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Current landscape of nonmedical vaccination exemptions in the United States: impact of policy changes

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Abstract

Introduction: In the United States, high childhood vaccination coverage has reduced the morbidity and mortality due to vaccine-preventable diseases. The success of vaccination programs in achieving this high coverage is due, in part, to vaccination mandates for school entry. All states have such mandates, but there is heterogeneity across the states in the allowance of non-medical exemptions (e.g. religious or personal belief exemptions) to these mandates.

Areas covered: We examine historical trends in non-medical exemption prevalence in the US, discuss recent state-level policy changes that may impact non-medical exemption prevalence, and review recent studies on the association between non-medical exemptions and infectious disease outbreaks.

Expert commentary: State-level implementation of mandates, and related allowances for medical and non-medical exemptions, varies greatly across the United States. Non-medical exemption rates have increased over the last two decades, with an increased risk of disease outbreaks in clusters of children with non-medical exemptions due to differences in state laws. Recent efforts to address non-medical exemption rates range from incorporating additional administrative requirements for exemptions and disallowance of any non-medical exemptions. Continued monitoring is needed to evaluate the impact of these changes on exemption rates, to develop optimal childhood vaccination policy across the United States.

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Declaration of interest

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Keywords

Vaccination mandates; school entry; exemptions; non-medical exemptions; state law

1. Introduction

Use of vaccines has led to dramatic decreases in the incidence of infectious disease, including eradication of smallpox while also nearing the eradication of polio [1]. In recent years, as the incidence of vaccine-preventable diseases has decreased, concerns about vaccine safety and the need for vaccination have increased [2–4]. While there are some adverse events that are linked to childhood vaccination, most are rare [5–8]. However, concerns about these adverse events as well as misperceptions about vaccine safety [9,10] have led to decreasing vaccination coverage and related increases in disease incidence [11,12].

One of the most common and successful methods for achieving and maintaining high vaccination coverage in the United States is the use of school-entry vaccination mandates, where states set minimum requirements for vaccination status that would make a child eligible to attend school [13–17]. As the majority of vaccines are given to children younger than kindergarten age [18], the initial school entry is the most common time for assessment of vaccination status, though records are usually verified annually [19,20]. In recent years, middle school entry vaccination requirements have been implemented, most commonly for tetanus, diphtheria, and acellular pertussis (Tdap) booster vaccination [21] and quadrivalent meningococcal conjugate vaccination [22], both of which are recommended at 11–12 years of age [23,24]. Less common are school entry mandates for human papillomavirus vaccination [25], which is also recommended at 11–12 years of age [26,27].

All states allow for medical exemptions to vaccination mandates, for instances when vaccination is medically contraindicated [28]. Additionally, most states offer some form of non-medical exemption, with only three states – West Virginia, Mississippi, and California – not allowing any exemptions to vaccination mandates for non-medical reasons [28].

If the proportion of children receiving exemptions from school entry vaccination mandates, the overall level of community protection may be affected. It is important to note that children with non-medical exemptions for kindergarten entry in a given school year do not stop contributing to diminished vaccination levels when the next cohort enters kindergarten. Rather, these un- or under-vaccinated children will continue to add to the overall absolute numbers of unprotected children in the community. This accumulation of susceptible children, along with children for whom on-time vaccination is deferred to later ages, can erode community protection levels sufficiently to allow outbreaks of disease (Figure 1) [29].

In this review, we examine historical trends in non-medical exemption prevalence in the US, discuss recent state-level policy changes that may impact non-medical exemption prevalence, and review recent studies on the association between non-medical exemptions and infectious disease outbreaks. Given the number of recent advances in our knowledge of nonmedical exemptions – including the epidemiology of non-medical exemptions and a

large number of legislative and administrative changes to nonmedical exemption requirements – there is a need to summarize and synthesize these recent advancements. This review presents our current state of knowledge regarding nonmedical exemptions in the United States.

2. Epidemiology of childhood vaccine uptake and school-entry exemptions

2.1. Temporal trends of childhood and kindergarten student vaccination coverage

Childhood vaccination coverage is assessed by the US Centers for Disease Control and Prevention (CDC) through two annual surveys. First, the National Immunization Survey (NIS) collects parental self-report of vaccine uptake for children aged 19–35 months of age, and requests parental permission to contact health-care providers to verify vaccination history [30]. Second, state immunization programs collect immunization and school-entry mandate exemption history for children in kindergarten in these states and reports this information to CDC for summarization [19]. Comparing these two data sources, collected at different childhood ages, provides a means to approximate delayed vaccination where catch-up could occur just prior to school entry when it is required.

In 2017, vaccination coverage for two key vaccination measures for children 19–35 months of age – receipt of at least 4 doses of diphtheria, tetanus, and acellular pertussis vaccine (DTaP) and receipt of at least one dose of measles, mumps, and rubella vaccine (MMR) – was 83.2% and 91.5%, respectively [31]. There is state-level heterogeneity in childhood vaccine coverage among the 50 states and District of Columbia. In 2016, state-specific estimates for at least 4 DTaP doses ranged from 75.1% to 92.8% and for at least one MMR dose ranged from 85.8% to 98.3% [32]. Over the last 22 years (1995–2017) when this type of surveillance has been conducted, annual national-level vaccination rates have remained relatively stable, ranging from 78.7% to 85.7% for at least 4 DTaP doses and 89.7% to 93.0% for at least one MMR dose [33,34].

For children in kindergarten in the 2017–2018 school year, the median national coverage for two doses of MMR was 94.3% and state level DTaP compliance (defined as receipt of either 4 or 5 doses of DTaP, based on state-level requirements for school entry) was 95.1% [20]; these estimates are similar to the coverage estimated for the 2016–2017 school year of 94.0% and 95.1%, respectively [19]. These discrepancies, for children on average about three years apart in age, highlight the success of school-entry mandates in mitigating early vaccination delays with more complete vaccination by the time of school entry. However, the differences in data collection methodology between these two surveillance systems do not provide the ability to make a direct comparison of vaccination rates. In the 2017–2018 school year, there was heterogeneity in kindergarten vaccine coverage among the 50 states and District of Columbia, with a range of 79.7% to >99.4% for DTaP compliance and 81.3 to >99.4% for at least two doses of MMR [20]. National-level kindergarten vaccination coverage is available back to the 2009–2010 school year. Over the last nine school years, annual national median vaccination rates have remained relatively stable, ranging from 94.2% to 96.1% for DTaP compliance and 94.0% to 94.8% for at least two MMR doses [35].

