

**COLORADO'S PERSONAL BELIEF EXEMPTION
POLICY FOR IMMUNIZATIONS:
STAKEHOLDER ENGAGEMENT PROCESS**

With recommendations from Stakeholder Working Group

Prepared by The Keystone Center - October 2013

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EXECUTIVE SUMMARY

As a condition of enrollment in a licensed child care facility and/or Colorado public school, Colorado law requires children to be immunized per the vaccine schedule required by the Colorado Board of Health (BOH) rule 6 CCR 1009-2, which closely aligns with the Center for Disease Control and Prevention's approved immunization schedule recommended by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologist (ACOG) unless they are exempt. In order to be compliant with BOH rule 6 CCR 1009-2, the school must have on file for each student the official certificate of immunization documenting that all required immunizations were received. If the student is not up to date on required immunizations, the school is to contact the parent to inform them that they have 14 days to either receive the immunization(s) or make a written plan to receive the immunization(s) and the student is referred to as being "in process." If the student does not fulfill the plan, the student shall be suspended or expelled from school for non-compliance as noted in Section 25-4-907, C.R.S. However, the student has the option of claiming an exemption in order to be in compliance. Currently, the state allows three different types of exemptions for immunizations:

- medical
- religious
- personal belief

Colorado's **Personal Belief Exemption (PBE)** policy for immunizations allows children to be exempt from state mandated vaccinations by submitting to the student's school a Certificate of Immunization with the statement of personal exemption signed by the parent(s) or the emancipated student indicating that they have a personal belief that is opposed to immunizations. (This exemption is only required to be completed upon enrollment and does not need to be revisited by the parent or student in subsequent years.)

Currently, PBEs are the primary reason for exemption in our state, with Colorado having among the highest rates of PBE in the nation. For the 2012-2013 school year, 4.3 percent of kindergarteners were not fully vaccinated upon school entry due to exemptions. Of the 4.3 percent of children exempted, 93 percent of those claimed a personal belief exemption.¹ The remaining exemptions claimed were for medical or religious reasons. This equates to almost 3,000 kindergarteners entering schools each year who are unimmunized against one or more for vaccine preventable diseases (VPD).

The ease of obtaining PBEs may play a role in the high rates of VPD. In states like Colorado, where parental signature alone is sufficient to claim an exemption, the incidence of pertussis (whooping cough) was 41 percent higher than in states with more restrictive methods.² Furthermore, states that permit exemptions with such ease are associated with higher rates of exemptions in schools³ and, within states; schools that have higher rates of exemptions may be associated with higher disease rates.⁴

The mission of the Colorado Department of Public Health and Environment (CDPHE) is to protect and improve the health of Colorado's people and the quality of its environment. Along with its partners throughout the State, CDPHE embarked on a collaborative process to better understand the current knowledge, attitudes, and beliefs around immunizations and exemptions in Colorado.

¹ Center for Disease Control and Prevention (CDC) Vaccination Coverage Among Children in Kindergarten — United States, 2012–13 School Year. *MMWR Morb Mortal Wkly Rep.* 2013;62(30):607.

² Omer SB, P. W. Nonmedical exemptions to school immunization requirements: Secular trends and association of state policies with pertussis incidence. *JAMA* 296, 1757–1763 (2006).

³ Boone v Boozman, 217 F Supp 2d 938 (ED Ark 2002).

⁴ Salmon DA, Omer SB, Moulton LH, et al. The role of school policies and implementation procedures in school immunization requirements and nonmedical exemptions. *Am J Public Health.* 2005;95:436–440

CDPHE, along with the Colorado Children’s Immunization Coalition (CCIC), an independent, nonprofit 501(c)3 organization whose mission is to strategically mobilize diverse partners and families to advance children’s health through immunization, partnered with The Keystone Center (Keystone), a neutral, third party facilitator whose mission is to bring together today’s leaders to create solutions to society’s pressing challenges. Over six months, CDPHE, CCIC, and Keystone planned and implemented a stakeholder engagement process involving eight sector specific focus group meetings, multiple key informant interviews, and three stakeholder meetings to achieve the following outcomes:

- Outcome 1: Stakeholders will gain a better understanding of the current state of personal belief exemption attitudes and opinions in Colorado based on reviewing a background report developed from sector-specific focus groups of health care providers, parents, school administrators, school nurses and public health officials.
- Outcome 2: Stakeholders will meaningfully participate in facilitated in-depth discussions on current personal belief exemption policies and practices in Colorado.
- Outcome 3: Stakeholders will generate potential policy and/or rule changes to the personal belief exemption system.
- Outcome 4: Stakeholders will make final recommendations on Colorado’s Personal Belief Exemption system to be formally submitted to CDPHE in a written report.

Throughout each step of the process, common themes continued to be voiced by each sector and group. The common themes that arose from the focus group meetings and key informant interviews, which provided groundwork for the final recommendations, included: education, informed consent, accurate and timely data, administrative processes, personal choice, and collaboration of State Agencies.

The 25 participating stakeholders, who were charged with deliberating and recommending high level proposals, reviewed the common themes from the focus groups and recommended the following with full consensus:

- Colorado Department of Education and/or Board of Education to hold school districts accountable for enforcing immunization policy.
- Colorado Department of Public Health and Environment, Colorado Department of Education and Colorado Department of Human Services to establish joint policy on immunization data collection and sharing.

Stakeholders recommended the following with majority support:

- Require education and/or counseling prior to claiming a personal belief exemption.
- Make publically available the publication of immunization and exemption rates by schools and licensed child care facilities.

Stakeholders also recommended the following with high levels of support:

- Annual renewal of the personal belief exemption.
- Medical or provider signature for the personal belief exemption.

Throughout the six month process, voices from all sides of the issue came together in good faith, to conduct deliberative conversations on the current and future landscape of immunizations and exemptions in Colorado. This report is meant to serve the following purposes:

- State and local elected and appointed officials throughout the State of Colorado may use this information to better serve the needs of their constituents.

- State and local health agencies may use this information to help set strategic goals and implement changes in policies and practices.
- Advocacy organizations may use this information to recommend policy of rule changes at the state and local level.
- Pediatric and family providers may use this information to inform changes in their practice.
- School administrators, superintendents and school nurses may use this information to inform changes in schools.
- Private sector interests may use this information to impact consumer and marketplace issues, such as vaccine administration and provider reimbursement fees.
- Individuals may use this information to advocate for changes in school health policies and practices.

GLOSSARY OF TERMS

Exemption- In the United States, all states require that children be vaccinated for certain diseases before school entry (the required immunizations vary by state). Several types of exemption may be allowed, depending on state and local regulations. An exemption is a form or other document that is submitted to the school prior to school entry that allows the child to attend school, without obtaining all the state required immunizations.

Family Educational Rights and Privacy Act (FERPA)- United States federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

Focus Group- A small group of people whose opinions about a topic are studied to determine the responses that can be expected from a larger group.

Health Official- A representative of a federal, state or local public health agency.

Licensed Child Care Facilities- Child care homes and centers, pre-school and school-age child care programs, summer camps, residential child care facilities, and child placement agencies licensed and monitored by the Colorado Department of Human Services, Division of Early Care and Learning.

Medical Practitioner- A professional who is legally certified to provide health treatments to patients through the promotion, maintenance or restoration of human health through the study, diagnosis, and treatment of disease, injury, and other physical and mental impairments. The license is usually issued by a medical services regulating body after vetting and evaluation. Specifically, for the purposes of this document, a medical practitioner is any professional licensed to provide immunizations.

Pertussis- Also known as whooping cough, is a highly contagious respiratory disease caused by the bacterium *Bordetella pertussis*, with symptoms such as uncontrollable, hacking coughing followed by a high-pitched intake of breath that sounds like "whoop." Pertussis most commonly affects infants and young children and can be fatal, especially in babies less than 1 year of age.

Pneumococcal Disease- An infection caused by the *Streptococcus pneumoniae* (*S. pneumoniae*) bacterium, also known as pneumococcus. Infection can result in pneumonia, infection of the blood (bacteremia/sepsis), middle-ear infection (otitis media), or bacterial meningitis. Children younger than 2 years of age are among those most at risk for disease.

Primary Care Provider- A generalist physician who provides definitive care to the undifferentiated patient at the point of first contact and takes continuing responsibility for providing the patient's care. Such a physician must be specifically trained to provide primary care services.

Recommended Vaccines- The Centers for Disease Control and Prevention (CDC) sets the U.S. immunization schedule to prevent 17 vaccine-preventable diseases that occur in infants, children, adolescents, or adults based on recommendations from the Advisory Committee on Immunization Practices (ACIP). The recommendations are based not only on available scientific evidence but also on expertise that comes directly from the ACIP. The ACIP reviews the *General Recommendations on Immunization* every 3 to 5 years and make recommendations on topics that relate to all vaccines, including timing and spacing of doses, precautions and contraindications, vaccine administration, and vaccine storage and handling.

Risk Profile– Also known as a safety profile, is a description of the number of benefits, types of benefits, and potential effects of benefits of a vaccine to the vaccine recipients as well as the number of risks, types of risks and potential effects of risks of a vaccine to vaccine recipients.

Vaccine Information Sheet (VIS)- A document produced by the Center for Disease Control and Prevention (CDC), that informs vaccine recipients- or their parents or legal representatives- about the benefits and risks of a vaccine they are receiving. All vaccine providers, public or private, are required by the National Vaccine Childhood Injury Act to give the appropriate VIS to the patient (or parent/legal representative) about the benefits and risks of a vaccine they are receiving.

Vaccine Preventable Disease- An infectious disease for which an effective preventive vaccine exists.

Varicella- Also known as the chickenpox virus, is a very highly contagious disease, that causes blister-like rash, itching, tiredness, and fever. Chickenpox can be serious, especially in babies, adults and people with weakened immune systems.

BACKGROUND

In early 2013, The Colorado Department of Public Health and Environment (CDPHE) in partnership with the Colorado Children’s Immunization Coalition (CCIC), an independent nonprofit 501(c)3 organization whose mission is to strategically mobilize diverse partners and families to advance children’s health through immunization, with funding and support from the federal Centers for Disease Control and Prevention (CDC) and The Colorado Trust’s Convening for Colorado Grant Program. To engage a wide range of stakeholders regarding Colorado’s current Personal Belief Exemption Policy for Immunizations, the Colorado Children’s Immunization Coalition applied for and received a Colorado Trust Convening for Colorado grant that provides support to bring people together to discuss issues central to advancing the health and well-being of Coloradans. The Keystone Center (Keystone), an independent neutral 501(c)3 facilitator whose mission is to bring together today’s leaders to create solutions to society’s pressing challenges, was selected to design and facilitate this process.

The rate of utilization of Personal Belief Exemptions (PBEs) to immunization requirements for public school and licensed child care enrollment is a growing concern in the State of Colorado and throughout the nation. The Colorado Certificate of Immunization form can be found in Appendix A. Within the Certificate of Immunization, the medical, religious, and personal belief exemptions can be found. PBEs are the primary reason for exemption from recommended immunizations and accounted for over 90 percent of all immunization exemptions for Colorado kindergarteners from 2003 – 2012. Colorado has among the highest rates of PBE in the nation with 4.3 percent of kindergarteners not fully vaccinated upon school entry.⁵ This equates to nearly 3,000 kindergarteners entering schools each year who are unimmunized against one or more vaccine preventable diseases (VPD). While this number has dropped over recent years, each year about 20 percent of children have incomplete vaccination forms upon enrollment. Compared with immunized children, unvaccinated children are at higher risk for VPDs.⁶ Historically, Colorado has had greater rates of VPD than the US for diseases such as pertussis, invasive pneumococcal disease, and varicella.⁷ In 2012, Colorado had a major outbreak of pertussis cases (1,494) with sustained high rates of pneumococcal disease (432 cases) and varicella (484 cases).⁸ In 2013, Colorado had an additional 919 cases of pertussis reported, through September, marking a continuing epidemic. A new study has shown that even when parents exempt or delay their children from receiving one or more shot in the recommended series against pertussis, the children were 19 to 28 times more likely to get whooping cough than kids who were caught up on their shots.⁹

The ease of obtaining PBEs may play a role in the high rates of VPD. In states like Colorado, where parental signature is sufficient to claim an exemption, the incidence of pertussis was 41 percent higher than in states with more restrictive methods¹⁰. Furthermore, states that permit exemptions easily are associated with higher rates of exemptions¹¹ and, within states; schools that permit exemptions easily are associated with higher exemption rates still.¹²

⁵ Center for Disease Control and Prevention (CDC) Vaccination Coverage Among Children in Kindergarten — United States, 2012–13 School Year. *MMWR Morb Mortal Wkly Rep.* 2013;62(30):607.

⁶ Feikin, D. R. Individual and Community Risks of Measles and Pertussis Associated With Personal Exemptions to Immunization. *JAMA: The Journal of the American Medical Association* 284, 3145–3150 (2000).

Salmon, D. A. *et al.* Health consequences of religious and philosophical exemptions from immunization laws: individual and societal risk of measles. *JAMA* **282**, 47–53 (1999).

