secondary preventive service in this context would be one that is specified for persons with certain diagnoses (for example, persons who are immunocompromised, for whom pneumococcal vaccines are recommended interventions).

To conduct this study, researchers reviewed state immunization laws using a typology that was developed in consultation with legal and immunization practice experts and that outlines the essential aspects of a comprehensive immunization coverage statute:

- Whether the state has developed an immunization mandate.
- Whether the law requires actual coverage or merely mandates an offer of coverage for a separate premium supplement.
- Whether all populations are protected by the mandate regardless of age, condition, or diagnosis.
- Whether the standard of coverage is specified or left to the insurer's own discretion.
- Whether otherwise applicable deductibles, coinsurance, copayments, or administration fees are imposed for immunizations.
- Whether coverage is preserved if the service is obtained from a non-network provider.<sup>5</sup>
- Whether insurers may exclude coverage under certain circumstances (e.g., where the immunization is available free of charge from a public source).
- Whether insurers must cover and pay at replacement cost or through direct delivery of biologicals to participating providers and health professionals.

Utilizing standard computerized legal research techniques, researchers conducted an on-line examination of state insurance laws that as of Winter 2003, regulated health insurance products sold in the state in either the individual or group market.<sup>6</sup> Thirty-three (33) jurisdictions were identified that maintain relevant statutes pertaining to immunizations. The evaluation was completed in two stages. First, researchers “unbundled” each statute into its components and compared each component against the elements of comprehensiveness, described above. Next, the elements were “rebundled” into four distinct, and increasingly relaxed hypothetical statutory “composites” in order to measure the number of state laws that could be considered “comprehensive” in their totality as opposed to each part. This part of the study focused on children, because of the virtual absence of coverage for adults. Due to the lack of statutory language, the “composite” test did not include either network or payment elements. The four comprehensiveness “composites” are depicted in Figure 1.

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<sup>5</sup> The United States Supreme Court has recently clarified that the regulation of provider networks constitutes regulation of the business of insurance. *Kentucky Association of Health Plans v Miller*, 123 S. Ct. 1471 (2003)

<sup>6</sup> The project was approved by the George Washington University Institutional Review Board, No. U010327ER.

**Figure 1.  
 Comprehensive Immunization Mandate “Composite” Statutes (Pediatric Coverage Only)**

Elements of composite statute	Composite 1	Composite 2	composite 3	composite 4
Age groups covered by mandate	Birth-18	Birth-18, or any subgroup	Birth-18, or any subgroup	Birth-18, or any subgroup
Standard of coverage	ACIP	ACIP	ACIP	ACIP, or another objective standard
Deductibles and cost sharing	Prohibited	Prohibited	Prohibited, or deductibles prohibited but copayments allowed	Prohibited, or deductibles prohibited but copayments allowed
States meeting standard	NONE	HI	HI, PA	AR, KS, HI, MN, MS, MO, NE, NY, NC, OK, PA, TX, VA, WV, WI
Cumulative Total	0	1	2	15

Note: The remaining 18 states with immunization statutes do not meet any of these composites.

## Findings

### *Any Immunization Coverage Mandate*

As of the winter 2003, 32 states and the District of Columbia utilized insurance laws that at least to some extent mandated immunization coverage: Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Kansas, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, Texas, Virginia, West Virginia, and Wisconsin.

### *Scope of Immunization Coverage Mandate*

Among the jurisdictions with any mandate:

- Fifteen states explicitly apply the mandate to both the group and individual insurance markets: (Colorado, Georgia, Kansas, Maryland, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Mexico, New York, Ohio, Oklahoma, Texas, Virginia)
- Seven states explicitly restrict the mandate to the group market: (California, Connecticut, Delaware, Hawaii, Louisiana, New Jersey, West Virginia)
- Eight statutes address all contracts of insurance (a general market): (Arkansas, District of Columbia, Illinois, Michigan, North Carolina, North Dakota, Rhode Island, Wisconsin), while three state laws explicitly refer to both the general and group markets: (Florida, Massachusetts, Pennsylvania)

### *Mandated Coverage versus Mandated Offer of Coverage*

All states except Mississippi mandate at least some actual coverage, although the precise nature of the mandate can vary in some cases. Mississippi mandates *an offer of coverage* rather than coverage itself. A mandated offer of coverage makes the selection of coverage potentially eligible for an additional premium charge, a factor that might cause some individual and group purchasers to reject the option. California has a mandatory offer provision applicable only to self-insured employer-sponsored health plans (in contrast to the state's mandatory coverage requirement in the insured market).<sup>7</sup>

### *Enrollee Populations Covered by Insurance Mandates*

Only three states, Florida, North Carolina and Virginia have mandated coverage for adults. Florida requires the administering of immunizations as part of post-delivery care for new mothers, and both North Carolina and Virginia incorporate coverage for adult females as part of ob-gyn care.