A summary of the vaccination coverage reported for the most recent seven school years (2011–2012 through 2017–2018) (national level, and state-level ranges) is presented in Table 1 [19,20,33,34,36–39,144].

2.2. Temporal trends of medical exemptions

The overall prevalence of medical exemptions is low (US national median medical exemption rate among kindergartners of 0.2% in the 2016–17 school year; state-level range 0.1% to 1.5%) [40], owing largely to relatively rare medical contraindications to vaccination [41], though the state-level variability is driven by differences in state-level policies [42]. Between the 2009–2010 and 2016–2017 school years, the national median prevalence of medical exemptions has remained constant, between 0.2% and 0.3%, with state-level ranges showing little heterogeneity over time, never exceeding the range of 0.1% to 1.6% over this period [43].

2.3. Temporal trends of non-medical exemptions

For the 2017–18 school year, the US median non-medical exemption rate among kindergartners was 2.0% (state-level range 0.1% to 7.5%) [40]. Between the academic years of 2011–12 to 2017–18, median total exemption percentages have slowly increased, with a rise from 1.2% to 2.0% (Table 1). Over this same period, the state-level range in proportion of children with non-medical exemptions increased from 0.4–5.7% to 0.1–7.5% [19]. A summary of the vaccination coverage reported for the most recent seven school years (2011–2012 through 2017–2018) (national level, and state-level ranges) is presented in Table 1 [19,20,33,34,36–39,144].

2.4. Association between state-level non-medical exemption policies and non-medical exemption rates

State laws mandating school required vaccines has proven to be effective to keep school children and the community free of vaccine-preventable diseases. Contrary to medical exemptions, non-medical exemptions are provided based on parental choice and not deemed to be medically necessary. Obtaining a non-medical exemption has been attractive to vaccine-hesitant parents for their child to still attend school with either a religious, philosophical, or personal belief exemption. Non-medical exemptions have been considered ethically necessary to maintain a balance between the protection of the public's health and parental rights [17]. For more than three decades Mississippi and West Virginia have not permitted nonmedical exemptions for school-entry vaccination mandates [44], with California eliminating non-medical exemptions in 2015 [45]. Historically, all states but these two have allowed religious belief exemptions. Furthermore, 20 states have permitted personal and philosophical belief exemptions [44].

Since school vaccination requirements vary by state the process for obtaining nonmedical exemptions do as well. In some states, the process to obtain a non-medical exemption is relatively simple while in other states the process is more difficult. The prevalence of nonmedical exemptions was compared to the relative difficulty required to obtain nonmedical exemptions in three studies spanning the period 1999 through 2016 [46–48]. Over these three evaluations of non-medical exemption rates and policies, the criteria for

assessing the ease of obtaining non-medical exemptions has changed. For both the period 1991–2004 and 2005–2011, ease was assessed against four criteria: (1) allowance of use of a form compared to a parent-written letter, (2) source of form (school or health department), (3) need for the form to be notarized, and (4) where letters were required, the extent to which parents had to determine the wording of the letter [46,48]. For the period 2011–2016, ease was assessed against these criteria, with the additional assessment of whether the parent had to visit the health department, whether a state official or religious leader needed to sign the form, and whether annual recertification was required [47].

In three studies, encompassing over 25 years of surveillance, consistent associations were found with higher non-medical exemption prevalence in states categorized as ‘easy’ or ‘medium’ difficulty for obtaining non-medical exemption, relative to states with higher difficulty, and the average annual increase in non-medical exemption prevalence was higher in ‘easy’ or ‘medium’ exemption criteria states compared to ‘difficult’ criteria states. As indicated in Section 2.3 above, increases in non-medical exemption prevalence slowed in recent years, and this effect was seen across state-level difficulty to obtain NME, including states with ‘easy’ exemption criteria. This leveling was observed for the period 2013–2015, and continued monitoring will be needed to determine if this pattern is being maintained over time [47]. A summary of the average annual change estimates, by difficulty to obtain exemptions, is presented in Table 2. The consistency of associations between ease of obtaining non-medical exemptions and higher non-medical exemption rates, over the period 1997–2013, has been summarized in a prior review [49].

A recent review [50] of nonmedical exemptions has highlighted the impact of ‘hot spots’ on the potential for vaccine-preventable disease outbreaks. These areas, with a large number of children with nonmedical exemptions, tend to be clustered in larger metropolitan areas in states with more lenient nonmedical exemption policies. This is notable because while there are potentially a large number of children susceptible to infectious diseases, such as measles, across the US [29,51], having clusters of these susceptible children in densely populated areas further increases the likelihood of large outbreaks.

2.5. Differences in non-medical exemption rates by type of school

In general, US private schools have higher rates of both medical and nonmedical exemptions than US public schools. For the 2009–2010 school year, the overall exemption rate for private schools was 2.2 times higher than that for public schools (4.3% compared to 1.9%), with a 1.7-fold increase for medical exemptions (0.58% compared to 0.34%), 2.5-fold increase for religious exemptions (2.1% compared to 0.8%) and 2.2-fold increase for personal-belief exemptions (6.1% compared to 2.8%) [52]. Over a fifteen year period in California, the non-medical exemption rate among students in private schools was 1.8 times higher than that for public schools; additionally, the average annual rate of increase of non-medical exemptions in private schools (10.1%) was higher than that for public schools (8.8%) [53].

Discussion of private schools need to account for differences in school type. Parents of children receiving education through other schooling systems, such as private, religious, Montessori, or Waldorf schools may hold different beliefs around vaccination. Montessori

and Waldorf schools are alternative school systems that focus on more individualized learning systems where children have more freedom in determining the course of their education, rather than standardized curricula [54,55]. One recent study of non-medical exemptions in alternative (i.e. Montessori, Waldorf, Holistic) schools in California found substantial differences in non-medical exemption prevalence (specifically personal belief exemptions) between children attend these schools and children attending public schools. The average personal-belief exemption prevalence across Waldorf schools was 45.1% – 19 times higher than that of public schools. While personal-belief exemption prevalence was lower in Holistic (7.4%) and Montessori (3.9%) school, as a whole, children attending alternative schools in California were 3.6 times more likely to have a personal-belief exemption compared to children in public schools [56]. Notably, the proportion of California private schools with kindergarten personal-belief exemption prevalence of at least 5% increased from 9% to 34% over the period 2000–2013 [56].