Glanz, J. M. *et al.* Parental refusal of varicella vaccination and the associated risk of varicella infection in children. *Arch Pediatr Adolesc Med* **164**, 66–70 (2010).

Atwell JE *et al.* *Pediatrics.* 2013; 132: 624–630; DOI: 10.1542/peds.2013-0878.

⁷ *MMWR*, 2012;60(51); 1762-1775. US rates calculated using US Census Bureau Population Estimate.

⁸ Colorado Department of Public Health and Environment Reported Cases of Vaccine Preventable Disease in Colorado, 2002-2012. *Disease Statistics and Reports* (2013).

⁹ *JAMA Pediatrics*, online September 9, 2013.

¹⁰ Omer SB, P. W. Nonmedical exemptions to school immunization requirements: Secular trends and association of state policies with pertussis incidence. *JAMA* **296**, 1757–1763 (2006).

¹¹ *Boone v Boozman*, 217 F Supp 2d 938 (ED Ark 2002).

¹² Salmon DA, Omer SB, Moulton LH, *et al.* The role of school policies and implementation procedures in school immunization requirements and nonmedical exemptions. *Am J Public Health.* 2005;95:436–440

PURPOSE OF THE PROCESS

This collaborative effort was aimed at the development of a set of consensus-driven recommendations for decision makers and partners, in order to address Colorado's Personal Belief Exemption Policy for Immunizations, and to better understand the current knowledge, attitudes, and beliefs around immunization exemptions in Colorado. This effort was realized through achieving the following outcomes:

- Outcome 1: Stakeholders will gain a better understanding of the current state of personal belief exemption attitudes and opinions in Colorado based on reviewing a background report developed from sector-specific focus groups of health care providers, parents, school administrators, school nurses and public health officials.
- Outcome 2: Stakeholders will meaningfully participate in facilitated in-depth discussions on current personal belief exemption policies and practices in Colorado.
- Outcome 3: Stakeholders will generate potential policy and/or rule changes to the personal belief exemption system.
- Outcome 4: Stakeholders will make final recommendations on Colorado's Personal Belief Exemption system to be formally submitted to the Colorado Department of Public Health and Environment in a written report.

STAKEHOLDER ENGAGEMENT PROCESS DESIGN

This stakeholder engagement process included engagement through sector-specific focus group meetings and key informant interviews, as well as the convening of a multi-stakeholder group aimed at developing recommendations to decision-makers and partners for improving Colorado’s Personal Belief Exemption Policy for Immunizations. This process began in April 2013 and concluded in October 2013.

There were a total of 57 participants in sector specific focus group and key informant interviews, and 25 stakeholders who participated throughout the engagement process. Recruitment for focus group meetings was performed through community organizations, local healthcare and public health associations, and online media sources. Key informant interviews were completed via phone to round out geographic diversity and sector gaps and in places in which participants were willing to participate but could not attend or call into a meeting. Stakeholders were chosen to participate in the Stakeholder Work Group based on their professional affiliations, personal experience and expertise in immunization policy.

PLANNING COMMITTEE

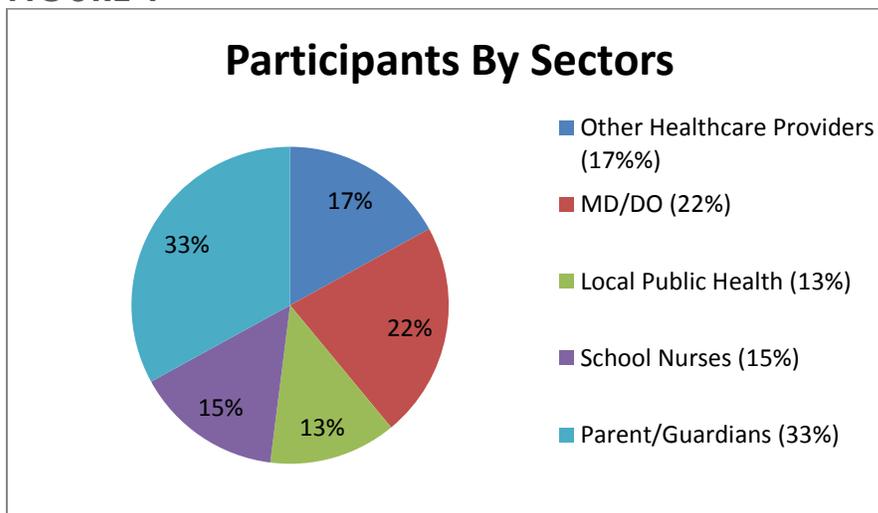
At the onset of the planning for this process, a planning committee was formed to help provide guidance for this effort. This planning committee included representatives from the CDPHE Immunization Section and the Colorado Children’s Immunization Coalition, in partnership with The Keystone Center. Support for this initiative was made possible through a grant from The Colorado Trust’s Convening for Colorado Grant Program and financial support from the CDC.

MEETING PARTICIPANTS

a. Focus Group Meetings

Small Focus Group meetings were the chosen methodology to engage participants at the on-set of this process. This format was chosen in an effort to engage participants in meaningful dialogue which would allow for cross conversation among participants and full engagement by a small number of individuals. A total of eight focus group meetings were held for five different sectors in Denver, Arapahoe, Boulder, Larimer, Pueblo, & Summit counties. The different sectors included local public health nurses, pediatricians, primary care providers, parents/guardians, and school nurses. Attempts were made to hold focus group meetings for school board members and school executives, however, due to the low registration, those meetings were cancelled and some of those members participated as key informants for interviews.

FIGURE 1



Participants were asked to register in advance of the meeting, and all meetings allowed for a small number of participants to call in if they were unable to attend in person. Participation in the focus group meetings was capped at 12 registrants to allow for comprehensive and in-depth conversations. All meetings lasted a little over an hour with Keystone facilitating general questions and sector specific questions. Questions centered on thoughts and opinions as well as strengths and weaknesses of the current personal belief exemption policy. Participants were then asked to suggest changes to the current policy, possible resources needed in the event of a policy change, and other considerations that should be discussed prior to implementation of the suggestions. The list of specific questions asked during the focus group meetings can be found in Appendix B.

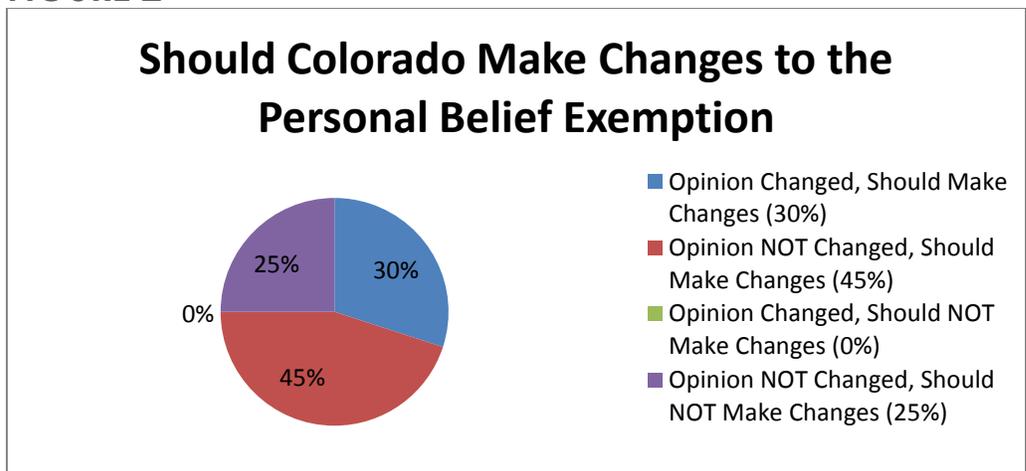
At the onset of the focus group meetings, participants were asked to complete a pre-meeting survey to provide demographic information about gender, age, race and ethnicity and education level as well as assess baseline knowledge, attitudes, and beliefs around Colorado’s Personal Belief Exemption Policy for Immunizations. At the conclusion of each focus group meeting, participants were asked to fill out a post meeting survey to assess whether their knowledge, attitudes or beliefs related to the policy had changed based on the conversation at the meeting. Participants were also asked for their level of agreement related to possible policy changes and for their evaluation of the meeting format, materials presented, and discussion. Aggregated results from the focus group meeting pre- and post- surveys can be found in Appendix C.

Of the 53 focus group participants who filled out the pre- and post-surveys:

- 91 percent were female and 9 percent were male;
- 86 percent of participants indicated that they were the parent or guardian to at least one child;
- 91 percent indicated they had a college degree with 51 percent indicating a graduate level degree.
- Participants indicated that their information and education regarding immunizations comes primarily from a health care professional and from self-education through the internet, peer reviewed research, books and news articles.

When surveyed as to whether Colorado should have a Personal Belief Exemption Policy for Immunizations, 65 percent of respondents indicated yes. Furthermore, when asked if Colorado should make changes to the current PBE policy, 75 percent of the participants who filled out the survey indicated that Colorado should make changes to the PBE policy, including 30 percent whose opinion changed after the focus group discussion in favor of modifying the policy. However, about 25 percent of participants stated that no change should be made to the current PBE policy at this time. (Figure 2)

FIGURE 2



b. Key Informant Interviews

In order to gain additional perspectives, Keystone conducted a small number key informant interviews with school executives, school board members, and rural healthcare providers. During these 30 to 40 minute phone conversations, Keystone engaged interviewees in discussion similar to that of the focus group meetings. Interviews focused on gaining perspectives from the interviewees on their individual thoughts and opinions about the current PBE policy, identifying the strengths and weaknesses of the current policy, and any suggestions for potential changes or procedural solutions related to the current policy.

c. Stakeholder Work Group Meetings

Three Stakeholder Work Group meetings were held throughout the Denver metro area. Meetings were open to the public for observation. The Stakeholder Working Group included diverse participants representing the depth and breadth of viewpoints on Colorado’s Personal Belief Exception Policy for Immunizations, including but not limited to representatives from the following communities: local and state public health officials, physicians, nurses and healthcare providers, state legislative representatives, school nurses and administrators, parents and guardians, and advocacy organizations. Although 25 stakeholders participated throughout the process, 40 stakeholders were invited to participate. Invited participants were allowed to send a representative similar in expertise and authority from their organization if they were unable to participate. Due to scheduling conflicts and competing priorities, many invitees could not participate in one or all of the meetings. A list of the participating Stakeholders can be found in Appendix D.

Each meeting lasted approximately five hours, allowing time for presentations, large and small group discussions, and preference polling for levels of agreement among participants. Protocols were developed prior to the first meeting were used to define the role of participants, a “good faith” approach to dialogue, matters of confidentiality and non-attribution, and the decision making process of the group. These protocols were circulated to participants prior to the first meeting and were finalized at the first meeting. These protocols can be found in Appendix D. During the course of the Work Group Meetings, members of the Planning Committee along with their colleagues presented both state and national data on immunizations, vaccine preventable diseases, local and national research conducted about exemptions, policy change dynamics and lessons learned from states around the nation. Keystone facilitated plenary and small group discussions of the Working Group and members of Keystone engaged participants in dialogue and deliberations focused on, thoughts and opinions regarding the current PBE policy, and possible upgrades to the current policy. Agendas for these meetings can be found in Appendix F.

MEETING DISCUSSIONS AND COMMON THEMES

a. Focus Group Meetings

Focus groups meetings were held for five key sectors (Local Public Health, Pediatricians, Primary Care Providers, Parents/Guardians, and School Nurses). Through facilitated small group discussion during the focus group meetings, participants identified the strengths and challenges of the current policy which can be found below.

Strengths of the Current PBE policy

- Parents/Guardians have a choice in the health care their child receives
- Ease of claiming a personal belief exemption
- Flexibility in vaccination schedules

Challenges of the Current PBE policy

- Ease of claiming a personal belief exemption
- The signing of the PBE may not accurately reflect the current state of vaccinations for a child
- Parents/Guardians may not have enough information to make an informed decision
- Could lead to an increase in uncertainty among parents and guardians as to the safety of vaccines, due to the mere fact that an exemption exists

Common themes that arose across all focus groups included: the need for increased education, the importance of informed consent, the need to improve the administrative processes, data needs, indication as to the reason for signing the PBE, and the importance of personal choice.

Increased Education – Participants expressed the importance and need for education for ALL parties including parents, providers, school executives, and others. Participants expressed the need for access to balanced scientific, evidence-based information from reputable and trusted sources regarding the benefits and risks of vaccination. Participants also highlighted the need for training and education for professionals including health care providers on respectful dialogue with parents including discussing the benefits and risks of vaccination, dispelling inaccurate information, answering questions related to vaccine ingredients and alternative vaccination schedules as well as education for school executives, nurses, and administrators on the current policy and the importance and role of vaccination in school settings.