All jurisdictions mandate coverage for children, but the coverage is limited by 16 different age ranges. As a result, even coverage for children varies widely. All states require coverage to commence "from the moment of birth," while coverage terminates from as young as the second birthday (Mississippi and Montana), to as old as "the attainment of nineteen years of age" (New York). Four mandates (Maryland, New Jersey, New Mexico, and Pennsylvania) utilize the term "child/adolescent" rather than defining a specific age after which the insurer is no longer obligated to pay for immunizations.

### *The standard of coverage for immunizations*

Six states require their insurers to follow the ACIP recommendations. Maryland, Montana, and Pennsylvania utilize ACIP exclusively, while California, Hawaii, and New Jersey also specify adherence to additional standards.

The remaining 27 states utilize a variety of sources to determine which vaccines must be covered, including:

- guidelines developed by the American Academy of Pediatrics (AAP);
- "prevailing medical standards," or "physician custom," which permits the treating physician or another individual, such as a state health commissioner, to determine which types and amounts of immunizations would be covered;
- specific delineation of the immunizations that must be covered, by category of vaccine; and
- statutory silence regarding the standard against which the adequacy of coverage will be measured (e.g., immunizations "as appropriate" or simply "immunizations")

### *Cost Sharing Design and Administration Fees*

*Patient cost sharing:* State immunization laws typically address cost sharing, at least with respect to immunizations subject to the coverage mandate. States are more likely to expressly prohibit

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<sup>7</sup> ERISA preemption principles suggest that even this mandated offer would not appear to bind self-insured plans. See, e.g., *Metropolitan Life Insurance Co. v. Massachusetts*, 471 U.S. 724 (1985). See generally, *Law and the American Health Care System*, *op. cit.*

deductibles (21 out of 33) than cost sharing (13 out of 33). Presumably, statutory cost sharing rules do not apply to immunizations that may be furnished but that are not covered by the mandatory coverage rule. Notably at least 4 states expressly permit the use of deductibles, which appear to be rising as health care costs grow.<sup>8</sup>

*Administration fees:* Of the 33 jurisdictions with immunization mandates, only West Virginia specifically permits payment for administration fees, while Rhode Island excludes coverage for the cost of vaccine. The remaining statutes are ambiguous or simply fail to address administration fees.

### *Network Limitations and Delivery and Replacement*

No state addresses the issue of insurer payment for provider immunization services through a replacement program, regulation of vaccine administration, or otherwise. Similarly, no state regulates insurer discretion over payment of out-of-network providers. No state law prohibits insurer exclusions when immunizations purportedly are available free of charge.

Despite the link in modern health insurance arrangements between coverage and receipt of care through provider networks, no state insurance laws address networks.

### *Assessing State Laws Against a Comprehensiveness Standard*

Although the majority of states have an immunization mandate on the books, no state has enacted a *comprehensive mandate*, that is, a law that mandates coverage of all children and all adults. Indeed, even where only children are concerned, no state mandates comprehensive coverage for both children and adolescents. Only Hawaii maintains what is defined in this study as a comprehensive statute for young children, requiring coverage at the ACIP standard of care and prohibiting point-of-service patient cost sharing (both deductibles and coinsurance).

### **Conclusion**

The results of this analysis suggest that although most states maintain immunization coverage mandates, these laws are limited when examined against the elements of a comprehensive standard of coverage. Even in the case of children and adolescents, state laws are limited in relation to well known, government-recommended and evidence-based standards of practice.

This clear gap between a known and scientifically based standard of practice and the legal standards that are established for insurance coverage raises broader questions regarding the impact of such coverage gaps on the ability of the health system to produce high quality care. Recently much attention has been paid to the issue of the quality of U.S. health care. But if there is no assurance that insurers, the primary means of financing health care in the U.S., will pay for health care at an evidence-based level, then it is virtually impossible to generate major improvements in health care quality.

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<sup>8</sup> The Kaiser Family Foundation and Health Research and Educational Trust, *Employer Health Benefits 2001 Annual Survey: Employee Contributions for Premiums and Cost Sharing – Section 7*. <http://www.kff.org> (accessed June 24, 2003).

Given the importance of ensuring adequate access to all government-recommended vaccines, state immunization laws should be strengthened. The fact that so many states maintain such laws should be taken as a sign of state interest in using insurance standards to achieve public health goals. Immunization coverage reform is particularly important at a time when the amount of federal funding available to directly fund public health interventions is so constrained, and when virtually all states are experiencing major budget crises.