These findings were mirrored in a study in New York State, which found that religious-based non-medical exemption rates for private schools (including both religious and secular schools) were 3.9 times (95% CI 3.2–4.9) higher than those in public schools (1.35% for private schools compared to 0.29% for public schools). In 2012, most private religious schools in New York State had religious exemption prevalence in the range of 0.3% to 2.7%, with one notable exception – Mennonite and Amish schools, in which 61.5% of children had religious exemptions. The secular private school religious exemption prevalence in New York in 2012 was 1.9% [57].

2.6. Socio-contextual factors associated with non-medical exemption rates

Over the period 1994–2009 in California, non-medical exemptions in rural schools were 1.7 times higher than those in urban areas. Additionally, non-medical exemption rates increased with census tract-level factors, including the percent of population that are white (1.03 times higher for each 1% increase in white population), and college educated (1.02 times higher for each 1% increase in the population with a college education), whereas non-medical exemption rates were lower in more populated areas (0.97 times lower for each increase of 1,000 population per square mile) and where household income was higher (0.91 times lower for each \$10,000 increase in median household income) [53]. In a separate analysis of California private schools, higher tuition, which served as a proxy for school-level population affluence, were associated with higher non-medical exemption rates [58]. These disparate findings, with regard to financial status, indicate the need for more detailed analysis beyond ecologic analyses, but accounting for the different ways that finances may be associated with vaccination decision-making. For example, while higher income families may be less likely to have nonmedical exemptions for their children, the subset of parents who choose higher tuition private schools may have different perspectives on the need for childhood vaccination.

3. Recent policy changes

3.1. Proposed and enacted policy changes

A previous review of exemption policies across the United States found that states with relaxed exemption procedures experienced increased exemption rates, and higher individual and community disease risk [49]. However, the last large scale review and summary of recently passed legislation changes related to immunizations contained information up to 2012 [59]. The most recent (2012–2018) data available are summarized here.

As of 2018, the state of vaccinations and exemptions in the United States (U.S.) remains a heterogeneous mix as each state maintains its own laws and policies related to vaccination requirements and allowable exemptions for early childhood school entrance and attendance. Currently, of all U.S. states, 18 (36%) allow for exemptions based on philosophical beliefs, 47 (94%) allow for exemptions on religious grounds, and all 50 (100%) allow medical (temporary and/or permanent) exemptions for vaccinations of children entering Kindergarten [60].

To assess recent legislative changes, we queried the National Conference of State Legislatures immunization legislation website [60], while also conducting on-line searches using the unquoted terms ‘allowable vaccine exemptions’, ‘vaccine exemptions policy’, ‘vaccine exemptions policy change’, and ‘vaccine policy change’ with the name of each state as part of the search. In the period 2014–2018, 26 states have introduced a total of 70 new legislative actions related to vaccination mandates and exemptions. Twenty four states (Alabama, Alaska, Arkansas, Florida, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Massachusetts, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Ohio, South Carolina, Tennessee, Virginia, Washington, Wisconsin, and Wyoming) did not introduce any new vaccine mandate legislation during this period.

Only 11 (16%) of these 70 introduced bills have been passed and accepted within a government body (see detailed information and references to specific state-level legislation in Table 3). Of these 11, there were 13 unique actions that fit into 7 distinct categories: updating the criteria to be met to obtain an exemption (e.g. provider review, notarized forms, education provision) (N = 6), removal of at least one type of exemption option (N = 2), exclusion of children with exemptions from school in the event of an outbreak (N = 1), making exemption data available to the public (N = 1), sharing healthcare records across healthcare providers and administrative organizations (N = 1), updating storage and retention requirements for the state immunization information system (N = 1), and expansion of vaccination requirements to pre-kindergarten entry (N = 1). A summary of the introduced, but not passed, legislation is presented in Table 4. It is important to note that not all modifications to nonmedical exemption requirements have come through legislative changes. For example, the Michigan Department of Health and Human Services updated their administrative rules regarding communicable diseases to require parental educational sessions prior to granting of nonmedical exemptions (see section 3.2.2 below for more detail). While the information in Tables 3 and 4 are specific to legislative actions, this accounting may be an underestimate of proposed or enacted changes if more states move to non-legislative changes to address nonmedical exemption requirements.

While a majority of introduced legislations focused on creating a more difficult environment to attain a vaccine exemption, 14 introduced bills focused on creating an environment more acceptable to vaccine exemption (Tables 3 and 4). However, no legislation introduced in efforts to reduce difficulty in receiving a nonmedical exemption was passed or accepted by a government body (Table 4).

3.2. Recently enacted legislation case studies

In recent years, there have been three states in which school entry exemption laws have been substantially altered – Washington in 2011, Michigan in 2015, and California in 2016 – for which detailed evaluation has been conducted. The changes, and recent evaluations of these changes in terms of vaccine coverage and exemption rates, are summarized for each state below.

3.2.1. Washington—Up to 2011, there has been little movement in new legislation related to vaccination requirements in the state of Washington, despite high exemption rates in the state [125]. In 2011, Washington implemented new policies (Senate Bill [SB] 5005) that mandated parental counseling prior to granting of vaccination exemptions. This process was put into place to ensure that parents were aware of the need for vaccination. According to Washington legislation, the state requires that a physician sign the exemption form indicating they have provided this counseling before the form can be submitted to public health authorities in the state [126], an extra step parents must now take in efforts to attain an exemption. Following implementation of SB 5005, historical nonmedical exemption rates were compared over seventeen school years (1997–98 to 2013–14) – including the period of SB 5005 implementation [127]. After implementation of SB 5005, there was an absolute reduction of exemption rates of 2.9 percentage points – a 40% decrease. That study also identified an association between implementation of SB 5005 and reduced geographic clustering of those with non-medical exemptions [127]. These findings indicate the potential broad impact a relatively minor adjustment to exemption requirements can have.

3.2.2. Michigan—Similarly, in 2015, administrative rules governing the granting of nonmedical exemptions in Michigan were modified to require that parents seeking vaccination exemptions for their children must first undergo an educational training in which they are provided information about various vaccinations and given an opportunity to ask questions, before a local health department official will sign their exemption waiver [128]. This update to nonmedical exemptions is noteworthy in that it was implemented through the Michigan Department of Health and Human Services administrative rules related to communicable diseases, and did not require legislative change.