Informed Consent– Informed consent was also addressed as a consideration. While the groups struggled to define exactly what informed consent would look like, there was a general recognition that parents and guardians should be aware of and understand what they are signing and the benefits and risks of vaccinations. Furthermore, there was concern from parent groups that the language would have to indicate that they understand the risks of claiming an exemption and not that they agree with the risk statement. Moreover, many participants implied their concern that true informed consent may not be taking place due to the wide variability in which the current policy is being implemented and enforced across that state.

Administration Process – Participants expressed concern about the administrative process of collecting immunization records or PBEs during school enrollment and feel that these processes could be improved. Across the state, there is wide variability as to how the current policy is being interpreted, implemented and enforced. Parents/guardians reported that they were not always told about the option of the PBE while others believe that the PBE is offered as a “quick fix” and used to ensure that children are in their seats for the official school seat count.

Data Needs – Participants expressed the need for additional data, including more timely data available on domestic and international outbreaks, updated risk profiles for vaccines, vaccination rates by school and district and a comprehensive, widely available and accessible system that tracks each child’s vaccinations available across sectors. Participants indicated that in order to truly understand the current landscape of immunizations and exemptions, more data is needed to understand the reasons why parents/guardians are choosing to sign the PBE. Participants suggested an optional checkbox on the exemption form to allow parents/guardians to indicate their reason for exempting. This could allow the state to obtain more accurate data as to the reason parents/guardians are choosing a PBE. Participants on all sides of this issue agreed more data would be helpful in order to protect our children’s and the community’s health.

Personal Choice- Participants expressed the importance of personal choice and the importance of autonomy in making personal medical decisions. While the importance of choosing what is best for one's children and family was brought up in each meeting, an underlying factor expressed by most, not all, stakeholders was the need to balance personal choice with the health of the community as a whole.

Many additional values, thoughts and opinions arose during the focus group meetings; however, the above six themes were common across all sectors and demographics. These common themes were brought to the stakeholders for further discussion and deliberation.

b. Key Informant Interviews

Key informant interviews were held to fill in sector and geographic gaps from the focus group meetings. The main focus of engaging key informants in this process was to understand the opinions of providers in rural areas as well as school executives and school board members.

Interviewees all reiterated the complexity of immunization issues and identified similar strengths and weakness of the current policy as those identified at the focus group meetings, as well as similar sentiments including: the importance of balancing personal choice with protection of community health, particularly those who cannot be vaccinated due to medical reasons or are not old enough to be vaccinated; schools within the same district have different processes for collecting immunization information; there is a need for collaborative policies across school districts among schools, health care providers, and government agencies; the need for more robust data collection and reporting; and the need and importance of increased education.

c. Stakeholder Meetings

Three Stakeholder Work Group meetings occurred during August and September of 2013 and were held in the Denver metro area. Meeting summaries are as follows:

MEETING 1: The first stakeholder meeting was convened on August 13, 2013 at The Colorado Trust building at 1600 Sherman Street, Denver CO. The meeting began with introductions of the participants followed by an overview of the process, the objectives and a review of the group protocols. Following housekeeping items, presentations were delivered to participants on the current landscape of immunizations and research in both Colorado and nationally. The group acknowledged that there are data gaps but that in the absence of all the data desired, the group was tasked with working together to discuss possible recommendations. The presentations continued with an overview of the common themes that were derived from the focus group meetings, which led into a discussion of the stakeholder's initial beliefs and opinions of the PBE. The presentation from Meeting 1 can be found in Appendix G.

Participants were asked to participate in an initial preference polling activity to indicate their levels of comfort with the initial list of recommendations. This polling indicated a strong level of comfort among participants for a recommendation to support the publically available publication of immunization rates by school and childcare centers, informed refusal, and requiring education/counseling prior to exemption. Moderate levels of comfort were indicated for a separate exemption form, mandatory acknowledgement of information about PBE, asking a parent to provider a reason for seeking a PBE and a medical or health practitioner signature for exemption. Participants were equally split on their level of comfort for the signature of a parent or no change to the current policy. At no point during the Stakeholder engagement process were the participants asked to rate their level of comfort to eliminate the PBE from the current immunization exemption policy.

Initial participant comments centered around the emotional toll on a parent or guardian in choosing whether to vaccinate and how that understanding could help guide exemption policy in the state. Furthermore, many participants saw an opportunity to further educate those who choose to sign the PBE out of convenience or lack of knowledge on the benefits of vaccination. There was also a discussion on how to help those who do not immunize due to the lack of access to vaccinations. Finally, the group discussed how there is a need for balance between informed consent, parental rights and the health of children and communities as a whole. Concern was also raised by some stakeholders regarding equal effort for both vaccination and signing the PBE.

Stakeholders then broke into small groups to discuss common themes, possible recommendations, and other considerations. The meeting concluded with participants completing a preference polling activity that gauged the stakeholders' level of comfort with recommendations brought forth from the focus group meetings. These recommendations ranged from no change to the PBE, to administrative changes and statutory changes.

FIGURE 3

If Colorado's immunization personal belief exemption includes:	Could be accomplished by BOH rule	Requires changes to statute
Informed Refusal ("understands the risks")	Yes	
Required Education/ Counseling prior to Exemption		Yes
Medical Practitioner or Health Official Signature for Exemption		Yes
Separate Exemption Form	Yes	
Exemption Approved by Health Department		Yes
Annual Renewal of Exemption		Yes
Publically Available Publication of Immunization Rates by School and Child Care Centers		Yes
Signature of Parent (NO CHANGE)	NA	NA
Signature of Notary		Yes
Ask parent to provide reason for exemption		Yes
Mandatory acknowledgement of information about PBE		Yes
Require that the parents or guardians sign a statement that delineates the basis, strength, and duration of their belief		
Require that exempted children be barred from school attendance and other group activities if there is an outbreak of a disease that is preventable by a vaccination from which they have been exempted.		
States that adopt provisions for personal belief exemptions should track exemption rates and periodically reassess the impact that exemptions may have on disease rates		

MEETING 2: The second stakeholder meeting was held on August 20, 2013, at the Colorado Department of Public Health and Environment at 4300 Cherry Creek Drive South, Denver, CO. The meeting began with introductions, followed by presentations and large group discussion. Information was presented to stakeholders regarding possible recommendations for changing Colorado's PBE policy, and how other states throughout the U.S. have made changes to their policies, including considerations for and lessons learned from these policy changes. Presentation from Meeting 2 can be found in Appendix H¹³. The

¹³ Note: Participants brought and shared information with each other; however, this information was not formally presented during the stakeholder meeting and therefore, not further addressed in this report.

group then discussed criteria that could help them evaluate the possible recommendations suggested thus far. These criteria included:

- accountability
- same level of effort
- simplicity
- risk versus benefit
- “freedom to” versus “freedom from”
- reasonable and meaningful
- informed consent
- standards
- resources
- consistency

These criteria laid the groundwork for the discussion around framing possible recommendations. Stakeholders then broke into two smaller groups for discussions facilitated by Keystone staff. The small groups discussed each proposed recommendation addressing levels of support, concerns, and other considerations.

The group then came back together for a plenary discussion, sharing levels of support and dissent as well as considerations for each recommendation. Following the discussion, stakeholders again took part in a preference polling exercise to determine their level of support for the recommendations. Each participant was given three polling dots to indicate their support for recommendations. All three dots could go to one recommendation or could be divided among the options. Furthermore, participants could also include an additional or revised recommendation that was not already an option. The recommendations that had the highest levels of support indicated through the preference polling included:

Recommendation	Preference Polling Results
Required education/counseling prior to exemption	16
Publically available publication of immunization rates by schools and child care centers	7
Medical practitioner or health official signature for exemption	6
Annual Renewal	4
Colorado Department of Education (CDE)/Board of Education to hold school districts accountable for immunization policy	2
CDPHE, CDE, and Colorado Department of Human Services establish joint policy on data collection and sharing	2
Use VIS as the educational piece	2
Exemption approved by Health Department	1
Mandatory acknowledgement of information about PBE	1
Informed refusal	1
No change to the current policy	1
Separate exemption form	0
Signature of notary	0

While there were other recommendations that garnered support, the following six recommendations had the highest level of support by a majority of the stakeholders in attendance.

MEETING 3: The third meeting was convened on September 12, 2013 at the Colorado Department of Public Health and Environment, Laboratory Services Division, 8100 Lowry Boulevard, Denver, CO. Due to the uncertainties of the weather and the flooding throughout the local communities, lower attendance as well as a shortened time frame was experienced at the third meeting. The third and final meeting was dedicated to narrowly defining the recommendation(s) and finalizing levels of support and considerations for the recommendations that the Working Group would put forward in the final report. The presentation from the third meeting can be found in Appendix I¹⁴. Below is a description of the recommendations along with the levels of support, and other considerations for each recommendation.

¹⁴ Note: Participants brought and shared information with each other; however, this information was not formally presented during the stakeholder meeting and therefore, not further addressed in this report.

FINAL RECOMMENDATIONS

The following two recommendations received full consensus of the group:

Recommendation 1: Colorado Department of Education and/or Board of Education to hold school districts accountable for immunization policy.

Participants felt strongly that the variability of how the current policy is being implemented by school executives, administrators, and superintendents leads to additional confusion and complexity for parents. The policy should be implemented and enforced universally across all school districts.

Recommendation 2: Colorado Department of Public Health and Environment, Colorado Department of Education and Colorado Department of Human Services to establish joint policy on immunization data collection and sharing.

The majority of the group felt that if the three agencies (CDPHE, CDE, DHS) came together to share data and exchange information, it would speak to a broader commitment to implementing and enforcing the PBE requirements. This type of collaboration would ensure consistency among agencies, create more accountability, and potentially aid in filling data gaps.

In addition to the two recommendations with full consensus, the following recommendations had majority support of Stakeholders:

Recommendation 3: Require education and/or counseling prior to exemption.

There was a high level of agreement among the group for education or counseling prior to a parent or guardian signing the PBE. Support for this recommendation was grounded in that all parents, no matter what their choice may be regarding vaccination, should be educated on the benefits and risks of immunizations. By requiring education or counseling prior to signing the PBE, the hope by the majority of participants was parents would have better knowledge and immunize their children after being informed of the benefits of vaccination. Furthermore, there was discussion that all providers should be educated as well in vaccine benefits and risks, as well as vaccine schedules, and respectful dialogue with patients.

Additional considerations:

- Some stakeholders commented that education alone would not create behavior change. Health care providers mentioned that education needed to start prior to the visit in which the child would be vaccinated; suggestions were made that this education should begin at the OB/GYN level prior to the birth of a child.
- The group discussed and considered the time providers take to discuss vaccination with clients and the group recommends that providers should be compensated for the time spent with patients. Because of the limited amount of time a provider can spend with a patient, parents/guardians should be primed with questions and information in order to understand the true risks and benefits of vaccination. It was brought up that many within our state do not have a medical home and therefore would not be best served by getting the education through a provider that they did not have a relationship with. Concern was also raised that education does not get to the issue of the number of parents/guardians who sign the PBE. A few stakeholders commented that many of the parents/guardians who sign the PBE are very well educated and moreover, it is a personal held belief and they should not be told what education is the best for them and what they should personally believe.

- Some discussion centered on what the education would look like and who would develop it. A stakeholder recommended that the Vaccine Information Sheet (VIS), which is already required by law, should be enough. However, most stakeholders thought that the VIS was a starting point and more information on the benefits and risks of vaccination should be communicated, ideally in-person to parents to allow for questions to be addressed through dialogue. Moreover, there was a conversation about online education for those who either choose not to visit a licensed provider or do not have access to a medical home or a provider. There was a high level of support for including an option for online education and/or counseling as an additional mechanism for achieving the education/counseling requirement. Nevertheless, a few stakeholders expressed concern on the depth of the education, and how to ensure that the parent/guardian understood what was presented.
- Participants expressed the importance of having adequate resources allocated to develop and disseminate the education component to ensure that this recommendation is not an unfunded mandate.
- Some participants expressed the importance of not creating an unfunded mandate through this policy change as well as having an evaluation piece included to monitor the impact.

Recommendation 4: Publically available publication of immunization and exemption rates by schools and licensed childcare centers.

There was a high level of support from Stakeholders to require publication of immunization and exemption rates by schools and licensed childcare centers. Rates would be published by CDPHE in the aggregate, and not attributed to specific children to alleviate privacy concerns and comply with the requirements of the Family Educational Rights and Privacy Act (FERPA).

Additional Considerations:

- The need for timely and valid data collection to ensure accurate information is analyzed and reported.
- Participants discussed the importance of timely and easy to access dissemination of the information and the importance of resources to support the collection and dissemination of this data.
- Participants cautioned that privacy concerns may arise when focusing on smaller schools or licensed childcare centers.
- This change could negatively impact businesses (licensed childcare centers), if parents choose not to take their children to a certain child care center based on the exemption rate. However, another stakeholder pointed out that parents have the right to be informed about where they take their children for child care but at the same time, it could lead to a false sense of security.

Stakeholders also considered the following recommendation with high levels of support:

Recommendation 5: Medical practitioner or health official signature for exemption.