While this change has not been formally evaluated for its impact on vaccination coverage, a qualitative assessment of healthcare providers who will be conducting these educational sessions identified some key themes, including a perception that the goal of this law was not to change the minds of parents refusing vaccine, but to work towards reestablishing trust in healthcare providers and the vaccination system. Some potential barriers, such as responding to more resistant parents with the bare minimum of education and the potential for burnout following these educational sessions was identified [129]. This is the last large scale change

to vaccination legislation in the state that was implemented, though, in 2017 the Michigan legislature introduced two separate bills aimed at prohibiting creation of new rules ‘that are more stringent than the vaccine exemptions currently in statute’ (Table 4). There have been no further actions on these two introduced bills.

3.2.3. California—Spurred by recent vaccine-preventable disease outbreaks, California enacted two distinct laws related to exemptions and vaccine requirements. First, in 2012, California law was updated such that as of 1 January 2014, individuals seeking non-medical exemptions would need to receive education and counseling from a healthcare provider about vaccination before the exemption form could be signed [130]. In an evaluation of fifteen cohorts of incoming students to California schools over the 2001–2 to 2015–16 school years, a decline in non-medical exemptions of approximately 0.3% per year was observed. However, enactment of this law did not change the observed clustering of non-medical exemptions that can lead to a greater risk of infectious disease outbreaks [131].

Following a large outbreak of measles in California in 2014–2015 [132], vaccine exemptions once again became a point of focus and, as such, the California legislature passed SB 277 in July 2016 (Table 3) [45]. This bill eliminated personal-belief exemption from any currently required vaccinations in California and ultimately led to an increase in childhood vaccination coverage by nearly 3% in the 2016–2017 school year [133–136].

Though vaccination rates in California have increased, percentage of medical exemptions acquired after the passing of SB 277 increased 300% from 0.17% to 0.51% while personal-belief exemption percentage dropped from 2.37% to 0.56%; this could be attributed to vaccine hesitant parents seeking ME’s from physicians willing to alter from recommended vaccination schedules [137].

3.2.4. Other states without published evaluations—Comparable to California, various states throughout the U.S. have implemented laws affecting vaccination uptake and exemption seeking for childhood vaccinations, including Minnesota, Utah, Connecticut, Vermont, and West Virginia [60].

In 2016, Minnesota enacted House Bill (HB) 2749 in efforts to increase early childhood vaccination by mandating all required childhood school vaccinations for prekindergarten students, an attempt to increase vaccination rates before students enter the school population in kindergarten [138].

In Utah, HB 308 requires the implementation of an online education module on preventable diseases and alters exemptions eligibility while also creating a new exemptions form which can be completed after the online education module, which must be renewed under certain conditions [139].

Connecticut HB 6949 requires an annual renewal of religious exemptions through the submission of a notarized statement specifying the religious objection to the required vaccination(s) [140].

Vermont enacted HB 98 which repealed its allowance for a non-religious personal belief exemptions, however this did not remove religious belief exemptions currently in place. Vermont's HB 98 also requires that school and child care facilities inform parents and guardians of vaccination rates for that school or child care center [141].

In 2015, West Virginia enacted SB No. 286 which requires a certified medical exemption request from a licensed physician which then is reviewed by an appointed public health immunization officer to determine the acceptability of the exemption request, a more complex exemption request process than other states [142].

States with a less convenient process to attain an immunization exemption, or with punishments for noncompliance with vaccination policies (e.g. exclusion from attendance in public schools), often present lower overall rates of vaccine exemptions among their kindergarten populations and, in turn, an overall greater rate of vaccine compliance [48,143]. The effect of this can be seen by decreasing exemption rates in states that introduced stricter vaccination laws like Michigan and California. In Michigan, rates of exemption fell from 5.3% in the 2014–2015 school year to 3.6% in the 2015–2016 school year and, as a whole, the United States has seen a 0.2% drop in exemption rates after several states have implemented stricter vaccine exemption policies and laws [144,145]. Continued evaluation of these policies will be needed to identify successes and barriers that may arise from implementing these new systems.

4. Impact of exemptions on disease incidence

Multiple studies have evaluated the association between state policies for obtaining non-medical exemptions [143] and both exemption rates and disease incidence [143].

As un- and under-vaccinated children continue to contribute to a growing pool of susceptible individuals, the risk for new infectious disease outbreaks increases. Prior studies have reviewed the connection between vaccine refusal in general (e.g. any state of being unvaccinated, across all ages) and outbreaks of measles and pertussis [12].

4.1. Pertussis

Geospatial analysis of the prevalence and distribution of non-medical exemptions and pertussis outbreaks have identified clusters of overlap, indicating higher non-medical exemption prevalence driving these outbreaks [46,146–148].

A large outbreak of pertussis consisting of 109 cases (5 laboratory-confirmed, 61 probable, and 40 suspected) in 2013 centered around a charter school in Florida in which most students were unvaccinated against pertussis, with 84% of unvaccinated children having religious exemptions [149].

A population based evaluation of religious exemptions in New York State identified a near doubling of religious exemptions between 2000 and 2011. Notably, 13 of 62 counties in New York State had religious exemption prevalence of at least 1% in 2011. Statistically significant associations were observed between prevalence of non-medical exemptions and pertussis incidence [150].

An analysis of 13 years of non-medical exemptions data found that not only did states with easier policies for obtaining exemptions have higher exemption rates, but they also had approximately 50% higher pertussis incidence [46].

A population-based study of case report forms for pertussis and measles outbreaks in Colorado found that children with non-medical exemptions were 6 times more likely to acquire pertussis and 22 times more likely to acquire measles, compared to vaccinated children [151].

4.2. Measles

Non-medical exemptions have epidemiological implications of increasing individual disease risk and population risk for disease outbreaks. A number of historical moments put these implications into perspective. Most notable in the United States being the measles outbreak in 1997 when 138 cases were reported. A single county in Utah had 107 of those measles cases due to that county having an exemption rate about 6 times the national average at the time. Individuals who were vaccinated represented approximately half of the cases, showing there are epidemiological implications on the community as a whole not just those who are unvaccinated [49].

A recent modeling study highlighted that a 5% decrease in measles vaccine coverage would result in a tripling of measles incidence in the United States [51]. Additional modeling, assessing state-level policies for obtaining non-medical exemptions, estimated that a state with an easy policy for obtaining non-medical exemptions would be 140% more likely to experience a measles outbreak compared to a state with a medium difficulty policy, and 190% more likely than a state with a difficult policy [152]. Looking at this issue from the other direction, another modeling study estimated the impact of increased measles vaccine uptake in children with non-medical exemptions – who are often distributed through the population heterogeneously – and found that a focus on schools with the lowest vaccine coverage and highest non-medical exemption rates would provide the best means for reducing the risk of measles outbreaks [153]. Combining these findings with the estimate that 1 in 8 children under the age of 18 years in the United States may be susceptible to measles [29], it is clear that there is little room for expansion in the number of children exempted from routine immunization requirements before larger scale outbreaks will be observed.

Recent measles cases and outbreaks have been traced to a combination of children with non-medical exemptions and international travel to locations where measles is still endemic. Notably, one case in 2004 was imported by a 19 year old college student who had remained unvaccinated against measles related to prior non-medical exemptions. The college attended by this study has been reported to have a high proportion of students with non-medical exemptions, and nearly a quarter of students who traveled to India in 2004 contracted measles. One student returned to the United States, sparking a large-scale public health initiative to prevent development of secondary cases, including mass vaccination clinics for individuals who may have had contact with the student.

As indicated above, a study of non-medical exemptions in Colorado estimated that children with non-medical exemptions were 22 times more likely to acquire measles than vaccinated children [153]. This estimate is in-line with a prior national-level estimate that children with non-medical exemptions were 35 times more likely to acquire measles than vaccinated children [154]. This study also assessed the risk of measles in non-exemptors as a function of exemption rates, findings that based on the level of mixing of exemptors and non-exemptors, that a doubling of non-medical exemption rates would increase measles incidence in non-exemptors by 6 to 31% [154].

5. Conclusions

Routine childhood immunization has dramatically increased child health and reduced the morbidity and mortality due to infectious diseases. One of the most successful means of achieving high childhood vaccination coverage is through vaccination requirements for school entry. There is a high degree of interconnectedness between state-level policy for vaccination mandates, allowances for exemptions, vaccination coverage, and infectious disease incidence and clustering. School-entry mandates in the US work because they strike a balance between changing the balance of convenience between exemption and vaccination while preserving parents' ability to not vaccinate their child, in most states.

When examined in totality, it is clear that high vaccine coverage, supported through strong school-entry mandates with the allowance for exemptions, can support the public health goal of reducing morbidity and mortality due to infectious disease. As state-level policies continue to evolve, continued evaluation will be critical to assess the impact on exemptions and vaccine coverage, while also monitoring for unintended consequences, such as increases in medical exemptions where non-medical exemptions are not allowed, and erosion of public trust in vaccination systems, potentially related to changes in exemption laws or removal of nonmedical exemption allowances. A recent study of health officials and immunization staff across California documented a number of concerns related to medical exemptions in the wake of the removal of nonmedical exemptions in that state. These include a lack of a standardized review process and concerns about the reasons for which medical exemptions were being granted. This report calls for updates to SB277 in California to include a standardized review of medical exemptions [155].

6. Expert commentary

Given the issues examined above, it is critical to consider how best to move forward to maintain high childhood vaccination coverage and reduce the risk of vaccine-preventable disease outbreaks.

Numerous proposals have been put forth on how best to address non-medical exemptions and the potential for resultant infectious disease outbreaks. One avenue, shown to work in California, is the elimination of all non-medical exemptions [45]. The American Academy of Pediatrics supports this direction, and has produced a policy statement calling for all states to eliminate non-medical exemptions from their state-level immunization policies [156]. However, the unintended consequence of an increase in medical exemption rates –

which notably tripled in California – highlights a potential pitfall with this approach. Parents may seek out physicians who are more willing to attest to medical contraindications in the absence of a non-medical exemptions allowance.

Other options that fall short of total elimination of non-medical exemptions – such as administrative requirements that shift the balance of convenience from exemption to vaccination – have shown an effect in reducing non-medical exemption rates [46,48,127]. With increasing attention on the availability of, and requirements for obtaining, non-medical exemptions, there have been numerous legislative actions proposed, as described above. Continued monitoring of the effect of passed legislation is critical to monitor best practices for the most effective use of school-entry vaccination mandates. Assessments done in California [133,134,157–159] and Washington [127] provide a framework for future evaluations.

Additionally, we have moved beyond analysis of aggregate national- or state-level exemption rates, to assessments at smaller geographic areas [53,133–135,147,159]. As we continue to refine the data available for these analyses, we can move to conduct more granular assessments of implementation, focusing on sub-state variability in implementation of these state-level policies.

Recently, there has been a focus on the use of psychological science in developing, implementing, and evaluating interventions to improve vaccination uptake [160]. These principles can be broadly applied to understand the implementation of state laws for school-entry mandates, and develop more indepth evaluation frameworks for assessing the use and modification of these mandates.

7. Five-year view

With some recent studies indicating the rise of non-medical exemptions has slowed [47] while other data indicates that, in the most recent birth cohorts, non-medical exemption rates are increasing [20], the next five years will be an important period for evaluation. Recent state-level legislation changes have the potential to strengthen our ability to prevent disease outbreaks, but with some early evidence of potential unintended consequence of increased medical exemptions, detailed monitoring will be essential. Regardless of the outcomes identified from long-term evaluation in California, Michigan, and Washington, the next five years will provide us with ample evidence to identify best practices and path ways forward. Taking a holistic view of state-level legislation and related exemption rates across the entire United States offers us the ability to take an evidence-based approach to future legislative changes related to non-medical exemptions.

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Key issues

- Increasing rates of non-medical exemptions to school-entry vaccination mandates increase the risk of vaccine-preventable disease outbreaks. Over nearly three decades, non-medical exemption rates have continued to increase, particularly in states with more lenient exemption criteria.
- In recent years, numerous legislative proposals have been brought forth that may impact non-medical exemptions, ranging from proposals to both tighten and loosen criteria to receive an exemption to complete removal of non-medical exemptions from state immunization laws.
- While new legislation has not been in place long enough for long-term evaluation, initial indications are that laws that add additional requirements for receiving non-medical exemptions have successfully reduce the number of exemptions sought and granted. Additionally, removal of the option of non-medical exemptions has reduced the non-medical exemption rate, but was accompanied by an increase in medical exemptions, which may mitigate efforts to improve vaccine coverage.
- Continued evaluation of requirements for, and prevalence of, non-medical exemptions in the context of these state laws will support the creation of a more detailed evidence base to guide future legislative initiatives.