There was some confusion around this recommendation. Questions remain as to whether the medical practitioner/health official would be the person to sign along with the parent for the PBE or whether the signature was in addition to the education and the parent/guardian signature. There was also a conversation as to whether it would be combined with other recommendations or be recommended alone. Many in the group believed that requiring a health professional to co-sign the PBE along with the parent would therefore reach the core characteristic of “equal effort.” Furthermore, the recommendation if combined with education was consistent with and reinforcing of the idea that parents should be required to undertake some form of education or counseling prior to making decision about vaccinating or not vaccinating their children. The group generally agreed that a health care provider or licensed vaccine provider would be an acceptable standard to co-sign a PBE with a parent. Again, the concern was raised by some stakeholders that this exemption is a personally

held belief and not a medical exemption and therefore, a medical practitioner/health official should not have to sign the exemption form to validate a person's personally held belief. While there was support for a medical practitioner/health official signature, the intended purpose of obtaining this signature remains unclear and this the recommendation had a lower level of support.

Recommendation 6: Annual renewal of exemption.

The conversation around annual renewal of exemptions began with taking a deeper look into how annual renewal would affect the following sectors: government, health care providers, schools, and parents/guardians. There was also a discussion around what the BOH rule requires to determine if a child is up to date with vaccinations in regards to school enrollment. It was determined that this recommendation would require a change in statute and more coordination between government agencies, schools and parents/guardians.

Additional Considerations:

- Additional resources may be needed to collect this information on an annual basis as well as if there could be a data sharing system that would make this recommendation dispensable.
- Renewal of exemptions should be on the same schedule as the vaccination schedule. The majority of the stakeholders supported that the PBE should be renewed more than the one time, which is the current requirement, however, there was no final determination as to what the renewal time would be. However, a minority of Stakeholders indicated that a one-time renewal was enough, especially for those parents/guardians who had education and understood the decision they were making.

CONCLUSIONS

This engagement process was successful in meeting the objectives set forth, including engaging stakeholders in meaningful dialogue to gain a better understanding of the current state of the PBE policy and to generate policy recommendations related to the PBE policy. The engagement process brought key sectors to the table to ensure that thoughtful dialogue surrounding the Personal Belief Exemption policy in Colorado occurred. Stakeholders came together and deliberated on the themes and data coming out of the focus group meetings and used this information along with data presented at meetings and information shared during discussions at the Work Group meetings to put forth recommendations for decision makers and partners throughout the State. Stakeholders held meaningful conversations not only around the recommendations itself, but around the strengths, values, concerns and considerations each recommendation carried. There were differing views concerning the PBE policy, but by having people at the table representing diverse voices from across the State, the recommendations developed represent the opinions of a majority of the stakeholders and are reflective of the current beliefs regarding the PBE in Colorado.

APPENDIX A: COLORADO PERSONAL BELIEF EXEMPTION FORM

Name _____ Date of Birth _____

Parent/Guardian _____

**STATEMENT OF EXEMPTION TO IMMUNIZATION LAW
(DECLARACIÓN RESPECTO A LAS EXENCIONES DE LA LEY DE VACUNACIÓN)**

IN THE EVENT OF AN OUTBREAK, EXEMPTED PERSONS MAY BE SUBJECT TO EXCLUSION FROM SCHOOL AND TO QUARANTINE.
SI SE PRESENTA UN BROTE DE LA ENFERMEDAD, ES POSIBLE QUE A LAS PERSONAS EXENTAS SE LES PONGA EN CUARENTENA O SE LES EXCLUYA DE LA ESCUELA.

MEDICAL EXEMPTION: The physical condition of the above named person is such that immunization would endanger life or health or is medically contraindicated due to other medical conditions.

EXENCIÓN POR RAZONES MÉDICAS: El estado de salud de la persona arriba citada es tal que la vacunación significa un riesgo para su salud o incluso su vida; o bien, las vacunas están contraindicadas debido a otros problemas de salud.

Medical exemption to the following vaccine(s):
La exención por razones médicas aplica a la(s) siguiente(s) vacuna(s):

Hep B DTaP Tdap Hib IPV PCV MMR VAR

Signed (Firma) _____ Date (Fecha) _____
Physician (Médico)

RELIGIOUS EXEMPTION: Parent or guardian of the above named person or the person himself/herself is an adherent to a religious belief opposed to immunizations.

EXENCIÓN POR MOTIVOS RELIGIOSOS: El padre o tutor de la persona arriba citada, o la persona misma, pertenece a una religión que se opone a la inmunización.

Religious exemption to the following vaccine(s):
Exención por motivos religiosos de la(s) siguiente(s) vacuna(s):

Hep B DTaP Tdap Hib IPV PCV MMR VAR

Signed (Firma) _____ Date (Fecha) _____
Parent, guardian, emancipated student/consenting minor
(Padre, tutor, estudiante emancipado o consentimiento del menor)

PERSONAL EXEMPTION: Parent or guardian of the above named person or the person himself/herself is an adherent to a personal belief opposed to immunizations.

EXENCIÓN POR CREENCIAS PERSONALES: Las creencias personales del padre o tutor de la persona arriba citada, o la persona misma, se oponen a la inmunización.

Personal exemption to the following vaccine(s):
Exención por creencias personales de la(s) siguiente(s) vacuna(s):

Hep B DTaP Tdap Hib IPV PCV MMR VAR

Signed (Firma) _____ Date (Fecha) _____
Parent, guardian, emancipated student/consenting minor
(Padre, tutor, estudiante emancipado o consentimiento del menor)

APPENDIX B: FOCUS GROUP MEETING DISCUSSION QUESTIONS

Colorado's Personal Belief Exemption Policy for Immunizations Stakeholder Engagement Process Focus Group Questions

General Focus Group Questions

- What are your thoughts and opinions regarding Colorado's current Personal Belief Exemption Policy for Immunizations?
 - What are the strengths of the current policy?
 - What are the weaknesses of the current policy?
 - Challenges?
 - Unintended consequences?
- What are your suggestions for revisions to Colorado's current Personal Belief Exemption Policy for Immunizations?
 - How should these revision(s) be realized?
 - How best should these changes be communicated to you and your constituents?
 - If revision(s) are made to the Exemption Policy, what barriers exist, if any, to the adoption of the changes?

Sector Specific Questions – additional questions

Physicians & Health Care Providers

- How does the current policy affect your practice? Patients?
- If revision(s) are made to the Exemption Policy, are there any specific needs that may arise for you or your practice (*i.e.*, technological or program changes, training and education for providers and/or staff)?

Education & Educator Organizations

- What are your main challenges with implementing this policy?
- How can these challenges be addressed?
- If revision(s) are made to the Exemption Policy, are there any specific needs that may arise for you or your constituents (*i.e.*, technological or program changes, revisions to school or district level policies, training and education for parents and guardians, tailored communications to parents and guardians)?

Parent, Guardian and Advocacy Organizations

- What has been your experience with schools and childcare facilities implementing this policy?
- If revision(s) are made to the Exemption Policy, are there any specific needs that may arise for you and your family (*i.e.*, technological or program changes, revisions to school or district level policies, training and education for parents and guardians, tailored communications to parents and guardians)?

Local Public Health Agencies & Organizations

- What are the main challenges with this current policy?
- How can these challenges be addressed?
- What are ways to strengthen the goal of this policy?
- If revision(s) are made to the Exemption Policy, are there any specific needs that may arise for you, your agency, and/or your members (*i.e.*, technological or program changes, training and education for staff, revisions to reporting requirements and/or data collection methods)?

APPENDIX C: AGGREGATED RESULTS FROM FOCUS GROUP MEETING PRE AND POST SURVEYS

PRE-MEETING SURVEY

Question	Totals				
Agree or Disagree: As a healthcare provider/ representative, I believe I have a significant role in helping patients understand Colorado's immunization policies.	Strongly Disagree 5	Disagree 0	Neutral 0	Agree 5	Strongly Agree 21
Agree or Disagree: As a parent/ guardian, I believe I believe my healthcare provider has a significant role in helping me understand Colorado's immunization policies	Strongly Disagree 2	Disagree 3	Neutral 6	Agree 7	Strongly Agree 0
Agree or Disagree: As a healthcare provider/ representative, I have enough information and resources on Colorado's immunization policies to advise my patients on their choices.	Strongly Disagree 2	Disagree 2	Neutral 4	Agree 13	Strongly Agree 10
Agree or Disagree: As a parent/ guardian, I have enough information and resources on Colorado's immunization policies to make decisions regarding immunizations for my child.	Strongly Disagree 2	Disagree 4	Neutral 1	Agree 1	Strongly Agree 10
Do you discuss Colorado's PBE policy with your patients/ community?	YES 18	NO 9	I am unfamiliar with the policy 3		
My health care provider has discussed Colorado's PBE policy for immunizations with me.	YES 6	NO 11	I am unfamiliar with the policy N/A		
Should Colorado have an immunization PBE policy?	YES 30	NO 16	I am unfamiliar with the policy 1		
Does Colorado's immunization PBE impact your patients/ community?	YES 29	NO 1	I am unfamiliar with the policy N/A		
Do you believe your child should be fully immunized to attend school?	YES 1	NO 15	I am unfamiliar with the policy 2		
Do you believe that all kids should be fully immunized to attend school?	YES 1	NO 14	I am unfamiliar with the policy 1		
Are you familiar with how schools and childcare facilities implement PBE policy for immunizations?	YES 11	NO 5	I am unfamiliar with the policy 1		

POST MEETING SURVEY

Question	Total						
Following today's meeting, do you have a better understanding of the immunization PBE policy in Colorado?	Yes 30				No 13	Do not know 4	
Following today's meeting, do you think Colorado should have a PBE for immunizations	Opinion has changed, Colorado should continue to have a PBE	Opinion has not changed, Colorado should continue to have a PBE		Opinion has changed, Colorado should not continue to have a PBE		Opinion has not changed, Colorado should not continue to have a PBE	
Following today's meeting, do you think Colorado should make changes to its PBE for immunizations	Opinion has changed, Colorado should make changes to its PBE policy	Opinion has not changed, Colorado should make changes to its PBE policy		Opinion has changed, Colorado should not make changes to its PBE policy		Opinion has not changed, Colorado should not make changes to its PBE policy	
Following today's meeting; do you think your child should be fully immunized to attend school?	Yes 1				No 14	Do not know 1	
Following today's meeting; do you think all children should be fully immunized to attend school?	Yes 1				No 13	Do not know 1	
Please indicate how strongly you agree or disagree with the he following potential changes to Colorado's PBE for immunization Policy							
	Agree strongly	Agree somewhat	Neither agree or	Disagree somewhat	Disagree strongly	Need more information	
Informed Refusal ("understands the risks)	28	5	0	1	3	3	
Required education/ counseling prior to exemption	21	3	3	0	11	2	
Medical Practitioner Signature for exemption	14	5	3	1	16	1	
Separate exemption form	17	9	3	3	5	2	
Exemption approved by Health Department	13	5	6	2	14	0	
Annual renewal of exemption	21	6	2	1	10	1	
Publically available publication of immunization rates by school	23	5	5	2	4	2	

DEMOGRAPHIC INFORMATION FROM FOCUS GROUP MEETINGS

Question	Totals						
Do you have Children?	Yes 42				No 6		
How old is your youngest child?	Average age 17.12 years of age						
What is your gender?	Male 5				Female 44		
How old are you?	18-24 0	25-34 6	35-44 17	45-54 11	55-64 11	65 or older 4	
What is the highest level of education you have completed?	Some high school 0	Graduated high school 0	Some College 4	Completed College 17	Some graduate school 3	Completed graduate school 25	
What is your race or ethnicity?	Hispanic White 5	Hispanic Black 0	Non-Hispanic white 42	Non-Hispanic Black 0	Asian 0	Other 1	
As a healthcare provider I describe myself as:	Family practice physician 5		Pediatrician 3	Mid-level primary Care provider 3			Other 6
What type of practice do you work for?	Solo Private Practice 5	Group Private Practice 3	Hospital Owned Practice 2	Safety-net clinic 1	Public Health agency 2	HMO 1	Other 2
I receive a majority of my information from:	Doctor 1	School Nurse 0	Local/State Health Dept 1	Internet/social media 4	Friends/family 2	Hospital/clinic 0	Other 9*