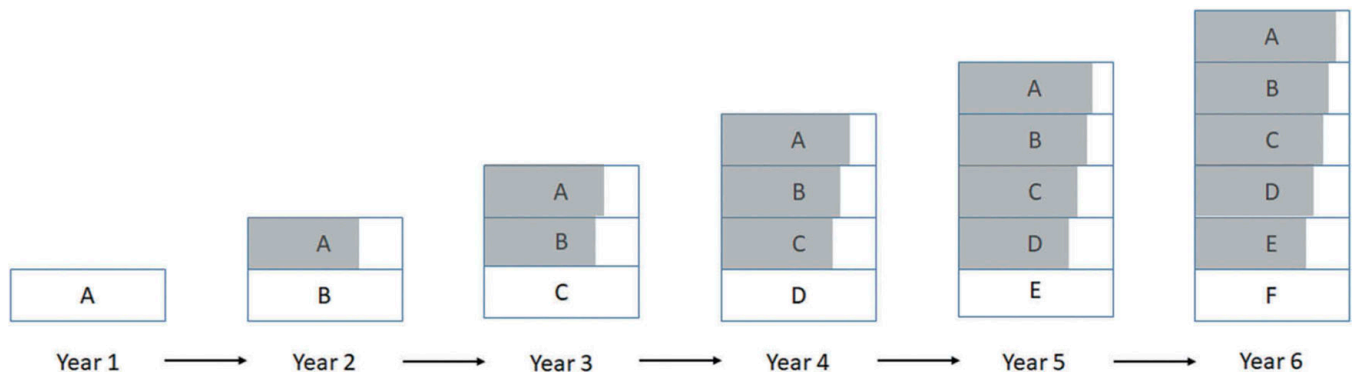


Figure 1.

Sequential, hypothetical measles, mumps, rubella vaccination coverage in a series of six birth cohorts. Box A represents children born in the first year of observation, would not be eligible for MMR vaccination until year 2. Similarly, Box B represents children born in the second year of observation, continuing on through Box F. In each year, vaccination coverage (shaded portion of each box) increases as previously unvaccinated children are caught up on missed vaccines. However, since 100% of children are not vaccinated, the cumulative number of unprotected children (unshaded portion of each box) increases over time, allowing for an accumulation of susceptible individuals in the population.

Table 1.

Measles, mumps, and rubella (MMR) and diphtheria, tetanus, and pertussis (DTaP) vaccination for children aged 19–35 months and children in kindergarten, and non-medical exemption prevalence to kindergarten vaccination mandates, United States, 2011–2018 [19,20,33,34,36–39,144].

	19–35-month-old MMR vaccination status ^b			19–35-month-old DTaP (4+ dose) vaccination status ^b			Kindergarten MMR vaccination status ^b			Kindergarten DTaP (4+ dose) vaccination status ^b			Kindergarten non-medical exemptions rate		
	National	Highest state	Lowest state	National	Highest state	Lowest state	National	Highest state	Lowest state	National	Highest state	Lowest state	National	Highest state	Lowest state
2011–2012 ^a	91.6	96.0	85.6	84.6	92.3	75.2	94.8	99.3	86.8	95.2	97.9	84.1	1.2	5.7	0.4
2012–2013 ^a	90.8	95.0	84.6	82.5	91.3	76.6	94.5	97.5	85.7	95.1	>99.9	82.9	1.5	5.7	0.2
2013–2014 ^a	91.9	96.3	86.0	83.1	93.3	74.3	94.7	>99.7	81.7	95.0	99.0	80.9	1.7	6.1	0.4
2014–2015 ^a	91.5	97.2	87.4	84.2	93.1	77.2	94.0	>99.2	86.9	94.2	99.6	84.3	1.5	5.9	0.5
2015–2016 ^a	91.9	97.5	83.4	84.6	92.0	76.4	94.6	99.4	87.1	94.2	99.6	88.2	1.6	6.2	0.6
2016–2017 ^a	91.1	98.6	85.6	83.4	94.0	76.2	94.0	>99.4	85.6	94.5	99.6	88.2	1.8	6.5	0.5
2017–2018 ^a	91.5	98.3	85.8	83.2	92.8	75.1	94.3	>99.4	81.3	95.1	>99.4	79.7	2.0	7.5	0.1

^aDate ranges represent school years for kindergarten vaccination coverage and non-medical exemption rates. The first year in the range (e.g. 2011 for 2011–2012) represents the year of assessment for 19–35-month-old vaccination coverage.

^bMMR: measles, mumps, rubella vaccine; DTaP: diphtheria, tetanus, acellular pertussis vaccine.

Table 2.

Average annual change in non-medical exemption rates for states classified on ease of obtaining non-medical exemptions, United States, 1991–2015 [46–48]. The average annual change was estimated through incidence rate ratios (IRR) and is interpreted as a percent change. For example, an IRR of 1.05 would correspond to a 5% average annual increase in nonmedical exemption rates over the study period.

Exemption ease	Annual change in exemption rate				
	1991–2004	2005–2011	2011–2012	2013–2015	
	IRR (95% CI)	IRR (95% CI)	IRR (95% CI)	IRR (95% CI)	IRR (95% CI)
Difficult	0.96 (0.86, 1.07)	1.06 (1.04, 1.18)	0.99 (0.80, 1.23)	1.04 (1.00, 1.08)	
Medium	0.99 (0.96, 1.03)	1.15 (1.09, 1.21)	1.32 (1.04, 1.67)	0.99 (0.95, 1.02)	
Easy	1.05 (1.01, 1.09)	1.14 (1.07, 1.20)	1.59 (0.97, 2.59)	0.95 (0.89, 1.01)	

Note that in the 2011–2015 analysis, the criteria classifying difficulty became more stringent, relative to earlier periods. Details on the criteria are presented in the manuscript.

IRR: incidence rate ratio; CI: confidence interval.

Table 3.

Vaccine mandate and exemption legislation ($N = 11$ laws) passed and/or enacted between 2014 and 2018 [60].

State	References	Introduced legislation title	Year introduced	Passed?	Overview
California	[45]	SB 277	2015	Yes; approved by Governor June 30 2015	Removed exemptions based on personal beliefs, including religious objections.
Connecticut	[140]	HB 6949	2015	Yes, signed 2 July 2015	Requires an annual, notarized statement from parents or guardians specifying religious objection to required vaccinations.
Delaware	[61]	HB 91	2016	Yes, signed 15 July 2015	Adds language around existing religious exemption that any child with an exemption who is unvaccinated, in the event of an outbreak of vaccine preventable disease, the child shall be temporarily excluded from attendance at the public school. It also provides review authority to the Division of Public Health for medical exemptions signed by a physician.
Georgia	[62]	HB 198	2018	Yes, signed into law 1 July 2017	Requires a school system that provides information on immunizations to also include recommendations from the ACIP, a description of covered diseases and other information. Requires the Department of Education to work with the Department of Public Health to develop educational resources.
Illinois	[63]	SB 1410	2015	Yes, signed 3 August 2015	Requires each public school district to make exemption data available to the public. Also requires parents or guardians who claim a religious exemption to detail their objections for specific immunizations, obtain a health care provider's signature, and submit an exemption certificate for each child before kindergarten, sixth and ninth grade. Local school authorities make decision on exemption application acceptability.
Minnesota	[138]	HB 2749	2016	Yes, May 3 2016	Applied its statutes related to public school immunization requirements and exemption criteria to its free voluntary prekindergarten program
South Dakota	[64]	HB 1059	2015	Yes, Signed by Governor 13 March 2015	Requires a child's immunization records to be shared among health care providers, federal and state health agencies, child welfare agencies, and schools, unless the patient or guardian signs a refusal. It requires providers to inform parents or guardians that they have the right to refuse disclosure of records.
Texas	[65]	HB 2171	2015	Yes, passed on June 17 2015	Written or electronic consent for including minor information in immunization registry must be obtained from a guardian before the minor's eighteenth birthday. Information will remain on the registry until the individual's twenty-sixth birthday, or can be removed prior to through submission of written or electronic request.
Utah	[66]	HB 308	2017	Yes; signed into law 24 March, 2017	Requires the Department of Health to create an online education module regarding certain preventable diseases and amends grounds for exemptions from required vaccines. This legislation also requires the renewal of vaccination exemptions under certain conditions and creates a new vaccination exemption form; this form can be completed online in tandem with the education module. Lastly, this bill discontinues the practice of allowing local health departments to vaccinate students and recover costs.
Vermont	[67]	H 98	2015	Yes, signed by governor on May 28 2015	Removed personal beliefs (philosophical beliefs) exemptions.
West Virginia	[142]	SB 286	2015	Yes, signed on June 16 2015	Requires certification by a licensed physician for medical exemption requests. It also authorizes the commissioner of the Bureau for Public Health to appoint an immunization officer to make determinations about requests for exemptions.

Vaccine mandate and exemption legislation (N = 59 bills) introduced but not passed or enacted within 18 states between 2014 and 2018 [60].

Table 4.

State	References	Introduced legislation title	Year introduced	Passed?	Overview
Arizona	[68]	HB 2466	2018	Pending	Public schools in Arizona would be required to post the immunization rates of students at the school.
Arizona	[69]	SB 1509	2017	Died in chamber	Would require public schools to post immunization rates on the school's website.
Colorado	[70]	SB 250	2017	Died in chamber	Would allow parents to submit a letter expressing opposition to immunization requirements. It also states that these parents will not be required to submit a specific form.
Connecticut	[71]	SB 840	2017	Died in chamber	Would require posting of immunization rates at every public and private school in the state.
Connecticut	[72]	HB 7059	2017	Died in committee	Would require the parents or guardian of a child claiming a religious exemption to attend an immunization education program administered by the Department of Public Health
Connecticut	[73]	HB 6971	2017	Died in committee	Would require a science-based educational session regarding the efficacy and safety of vaccines for those seeking an exemption for religious reasons
Hawaii	[74]	HB779	2017	Died in committee	Allows parents to use philosophical exemptions to immunization requirements for their children.
Maine	[75]	HP 0310	2016	Pending	Would amend the state's philosophical exemption by requiring parents to first receive a signed letter from their doctor certifying that they have reviewed "the risks and benefits of immunization".
Maine	[76]	HP 419	2015	Not Passed, May 29 2015	Would do away with the philosophical exemptions once allowed for students in Maine.
Maryland	[77]	HB 687	2015	Withdrawn, March 17 2015	Would do away with religious exemptions in Maryland.
Michigan	[78]	HB 4425	2017	Pending	Prohibits promulgation of rules that are more stringent than the vaccine exemptions currently in statute.
Michigan	[79]	HB 4426	2017	Pending	Prohibits promulgation of rules that are more stringent than the vaccine exemptions currently in statute.
Minnesota	[80]	SF 380	2014	Died in chamber, March 23 2015	Would do away with conscientious belief exemptions in place and replace them with personal belief exemptions. This would require the parent to obtain a certificate of exemption that includes a statement from a physician verifying that they have reviewed information about "the risks and benefits" of vaccination.
Mississippi	[81]	HB 130	2015	No	Designed to establish guidelines for obtaining a conscientious belief exemption.
Missouri	[82]	HB 332	2017	Died in committee	Blocks the use of varicella and zoster vaccines containing "foreign human DNA contaminants" to patients in public health clinics.
Missouri	[83]	HB 846	2015	Pending	Requires that parents be notified if any student at their child's school has not been immunized.
Missouri	[84]	HB 976	2015	Pending	Would extend the notification requirement to parents with a child in preschool, nursery school or a daycare center.