* Self-educated, books, journals

APPENDIX D: LIST OF PARTICIPATING STAKEHOLDERS

Name	Title	Organization
Cody Belzley	VP, Health Initiatives	Colorado Children’s Campaign
John Bender, MD, FAAFP	Present Elect, Colorado Medical Society	Miramont Family Medicine
Elaine GantzBerman	Board Member	State Board of Education
Travis Berry	Contract Lobbyist	Politicalworks, LLC
Matt Dorighi, MD		Cherry Creek Pediatrics – CAAP
Tista Ghosh*	Interim Chief Medical Officer	Colorado Department of Public Health and Environment (CDPHE)
Debbie Hamilton, MD		Holistic Pediatric Consulting
Paulette Joswick, RN	Director of Health Services	Douglas County School District
Sundari Kraft	Parent Advisory Board Member	Voices for Vaccines
Representative Lois Landgraf		Colorado Legislature
Mike Masteller, DC, DABCO	President	Colorado Chiropractic Association
Scott Matthews	Director of Program Services	March of Dimes
Michelle Miller	CEO	Colorado Rural Health Center
Senator Jeanne Nicholson		Colorado Legislature
Sean O’Leary, MD, MPH	Assistant Professor	Children’s Hospital Colorado/University of Colorado
Kathleen Patrick, RN	Assistant Director- Student Health Services	Colorado Department of Education
Lena Peschanskaia*	Chief Financial and Policy Manager for Public Health Programs	Colorado Department of Public Health and Environment (CDPHE)
Ben Price	Executive Director	Colorado Association of Health Plans
Theresa Rapstine, BSN, RN	Coordinator	Healthy Child Care Colorado
Joni Reynolds	Public Health Director	Colorado Department of Public Health and Environment (CDPHE)
Christopher Stanley, MD	Member	Colorado Board of Health
James Todd, MD	Director, Epidemiology, Clinical Outcomes and Clinical Microbiology	Colorado Children’s Hospital
Meghan Treitz, MD	Member	CAAP
Stephanie Wasserman	Executive Director	Colorado Children's Immunization Coalition
Jennifer Weaver**		Colorado Attorney Generals Office
Michelle Wilson		Public Health Nurses Association of Colorado
Theresa Wrangham	Executive Director	National Vaccine Information Center

*Participated as an alternate for the Colorado Department of Public Health and Environment

**Participated as an observer

APPENDIX E: STAKEHOLDER WORK GROUP PROTOCOLS

Colorado's Personal Belief Exemption Policy for Immunizations Stakeholder Engagement Process

Stakeholder Working Group Protocols

About This Document

This document provides the Stakeholder Working Group Members and Observers with guidelines and protocols for their participation in the Stakeholder Engagement Process and their work together to create recommendations on Colorado's Personal Belief Exemption Policy for Immunizations. This set of protocols will serve as the "participant ground rules" for the group's interactions throughout the meetings of this process. This document is in draft form, and participants are expected to review the content of these protocols before the first meeting of the Stakeholder Working Group. Time will be provided at the beginning of the meeting to raise any issues or propose modifications to these protocols. Through a facilitated conversation on August 13, 2013, participants will have the opportunity to make any necessary clarifications and modifications to ultimately finalize these protocols.

Stakeholder Working Group Desired Outcomes

Development of a set of consensus-driven recommendations for decision-makers and partners, in order to address Colorado's Personal Belief Exemption Policy for Immunizations, and to better understand the current knowledge, attitudes, and beliefs around immunization exemptions in Colorado.

This collaborative effort is aimed at:

- Outcome 1: Stakeholders will gain a better understanding of the current state of personal belief exemption attitudes and opinions in Colorado based on reviewing a background report developed from sector-specific focus groups and key informant interviews of health care providers, parents, school administrators, school nurses and public health officials.
- Outcome 2: Stakeholders will meaningfully participate in facilitated in-depth discussions on current personal belief exemption policies and practices in Colorado.
- Outcome 3: Stakeholders will generate potential policy and/or rule changes to the personal belief exemption system.
- Outcome 4: Stakeholders will make final recommendations on Colorado's Personal Belief Exemption system to be formally submitted to the Colorado Department of Public Health and Environment in a written report.

The Stakeholder Working Group will include diverse stakeholders representing the depth and breadth of viewpoints on Colorado's Personal Belief Exception Policy for Immunizations, including but not limited to representatives from the following communities: local and state public health officials, physicians, nurses and healthcare providers, school nurses and administrators, parents and guardians, and advocates. This Group will be convened by Keystone and can expect to meet in person for up to three scheduled meetings during the duration of this process. At the conclusion of this process, Keystone will submit a report outlining the process, deliberations and capture levels of agreement related to recommendations of the Stakeholder Working Group. Support for this initiative was made possible through a grant from The Colorado Trust Convening for Colorado Grant Program and the Centers for Disease Control and Prevention.

Participant Protocols

Expectations of Participants

Members of the Stakeholder Working Group are asked to develop consensus recommendations that address Colorado's Personal Belief Exemption Policy for Immunizations. Specifically, group members are asked to:

- Support the process through attendance and engagement in discussions in and outside of the Stakeholder Group Meetings.
- Review, refine, and agree upon draft recommendations during meetings and via email, as needed.

Decision-making

The Stakeholder Working Group is not a decision-making body, but rather a working group designed to provide input, exchange information and views, and undertake efforts to promote cooperative problem solving and foster good working relationships among stakeholders who hold differing views. Wherever possible, the group will strive to reach the highest levels of agreement on recommendations for Colorado's Personal Belief Exemption Policy for Immunizations. A high level of agreement means the groups as a whole supports the agreement. Although an agreement may not necessarily represent any one member's ideal resolution, it can be characterized as a decision that all participants can live with or do not oppose.

If agreement cannot be reached, after exhausting all reasonable efforts; or if it is the judgment of the facilitators and others that the agreements are in jeopardy for the sake of reaching consensus, then the Stakeholder Working Group may agree to present the differing perspectives for consideration. Documents representing viewpoints that are not based on consensus will be labeled appropriately.

Effective Dialogue & Good Faith

Stakeholder Working Group Members will be expected to participate in good faith. Good faith means participation that is open, honest, and dedicated to a resolution that meets the objectives of the meeting and respects the interests of all participants.

Stakeholder Working Group Members are asked to honor the following discussion principles:

- ***Respect for the collaborative process.*** We are in search of shared solutions to shared challenges. Actively listen to others, maintain focus, and be sensitive to the length, tone and pertinence of comments. Please keep individual comments brief so that multiple individuals have an opportunity to weigh in on a given question or topic.
- ***Comments made during meeting discussions are off the record and not for attribution.*** Participants are welcome to share their personal views and ideas regarding the dialogue with others outside of this process. No participant should quote another participant or characterize their views outside of the meetings without her/his express permission, nor should they attempt to speak on behalf of the entire participant group unless authorized by the full group.
- ***External communications.*** Following the meetings, members are free to speak about their own views and those of their organizations. However, members will not attribute statements to others or attempt to speak for the entire group.

Additional expectations for constructive and productive dialogue include the following:

- Participants will strive for effective dialogue, which involves:
 - Actively listening and attempting to understand and appreciate the needs and ideas of others,
 - Being clear and honest in the expression of one's own needs and ideas,
 - Generating ideas and options that consider all key interests that have been raised,
 - Offering solutions in addition to critiques, and
 - Allowing all participants to participate.

- Participants will treat others in the process with respect and patience. In any public or private discussions of the process, participants/members will be respectful of each other and be aware of the implications of what they say for the relationships and trust among members.
- Participants will assist the facilitators in maintaining the meeting schedule and enforcing the protocols and responsibilities of the group.
- Participants will strive to build productive relationships with all members.
- Participants will be asked to stay focused on the agenda.
- Participants should consider discussions to be confidential and not for attribution to individuals or organizations.
- While participants serve in the group as individuals, they will work actively within their respective communities and organizations to support the work of the meeting.

Designees

Each invited participant of a member organization may designate a single, official alternate to participate in her or his stead if she or he cannot attend a Stakeholder Group Meeting. The alternate should be from the same organization and of the same decision making authority as the person she or he is representing. Alternates must be approved by the meeting facilitators, and will be noted as official alternates on the formal participant list.

Roles & Responsibilities of Other Parties

Planning Committee

The Planning Committee will be made up of representatives from The Keystone Center, Colorado Children’s Immunization Coalition and the Colorado Department of Public Health and Environment-Immunization Section. This Committee will be responsible for the overall planning and execution of the Stakeholder Engagement process. Members of the Planning Committee have substantive expertise or may be representing the agencies that will, in part, be recipients of the deliverables and outcomes of this effort. Committee members will specifically be asked to:

1. Periodically share their strategic advice regarding the design and content of the engagement process, including the review of substantive meeting materials,
2. Attend the stakeholder meetings as observers, and
3. Provide a substantive review of any draft recommendation(s).

Meeting Observers

A number of local and state agency representatives may be present to hear firsthand the deliberations of the Stakeholder Working Group Meetings and to respond as needed to any questions that may arise. While meeting discussions will generally be limited to the Stakeholder Working Group, agency staff with particular expertise may be invited to participate in periodic discussion of specific agenda topics as appropriate (while not serving as parties to agreements).

More About the Planning Committee Members

The mission of the Colorado Children’s Immunization Coalition is to strategically mobilize diverse partners and families to advance children’s health through immunization.

www.childrensimmunization.org

The mission of the Colorado Department of Public Health and Environment is to protect and improve the health of Colorado’s people and the quality of its environment.

www.cdphe.state.co.us

The mission of The Keystone Center is to bring together today’s leaders to create solutions to society’s pressing challenges.



Colorado Department
of Public Health
and Environment



THE
COLORADO
TRUST



Colorado Children's
Immunization Coalition
www.childreimmunization.org

Support for this process has been made possible through The Colorado Trust's Convening For Colorado Grant Program

APPENDIX F: AGENDAS FOR STAKEHOLDER MEETINGS

STAKEHOLDER MEETING 1

Colorado Personal Belief Exemption Policy for Immunizations Stakeholder Work Group Meeting

Tuesday, August 13, 2013

11:00 am - 4:00 pm

The Colorado Trust, 1600 Sherman Street, Denver, CO 80203

- 11:00 am Welcome, introductions & Polling Activity – *All*
- 11:20 am Overview of Process
- “How did we get here” – *Diana Herrero, CDPHE*
 - Purpose, goal, and focused objectives – *Johanna Gibbs, The Keystone Center*
 - Agenda review and key meeting protocols – *Johanna Gibbs, The Keystone Center*
- Q& A to Follow*
- 11:45 am Overview of Immunization Data and Research – *Rachel Herlihy & Diana Herrero, CDPHE*
Q& A to Follow
- 12:45 pm Break
- 1:00 pm Working Lunch: Presentation of Themes and Data from Focus Group Meetings – *Johanna Gibbs, The Keystone Center*
- 1:30 pm Discussion of Initial Thoughts & Options on the PBE– *Johanna Gibbs, The Keystone Center*
- 2:15 pm Break
- 2:30 pm Small Group Discussions Focused on Recommendations & Report Out
- 3:45 pm Next Steps – *Johanna Gibbs, The Keystone Center*
- 4:00 pm Adjourn for the day

STAKEHOLDER MEETING 2

Colorado Personal Belief Exemption Policy for Immunizations Stakeholder Work Group Meeting

Tuesday, August 20, 2013
12:30 pm – 5:00 pm
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Meeting Room C1A
Denver, CO 80246

- 12:30* pm Welcome and Reflections from Meeting #1
** Lunch will be served*
- 12:45 pm Review of Meeting Scope, Desired Outcomes, Core Values & Outputs
- 1:15 pm Review of Potential Recommendations
- Review of case studies & data
- 2:30 pm Group Discussion: What considerations should be taken into account when considering this policy (or policies) change(s)?
- 2:50 pm Break
- 3:00 pm Small Group Discussion of Recommendations
- Discussion Questions:
 - Are there recommendations that can easily be removed from the list?
 - Are there any recommendations that should be amended slightly, or added?
 - In light of the case studies and data presented, is there a recommendation (s) that rises to the top for you in terms of a preferred change to the current policy?
- 3:45 pm Small Group Report Out & Plenary Discussion
- 4:15 pm Preference Polling on Recommendations and Group Discussion
- 5:00 pm Adjourn for the day

STAKEHOLDER MEETING 3

Colorado Personal Belief Exemption Policy for Immunizations Stakeholder Work Group Meeting

Thursday, September 12, 2013

9:00 am – 2:00 pm

Colorado Department of Public Health and Environment

Laboratory Services Division

8100 Lowry Boulevard

Denver, CO 80230

- 9:00 am Welcome and reflections from meeting #2
** Coffee will be provided*
- 9:15 am Review of meeting scope, desired outcomes for meeting and process & core values
- 9:30 am Review of Outputs
- Format, level of detail for recommendations
- 10:00 am Review of potential criteria for reviewing recommendations
- 10:45 am Discussion: review of potential recommendations
- 12:00 pm Lunch
- 12:30 pm Continued discussion: review of potential recommendations
- 2:00 pm Adjourn for the day

APPENDIX G: SLIDE PRESENTATION FROM FIRST STAKEHOLDER MEETING



1

COLORADO'S PERSONAL BELIEF EXEMPTION POLICY FOR IMMUNIZATIONS

STAKEHOLDER ENGAGEMENT MEETING

AUGUST 13, 2013

Purpose

- Our purpose is to help build a greater understanding of knowledge, attitudes and beliefs of Colorado's current immunization landscape and the Colorado Personal Exemption Policy for immunizations.
 - The Personal Belief Exemption stakeholder engagement process is a partnership between the Colorado Children's Immunization Coalition (CCIC) and the Colorado Department of Public Health and Environment (CDPHE).