State	References	Introduced legislation title	Year introduced	Passed?	Overview
New Jersey	[85]	S 801	2016	Died in committee	Requires the guardian seeking a religious exemption to include a written explanation of why the vaccination conflicts with confirmed religious tenets or practices of the student. It also states that a general philosophical or moral objection to the vaccination is not sufficient.
New Jersey	[86]	A 169	2016	Died in committee	Permits exemption from mandatory immunization for students in writing for any reason
New Jersey	[87]	A 2727	2016	Died in committee	Provides for conscientious exemption to mandatory immunizations
New Jersey	[88]	Senate, No. 1147	2014	Pending	Would tighten the state's exemption law by making it harder for parents to mask philosophical objections behind protections in place for those seeking a religious waiver. Parents seeking a religious exemption would first need to obtain a notarized letter explaining "the nature of the person's religious tenet or practice that is implicated by the vaccination and how the administration of the vaccine would violate, contradict or otherwise be inconsistent with that tenet or practice".
New York	[89]	A 08123: Philosophical Exemption to Immunizations Act	2017	Pending	Would add a personal belief waiver to the state's existing religious exemption. New York [90] S 52 2017 Pending Repeals provisions in the health care code relating to exemption from vaccination
New York	[90]	S 52	2017	Pending	Repeals provisions in the health care code relating to exemption from vaccination due to religious beliefs.
New York	[91]	S 163	2017	Pending	Allows the protections of the medical exemption from mandatory immunizations for students to include professional assessments of physicians, nurse practitioners and physician assistants in the care of their individual patients.
New York	[92]	S 5-1	2017	Pending	Establishes a protocol with specific criteria regarding religious exemption to immunization form.
New York	[93]	S 2955	2017	Pending	Requires school districts to report to the department of education data regarding exemptions to vaccinations.
New York	[94]	S 3546	2017	Pending	Would require parents seeking a religious exemption for their child to file an affidavit from a physician that the parent or guardian has received information about the risks to the unvaccinated child and other individuals.
North Carolina	[95]	SB 346: Enact Stricter Immunization Requirements	2015	Referred to committee on health care, 23 March 2015	Would repeal the state's current religious exemption.
Oklahoma	[96]	SB 725	2017	Died in chamber	Would require that schools report immunization rates and exemption data to the state Department of Health.
Oklahoma	[97]	HB 1386	2017	Died in committee	States that the parent or guardian must give informed consent prior to vaccinating a child which should include receipt of the Vaccine Information Statement for each vaccination given, information on the National Vaccine Child Injury Act, and other information.
Oregon	[98]	SB 579	2017	Failed, July 7 2017	Requires health care practitioners, before administering vaccination to child, to obtain informed consent from the parent of the child or, if child is emancipated or has reached age of majority, from the child.
Oregon	[99]	SB 580	2017	Failed, July 7 2017	Would require health care practitioners, before administering vaccination to child, to provide written notice of each vaccination that the child is required to receive as condition of attending school or children's facility in the state. It would also inform the parent of each exemption to vaccine requirements

State	References	Introduced legislation title	Year introduced	Passed?	Overview
Oregon	[100]	SB 869	2017	Failed, July 7 2017	Very similar to SB579.
Oregon	[101]	SB 895	2015	Pending	Would require schools to post data on the number of children exempted from vaccinations.
Oregon	[102]	SB 442	2015	Pending	Would require a parent to meet with a physician to discuss the “risks and benefits” of immunization before obtaining a waiver.
Pennsylvania	[103]	SB 217	2017	Pending	Would eliminate exemptions for strong moral and ethical convictions. This would also eliminate some aspects of personal belief exemptions, though religious exemptions are still allowable.
Rhode Island	[104]	SB 47	2017	Died in committee	Makes changes to the department of health’s authority to mandate certain vaccinations, reinstates philosophical exemption to vaccinations, and requires public hearings when changes to required vaccinations are proposed.
Rhode Island	[105]	H 5681	2017	Died in committee	Provides an exception to required school immunizations for pupils whose personal beliefs are contrary to immunization and/or testing; essentially this would open exemptions to include personal belief exemptions.
Rhode Island	[106]	S 0381	2015	Yes, March 26 2015	Would repeal the state’s current religious waiver to vaccination.
Texas	[107]	HB 1124	2017	Died in committee	Mandates the development of an affidavit of exemption form by the state Department of Health Services which would include a section where the person indicates that they understand the risks and benefits of their child not being vaccinated.
Texas	[108]	SB 1010	2017	Died in committee	Would require each school to report immunization and exemption data to the state Department of Health Services. The department would be required to post the data in electronic form and on the department’s website.
Texas	[109]	HB 1029	2017	Died in committee	Require informed consent to immunizations for children.
Texas	[110]	SB 479	2017	Died in committee	Require informed consent to immunizations for children.
Texas	[111]	HB 241	2016	Died in committee	Would require a healthcare practitioner to provide counseling before conscientious or religious exemption to vaccines can be granted.
Texas	[112]	HB120	2016	Died in committee	Would remove conscientious and religious belief exemption and replace it with “non-medical” exemption.
Texas	[113]	HB126	2016	Died in committee	Would require recipients of conscientious and religious exemptions to complete an educational module relating to vaccines.
Texas	[114]	SB 547	2015	Pending	Would require epidemiological reports of disease outbreaks and of individual cases of disease suspected or known to be of importance to the public health. The department shall prepare and submit to the legislature and the governor a report on outbreaks of vaccine preventable diseases and de-identified immunization exemption data.
Texas	[115]	SB 480	2015	Pending	Specifies conditions under which a pharmacist may administer medication, including an immunization or vaccination.
Texas	[116]	HB 2429	2015	Pending	Determining who can provide consent for a minor for medical care, including immunization services.
Texas	[117]	HB 2474	2015	Died in committee	Requires epidemiological reports of disease outbreaks and of individual cases of disease suspected or known to be of importance to the public health, including vaccine preventable diseases. The department will evaluate the reports to determine the trends involved and the nature and magnitude of the hazards.

State	References	Introduced legislation title	Year introduced	Passed?	Overview
Texas	[118]	HB 2902	2015	Pending	The Department of State Health Services will create a biennial report on vaccination exemptions and any outbreaks of vaccine preventable diseases. The report will be available online to the public.
Texas	[119]	HB 2006	2015	Pending	Details guidelines for acquiring exemption for childhood and adolescent vaccinations for Texas youth. Details who is eligible for exemptions.
Texas	[120]	HB 1593	2015	Pending	Explains the need for notifying parents of student immunization status at their child's school. Schools must provide parents information on the number of students enrolled at the school who have not obtained the immunizations required for that school year by the Department of State Health Services. If all students have received immunization, notification of immunization status for the school is not necessary.
Texas	[121]	HB 1674	2015	Pending	Requires that parents seeking exemptions based on religious or philosophical beliefs be counseled by a physician and informed of the benefits and risks of vaccination before signing exemption waiver.
Texas	[122]	HB 465	2014	Pending	Calls for the creation and maintenance of an immunization registry. Registry should develop guidelines to protect the confidentiality of patients, inform the individual or individual's legally authorized representative about the registry and that registry information may be released, and permit a guardian to request withdrawal of an individual's information.
Texas	[123]	HB 212	2014	No	Guidelines for minor consent to immunization for minors committed to Texas juvenile justice department.
Texas	[124]	SB 29	2014	Pending	Calls for the development of guidelines to protect the confidentiality of patients, inform the individual or guardian about the registry and that registry information may be released, and permit the individual or guardian to request that the individual's information be removed from the registry.