Call to action

- Personal Belief Exemptions are a growing concern in the state of Colorado
- Colorado has among the highest rates of PBE in the nation with 4.3% of kindergarteners not fully vaccinated upon school entry
- In 2012, Colorado has had a major outbreak of pertussis (whooping cough), along with high rates of pneumococcal disease (pneumonia) and varicella (chicken pox)
- Funding available now to evaluate PBE in the state

Planning Committee

- CDPHE
 - The mission of the Immunization Section is to ensure the prevention of vaccine-preventable diseases in Colorado by increasing and maintaining vaccine coverage and assuring access to immunization services.
- CCIC
 - The Colorado Children's Immunization Coalition promotes improved access, delivery, and demand for children's vaccinations to keep Colorado healthy.
- The Keystone Center (Keystone)
 - A non-profit, neutral facilitator, retained to conduct the stakeholder engagement process through focus groups and facilitated meetings.

Planning Committee

- CDPHE
 - Jamie D'Amico, RN, MSN, CNS
 - Rachel Herlihy, MD, MPH
 - Diana Herrero, MS
 - Shannon Rossiter, JD, MPH
- CCIC
 - Stephanie Wasserman, MSPH
 - Camron Bridgford
 - Meredith Kersten
- Keystone
 - Johanna Gibbs
 - Brooke Trainum

Funding

- Funding for this effort comes from the Centers for Disease Control and Prevention and The Colorado Trust's Convening for Colorado program
- 2012 Prevention and Public Health Funds – through CDC
 - Funding used to reach out to stakeholders throughout Colorado to facilitate discussion around the current exemption policy
 - Improve school immunization rates
 - CDC Best Practice

Funding [CONTINUED]

- The Colorado Trust's Convening for Colorado program provides support to bring people together to discuss issues central to advancing the health and well-being of Coloradans.
 - Convenings provide dedicated time for people to share information, learn from experts, personally engage and actively deliberate with the goal of tackling a tough challenge or taking advantage of a timely opportunity.
 - Whether participants have shared or disparate views, are from diverse geographic regions or the same neighborhood, are from one sector or an array of occupations, a collaborative dialogue can serve as a powerful means to help achieve change.

Objectives

- Engage several sector-specific focus groups to gather perspectives and input on Colorado's Personal Belief Exemption Policy for Immunizations.
- Utilize information gathered from the sector-specific focus groups to inform a multi-stakeholder engagement process that will seek to gather perspectives, recommendations for improvement, and a better understanding of opinions regarding Colorado's Personal Belief Exemption Policy for Immunizations.
- Develop a document that provides an overview of Colorado's current immunization exemption landscape, describes the stakeholder engagement process and outcomes, and details a consensus-driven set of recommendations related to the state's Personal Belief Exemption Policy for Immunizations.

Desired Outcomes

- Outcome 1:** Stakeholders will gain a better understanding of the current state of personal belief exemption attitudes and opinions in Colorado based on reviewing a background report developed from sector-specific focus groups of health care providers, parents, school administrators, school nurses and public health officials.
- Outcome 2:** Stakeholders will meaningfully participate in facilitated in-depth discussions on current personal belief exemption policies and practices in Colorado.
- Outcome 3:** Stakeholders will generate potential policy and/or rule changes to the personal belief exemption system.
- Outcome 4:** Stakeholders will make final recommendations on Colorado's personal belief exemption system to be formally submitted to the Colorado Department of Public Health and Environment in a written report.

Agenda Review

Morning	Afternoon
<ul style="list-style-type: none"> • Welcome & Introductions • Overview of Process <ul style="list-style-type: none"> • How did we get here? • Purpose, objectives and desired outcomes • Review of Group Protocols/Charter • Overview of Data and Research 	<ul style="list-style-type: none"> • Discussion of Initial & Opinions of the PBE • Overview of Themes & Data from the Focus Groups • Discussion of the Current Policy • Next Steps

Housekeeping

- MEETING MATERIALS**
- Folders
- MEETING PROTOCOLS**
- Discussion tools
 - Role of observers
- WHO'S HERE TO HELP**

Group Protocols

- Serve as guidelines and protocols for their participation in the Process
 - "Ground Rules" for the group's interactions
- Opportunity to discuss, propose modifications to these protocols.
 - Decision making
 - Roles & Responsibilities



At the break

13

- **PURPOSE:**
Gauge initial thoughts/feelings/reactions

RED – I'm not supportive/Uncomfortable

YELLOW – Uncertain/Needs more discussion

GREEN – Supportive/Comfortable



14

SUPPORT FOR THIS PROCESS HAS BEEN MADE POSSIBLE THROUGH THE COLORADO TRUST'S CONVENING FOR COLORADO PROGRAM



IN PARTNERSHIP WITH



15

"THE BEST WAY OUT IS THROUGH"

--ROBERT FROST

16

Next Steps

FUTURE MEETINGS

- **August 20, 2013** – 12:30 pm – 5:00 pm
 - CDPHE
- **September 12, 2013** – 9:00 am – 2:00 pm
 - CDPHE

Current and Trending Immunization Data

DIANA HERRERO, MS
INTERIM DIRECTOR, IMMUNIZATION SECTION
COLORADO DEPARTMENT OF PUBLIC HEALTH &
ENVIRONMENT



Topics

- National Immunization Survey
- Vaccine Preventable Disease Rates
- Kindergarten School Survey
- Local School District Data
- Exemptions by State
- Colorado's Current Exemption Statute/Rule



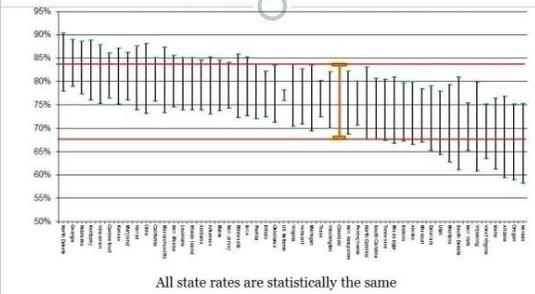
2011 National Immunization Survey

2011 National Immunization Survey

- Coverage rates for children 19 – 35 mos. born between January 2008 and July 2010
- Given the length of time required to produce and publish results, these published results reflect immunization practices 2 to 4 years in the past.
- Complex statistical methods are used to adjust for children whose parents refuse to participate, those who live in households without telephones, or those whose immunization histories cannot be verified through their providers.

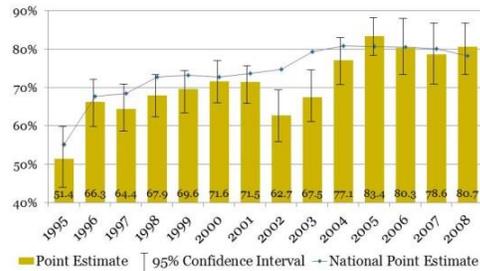


Up to Date Vaccination Series* for Children 19-35 mos
2011 NIS Data



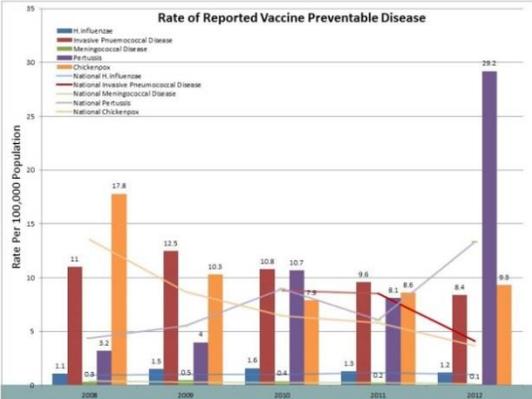
*4:3:1:3:1 Series - 4 DTaP, 3 Polio, 1 MMR, 3 Hib, 3 HepB and 1 Varicella

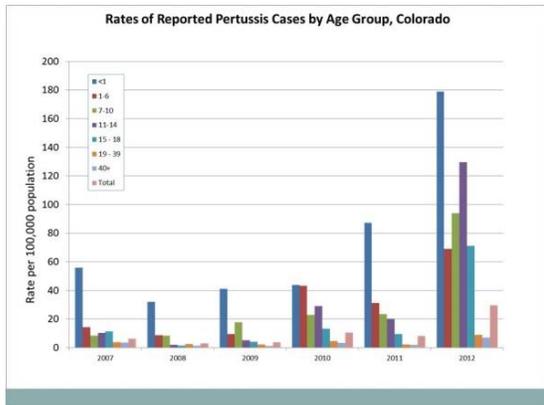
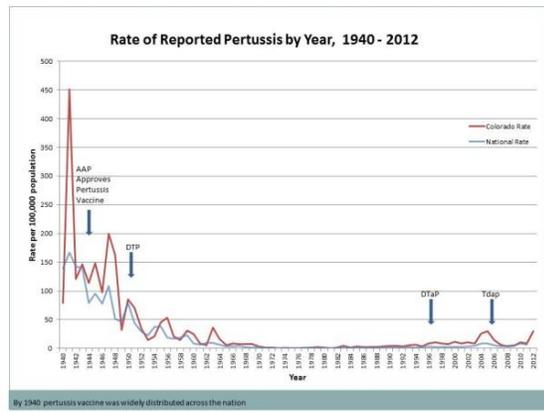
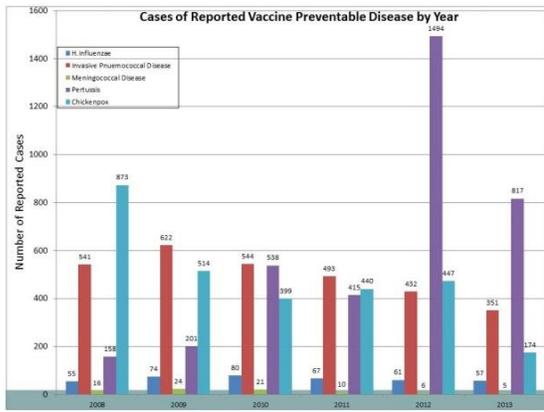
4:3:1:3:1* Up to Date Vaccination Series among Colorado Children 19-35 Months
1995 – 2008 National Immunization Survey



*4:3:1:3:1 Series - 4 DTaP, 3 Polio, 1 MMR, 3 Hib and 3 HepB

Trends in Vaccine Preventable Disease in Colorado





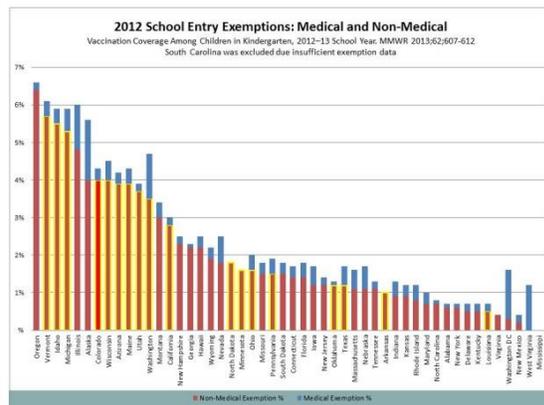
If all kiddos were vaccinated...

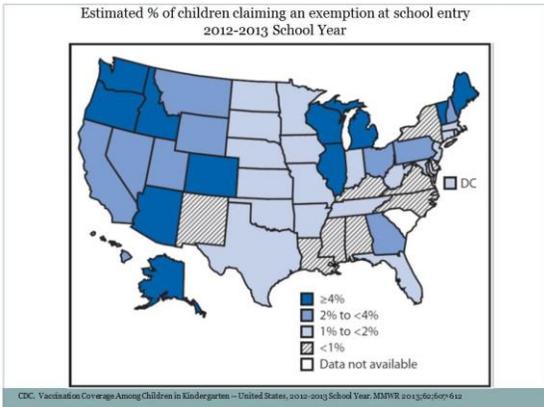
For each birth cohort vaccinated against 13 diseases in accordance with the 0-6 yr schedule, in Colorado this translates to:

- 652 lives saved
- 310,608 cases of disease prevented
- \$211,213,684.80 million dollars in direct costs saved
- \$1,070,045,800.20 billion dollars in direct plus indirect (societal) costs are saved
- \$10.20 saved for every one dollar invested in 0-6yo vaccinations

Extrapolation to Colorado from a study by Zhou et al, Arch of Ped & Adol Med 2005. Presented by Dr. Ann Shuckett at NCC 2011.

2012 Colorado School Survey



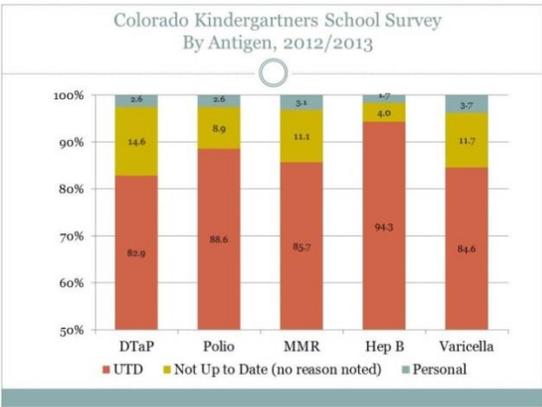
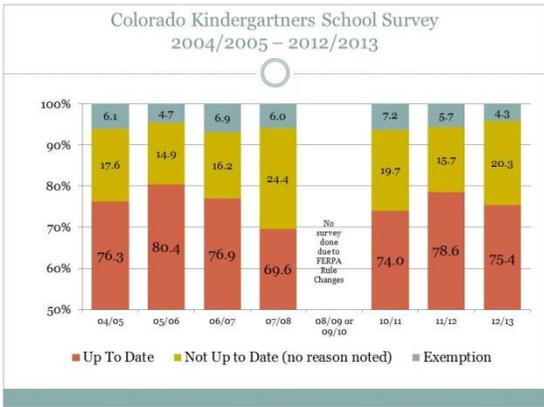


Kindergartners Up to Date or In Compliance with Colorado School Immunization Requirements

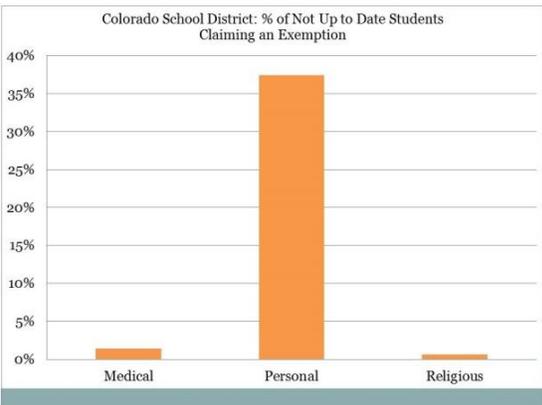
2012/2013 Colorado School Survey of Kindergartners

School Immunization Status	Percentage	Range with Confidence Intervals
Up to Date at Kindergarten Entry (Had received all required immunizations for school entry)	75.4%	70.6-79.8.0
<ul style="list-style-type: none"> 5 DTaP or 4 with the 4th or 5th dose on or after 4th birthday 2 MMR 4 Polio or 3 with the 3rd on or after the 4th birthday 3 Hepatitis B 2 Varicella 	80.3%	75.7-84.3
In Compliance at Kindergarten Entry (Received all required immunizations, or took a medical, religious or personal exemption or are in the process of being immunized)		

Colorado Department of Public Health and Environment

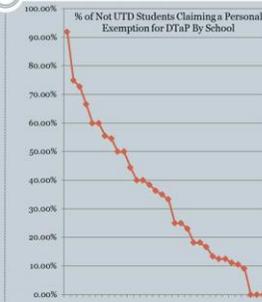


Local School District Data



2012-2013 Colorado School District Exemption Detail for Kindergartners at School Entry

- Individual schools had UTD rates for DTaP that ranged from 31% to 96%.
- Out of all students that were not UTD, individual schools had a personal exemption rate for DTaP that ranged from 0% to 92%.
- High exemption rates and Low UTD rates at specific schools typically had a small kindergarten student population.
- 31% of schools in this district had at least 50% of students claiming a personal belief exemption when the students were not UTD.



Comparing Aurora Public School Data to CIIS Data

The Number of Children in the Aurora Public School (APS) Data with an Exemption for Each Required Vaccine and the Number of Those Children Found in CIIS that Actually had a Vaccine Administration Date, 2008/2009 School Year

Vaccine	# of children in APS data with an exemption	# of those children found in CIIS with a shot administration date
DTaP	538	324 (60.2%)
MMR	432	257 (59.5%)
Polio	380	220 (57.9%)
Hep B	384	225 (58.6%)

Exemptions by State

States with Exemptions (by 2014)

Exemptions

Medical
50 states

Religious
48 states

Personal
Belief
18 states

Personal Belief Exemptions to school immunization requirements



18 states allow exemptions for non-medical, non-religious reasons

States enacting legislation to strengthen non-medical exemptions in 2011-2013



Colorado's Personal Belief Exemption Statute/Rule

What is required by Colorado statute?

- **SCHOOL ENTRY IMMUNIZATION - C.R.S. 25-4-901 (2012), 25-4-903.**
Exemptions from immunization
- (2) It is the responsibility of the parent or legal guardian to have his or her child immunized unless the child is exempted pursuant to this section. A student shall be exempted from receiving the required immunizations in the following manner:
 - (a) By submitting to the student's school certification from a licensed physician or advanced practice nurse that the physical condition of the student is such that one or more specified immunizations would endanger his or her life or health or is medically contraindicated due to other medical conditions; or
 - **(b) By submitting to the student's school a statement of exemption signed by one parent or guardian or the emancipated student or student eighteen years of age or older that the parent, guardian, or student is an adherent to a religious belief whose teachings are opposed to immunizations or that the parent or guardian or the emancipated student or student eighteen years of age or older has a personal belief that is opposed to immunizations.**
 - (3) The state board of health may provide, by regulation, for further exemptions to immunization based upon sound medical practice.
 - (4) All information distributed to parents by school districts regarding immunization shall inform them of their rights under subsection (2) of this section.



Colorado BOH rule

- **6 CCR 1009-2 - RULES PERTAINING TO THE INFANT IMMUNIZATION PROGRAM, THE VACCINES FOR CHILDREN PROGRAM, AND THE IMMUNIZATION OF STUDENTS ATTENDING SCHOOL**
- **ii. Exemptions From Immunization**
 - It is the responsibility of the parent(s) to have his or her child immunized unless the child is exempted. A student may be exempted from receiving the required immunizations in the following manner:
 - **A. Medical exemption -** By submitting to the student's school a Certificate of Immunization with the statement of medical exemption signed by an advanced practice nurse or physician licensed to practice medicine or osteopathic medicine in any state or territory of the United States indicating that the physical condition of the student is such that immunizations would endanger his/her life or health or is medically contraindicated due to other medical conditions.
 - **B. Religious exemption -** By submitting to the student's school a Certificate of Immunization with the statement of religious exemption signed by the parent(s) or the emancipated student indicating that the parent(s) or emancipated student is an adherent to a religious belief whose teachings are opposed to immunizations.
 - **C. Personal belief exemption -** By submitting to the student's school a Certificate of Immunization with the statement of personal exemption signed by the parent(s) or the emancipated student indicating that the parent(s) or emancipated student has a **personal belief that is opposed to immunizations.**
 - **D. In the event of an outbreak of disease against which immunization is required, no exemption or exception from immunization shall be recognized and exempted persons may be subject to exclusion from school and quarantine.**
 - **E. All information distributed to the parent(s) by school districts regarding immunization shall inform them of their rights under II(A-C).**



How is an Exemption Claimed?



Legislative or administrative changes?

If Colorado's immunization personal belief exemption includes:	Could be accomplished by BOH rule	Requires changes to statute
Informed Refusal ("understands the risks")	Yes	
Required Education / Counseling prior to Exemption		Yes
Medical Practitioner or Health Official Signature for Exemption		Yes
Separate Exemption Form	Yes	
Exemption Approved by Health Department		Yes
Annual Renewal of Exemption		Yes
Publicly-Available Publication of Immunization Rates by School and Child Care Centers		Yes
Signature of Parent (NO CHANGE)	NA	NA
Signature of Notary		Yes
Ask parent to provide reason for exemption		Yes
Mandatory acknowledgement of information about PBE		Yes

Questions?

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Personal Belief Exemptions: A Review of the Literature

RACHEL HERLIHY, MD, MPH
DEPUTY DIRECTOR, DIVISION OF DISEASE
CONTROL AND ENVIRONMENTAL
EPIDEMIOLOGY

COLORADO DEPARTMENT OF PUBLIC
HEALTH & ENVIRONMENT

Communicable Disease Control

- CDPHE Mission: "To protect and improve the health of Colorado's people..."
- Environmental Sanitation
- Health Care Facilities
- Food Safety
- Surveillance
- Immunizations

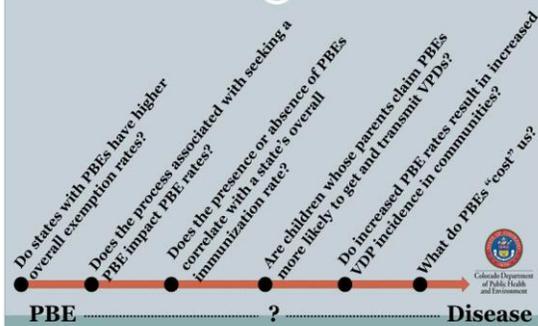


What have immunizations and immunization policy achieved in the U.S.?

- One of the most significant public health interventions in history
- Four diseases have been eliminated (no endemic disease):
 - Smallpox (1949)
 - Polio (1979)
 - Measles (2000)
 - Rubella (2004)
- Dramatic reductions in diphtheria, tetanus, mumps, pertussis, hepatitis A, hepatitis B, varicella, Hib, S. pneumo
- Hundreds of thousand of deaths prevented, tens of billions of dollars saved
- One of the most cost-effective components of our public health system



Why do PBEs matter?



QUESTION 1:

Do states with PBEs have higher overall exemption rates?

PBEs and Non-medical Exemption Rates

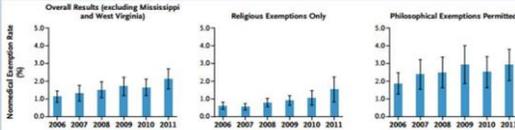
- Medical: all states, Religious: 48 states, PBE: 18/19 states
- Omer et al. examined non-medical exemption rates from 1991-2004:
 - At baseline no difference in non-medical exemption rate in states with and without PBEs
 - From 2001 on, states with PBE have higher rate
 - Rate increased 6% annually in states with PBEs
 - No significant change in states without PBEs



Omer et al., JAMA 2006;296(14)

2012 Update on Non-Medical Exemption Rates, Impact of PBE

- Omer et al. update with 2005-2011 data
- States with PBEs had non-medical exemption rates 2.54x (1.68-3.84) as high as rates in states with only religious exemption
- Average rate increase was HIGHER for religious only, but not statistically significant



Omer et al., N Engl J Med 2012;367(12)

Comparison of State Exemption Rates- 2011-2012 National Report on Vaccination Coverage Among Kindergartners

	Overall Exemption Rate Mean (CI)	Median Overall Exemption Rate	Non-Med Exemption Rate Mean (CI)	Median Non-Med Exemption Rate
States w/ PBE*	3.4 (2.5-4.3)	3.8	3.1 (2.2-4.0)	3.5
States w/o PBE	1.9 (1.3-2.5)	1.3	1.6 (1.0-2.1)	1.0
All State Combined	2.5 (1.9-3.0)	1.6	2.1 (1.6-2.6)	1.2

*States with PBEs include: Arizona, Arkansas, California, Colorado, Idaho, Louisiana, Maine, Michigan, Minnesota, North Dakota, Ohio, Oklahoma, Pennsylvania, Texas, Utah, Vermont, Washington, Wisconsin



Summary data prepared by Lane Wake, Data Analyst, CDPHE Immunization Section

Arkansas Experience

- Federal court ruling affected religious exemption
- New legislation made PBE available
- Total number of exemptions increased annually from baseline (529) to:
 - 651 (23%)
 - 764 (17%)
 - 1145 (50%)
- Nonmedical exemptions clustered geographically



Thompson et al., Am J Prev Med 2007;32(3)

QUESTION 1:

Do states with PBEs have higher overall exemption rates?

Yes. States with PBEs have higher non-medical exemption rates than states with only religious exemptions. In one state's experience, adding a PBE resulted in increased non-medical exemption rates.

QUESTION 2:

Does the process associated with seeking a PBE impact PBE rates?

Re-stated...

DO "EASY" PBE PROCESSES RESULT IN HIGHER PBE RATES?

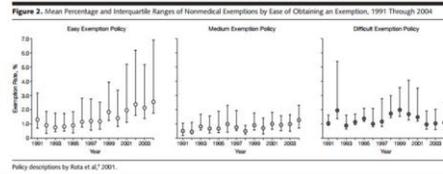
Processes for Obtaining Non-medical Exemptions

- Rota et al., Am J Public Health, 2001
 - Significant association found between the percentage of exemptions claimed and the complexity of obtaining an exemption
 - Level 1: parental signature, form available at school
 - Level 2: parental signature + [form only available at health department] OR [parent letter or statement]
 - Level 3: notarized signature on form/letter OR [Form only available at health department AND parental letter or statement] OR [Letter from religious or state official]
 - Requiring parental effort “may ensure that parental resolve to choose the exemption option is deeply held and not a matter of convenience...”



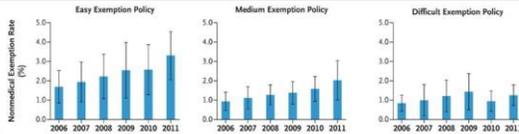
Processes for Obtaining Non-medical Exemptions (2)

- Omer et al., JAMA, 2006
 - At baseline, states with easy exemption process had significantly higher nonmedical exemption rate than medium states, but not difficult states
 - In 2002 and 2003, states with easy exemption process had significantly higher nonmedical exemption rate than medium and difficult states
 - Exemption rate significantly increased from 1991 to 2004 in easy states, but not medium or difficult states



Processes for Obtaining Non-medical Exemptions (3)

- Omer et al., NEJM, 2012- Update of previous study
 - Nonmedical exemption rate in states with easy policy was 2.31x states with difficult policies
 - States with easy policy increased to 3.3%, an annual increase of 13%
 - States with difficult policy increased to 1.3%, an annual increase of 8%
 - Compared to previous study, nonmedical exemptions have increased and the rate of increase has accelerated



QUESTION 2:

Does the process associated with seeking a PBE impact PBE rates?

Yes. Several studies have demonstrated that states with easier processes have higher nonmedical exemption rates.

Re-stated...

DO STATES WITH PBE HAVE LOWER IMMUNIZATION RATES?

QUESTION 3:

Does the presence or absence of PBEs correlate with a state's overall immunization rate?

PBEs and Immunization Rates

- **2010 National Immunization Survey:**
 - 3 of 10 states with highest coverage allow PBEs
 - 3 of 10 states with lowest coverage allow PBEs
- **Why?**
 - Those seeking an exemption find a way to claim a medical or religious exemption in states in which PBEs are not allowed.
 - Stadlin et al., JID, 2012, found the highest rates of medical exemptions in states with difficult nonmedical exemption criteria and easy medical exemption criteria



QUESTION 3:

Does the presence or absence of PBEs correlate with a state's overall immunization rate?

No. Individuals may obtain other types of exemptions. Simply eliminating PBE is unlikely to increase immunization coverage.

QUESTION 4:

Are children whose parents claim PBEs more likely to get and transmit VPDs?

(Individual Risk)

PBEs and Individual Risk

- Feikin et al., JAMA 2000 (Colorado 1987-1998, Retrospective Cohort)
 - Exemptors 22.2 times more likely to acquire measles
 - Exemptors 5.0 more likely to acquire pertussis
- Salmon et al., JAMA 1999 (U.S., Retrospective Cohort)
 - Exemptors 33 times more likely to contract measles
- Glanz et al., Pediatrics 2009 (Colorado 1996-2007, Case-Control)
 - Vaccine refusers had a 23-fold higher risk for pertussis
- Glanz et al., Arch Pediatr Adolesc Med (Colorado 1998-2008, Case-Control)
 - Vaccine refusers had a 9-fold higher risk of varicella
- CDC MMWR, 2008 (U.S., Descriptive Analysis)
 - 131 cases of measles from Jan-July 2008
 - 112 unvaccinated/unknown, 95 were eligible for vaccination
 - 66% of the 95 eligibles had PBE or religious exemption
- Fiebelkorn et al., J Infect Dis 2010 (U.S., Descriptive Analysis)
 - From 2004-2008, 68% of measles cases in U.S. were among age-eligible children with PBEs



QUESTION 4:

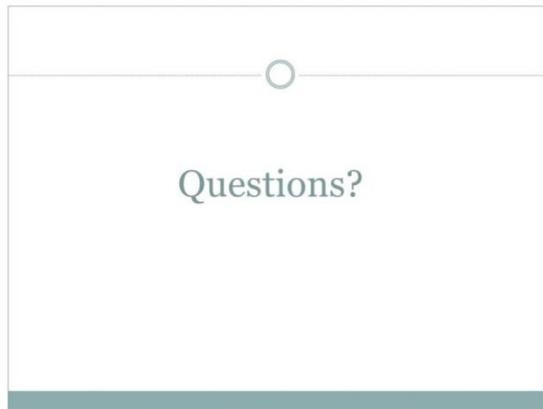
Are children whose parents claim PBEs more likely to get and transmit VPDs?

Yes. Estimates of how much vary from disease to disease and from study to study.

QUESTION 5:

Do increased PBE rates result in increased VDP incidence in communities?

(Community Risk)





1

THEMES AND DATA FROM FOCUS GROUP MEETINGS & KEY INFORMANT INTERVIEWS

COLORADO'S PERSONAL BELIEF EXEMPTION POLICY
FOR IMMUNIZATIONS

STAKEHOLDER ENGAGEMENT MEETING
AUGUST 13, 2013

Focus Group Meetings & Key Informant Interviews

2

Focus Groups by Sector

3

- 8 Focus Groups with up to 12 participants
 - Primary Care Providers (2)
 - Pediatricians
 - School Nurses
 - Local Public Health (2)
 - Parents (2)
- A total of 53 participants.
 - 48 females & 5 males
 - 86% of participants have at least one child
 - Reside in Arapahoe, Boulder, Denver, Douglas, La Plata, Jefferson, Larimer, Pueblo, Summit, Weld
- Interviews conducted to fill gaps in participation
 - Education sector
 - Rural providers

Focus Group Participants

4



Focus Group Participants

5

- All participants had at least some college education
 - 91% are college graduates
 - 51% had a graduate degree
- Education on Immunizations
 - From health care professional
 - Self educated: internet, books, news articles

Participant Beliefs and Opinions

6

Should Colorado Have a Personal Belief Exemption Policy for Immunizations?

65% responded Yes

Should Colorado Make Changes to the PBE?

7

	Total	Percentage
Opinion changed, Should make changes	14	30%
Opinion NOT changed, Should make changes	21	45%
Opinion changed, Should NOT make changes	0	0%
Opinion NOT changed, Should NOT make changes	12	25%

Survey Results

8

Annual Renewal

	Total	Percentage
Strongly agree	21	51%
Agree somewhat	6	15%
Neutral	2	5%
Disagree somewhat	1	2.5%
Disagree strongly	10	24%
Need more information	1	2.5%

Informed Refusal

	Total	Percentage
Strongly agree	28	70%
Agree somewhat	5	12.5%
Neutral	3	7.5%
Disagree somewhat	1	2.5%
Disagree strongly	0	0%
Need more information	3	7.5%

Survey Results

9

Publicly Available Publication of Immunization Rates by School

	Total	Percentage
Strongly agree	23	56%
Agree somewhat	5	12%
Neutral	5	12%
Disagree somewhat	2	5%
Disagree strongly	4	10%
Need more information	2	5%

Medical Practitioner Signature for Exemption

	Total	Percentage
Strongly agree	15	37%
Agree somewhat	5	12%
Neutral	3	7%
Disagree somewhat	1	2%
Disagree strongly	16	40%
Need more information	1	2%

Focus Group Inquiry

10

- Aimed at:
 - Strengths
 - Challenges/Weaknesses
 - If revisions are made, specific needs that may arise
 - Recommendations for revisions
 - Sector specific recommendations
 - i.e. effect on practice, experience in schools/childcare facilities, experience from a parents perspective, etc.

Strengths of the Current PBE Policy *as identified in the Focus Group Meetings & Interviews*

11

- Choice and ease.
- Power for parents to make choices for their own children.
 - Right to choose medical interventions.
 - Making choice for 1 child vs. making decision for great # of children.
- Allows for flexibility in vaccination schedules.

Weaknesses/Challenges of PBE Policy *as identified in the Focus Group Meetings & Interviews*

12

- Ease.
- Parents do not have enough information to make informed decisions.
- In many Healthcare settings, providers lack time to adequately discuss vaccinations decisions/answer questions.
- Signing the PBE may not accurately reflect the current state of vaccinations for the child.
 - Currently does not account for alternative vaccination schedules, challenges in record location, etc.
- PBE could lead to increased concern of risk.

Additional Resources/Needs *as identified in the Focus Group Meetings & Interviews*

13

- Education
 - Education for parents
 - ✦ Risk
 - Common side effects vs. adverse reactions.
 - ✦ Vaccination inserts.
 - ✦ Information from trusted sources.
 - Training for professionals
 - ✦ Healthcare providers: respectful dialogue, vaccination ingredients, alternative schedules.
 - ✦ School executives: Importance of vaccinations in the school setting.

Additional Resources/Needs Cont. *as identified in the Focus Group Meetings & Interviews*

14

- Data
 - Real time information available on outbreaks- *domestic and international*.
 - Updated risk profiles for vaccinations.
 - Rates of unvaccinated, partially vaccinated, and fully vaccinated children by school district/site.
 - Comprehensive system that tracks each child's vaccinations- *available across sectors*

Additional Resources/Needs Cont. *as identified in the Focus Group Meetings & Interviews*

15

- Administrative
 - Billing/procedure code for vaccination consultation and education.
 - ✦ Vaccination consultation start with OBGYN.
 - Administrative staff should not field school entry.
- Other
 - Increase access
 - ✦ Mobile clinics/school based clinics
 - PBE should apply to adults in the workplace.

Recommendations From Initial Inquiry

16

- No change to the current policy
- Informed refusal ("I understand the risks")
- Require education prior to signature
- Additional signature required (DOH/Practitioner)
- Signature should include indication for why parent is signing (lost records, alternative schedule, unvaccinated)
- Separate exemption form
- Life time exemption
- Publicize immunization rates by district/site.

APPENDIX H: SLIDE PRESENTATION FROM SECOND STAKEHOLDER MEETING



1

COLORADO'S PERSONAL BELIEF EXEMPTION POLICY FOR IMMUNIZATIONS

STAKEHOLDER ENGAGEMENT MEETING
AUGUST 20, 2013

2

Agenda Review

- Welcome & Reflections from Meeting #1
- Review of Meeting Scope, Desired Outcomes, Core Values & Outputs
- Review of Potential Recommendations
- Review of case studies & data
- Small Group Discussion of Recommendations
- Small Group Report Out & Plenary Discussion
- Preference Polling on Recommendations and Group Discussion
- Next Steps

3

Scope Review

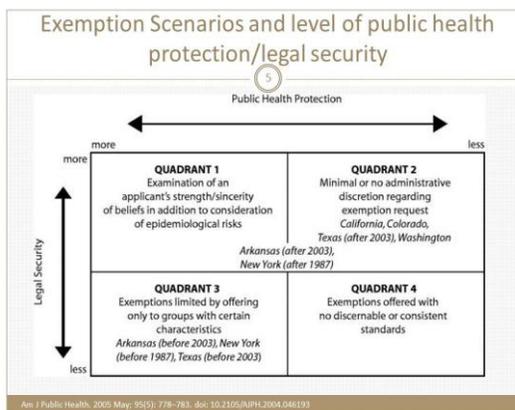
- Stakeholders will generate potential policy and/or rule changes to the **Personal Belief Exemption** system, if it is believed policy and/or rule changes are needed.
 - Narrowly focused on the Personal Belief Exemption Policy
- Final recommendations on PBE will be formally submitted to the CDPHE in a written report outlining the process, deliberations and capturing the levels of agreement related to the recommendations.
- Recommendations should be **high level**

4

Guiding Principles for Crafting a Draft Nonmedical Vaccination Exemption Provision

- While recognizing and protecting the importance of individual freedoms and parental autonomy, legally and ethically these may be limited when they affect the health of others.
- Forcing vaccination upon parents who have strongly held conscientious beliefs opposed to vaccination may negatively affect their families.
- Imposing vaccination on a significant number of families may create a public backlash that undermines support for any school immunization requirements.
- School immunization requirements should carefully balance the public benefit of universal vaccination with individual freedoms and parental autonomy in vaccination choice.
- Permitting parents to opt out of school immunization requirements for reasons of strongly held and well-informed conscientious beliefs may reduce the negative impact that mandatory school immunization laws have on such individuals.
- Conscientious exemptions from school immunization requirements may help to sustain the broad community consensus required for immunization programs.
- Health departments should support legislation ensuring documentation of conscientious and well-informed beliefs against vaccination. The legislation should ensure that the path of least resistance encourages parents to comply with school immunization requirements rather than claiming an exemption simply because it is more convenient than having the child immunized.
- All parents should be informed about the risks and benefits of vaccination. Parents considering exemptions should be explicitly informed about the risks of not vaccinating their children.
- Health departments should have the final authority to grant or deny exemption requests based upon individual or community risks associated with exemptions and the sincerity of the applicant's beliefs.

Am J Public Health. 2005 May; 95(5): 778-783. doi: 10.2105/AJPH.2004.046193



If Colorado's immunization personal belief exemption includes:	Could be accomplished by BOH rule	Requires changes to statute	Supported By:
Informed Refusal ("understands the risks")	Yes		IDSA, PIDS, NACCHO, ASTHO
Required Education / Counseling prior to Exemption		Yes	PIDS
Medical Practitioner or Health Official Signature for Exemption		Yes	
Separate Exemption Form	Yes		
Exemption Approved by Health Department		Yes	
Annual Renewal of Exemption		Yes	IDSA, PIDS, NACCHO
Publicly Available Publication of Immunization Rates by School and Child Care Centers		Yes	
Signature of Parent (NO CHANGE)	NA	NA	
Signature of Notary		Yes	
Ask parent to provide reason for exemption		Yes	
Mandatory acknowledgement of information about PBE		Yes	
Require that the parents or guardians sign a statement that delineates the basis, strength, and duration of their belief		Yes	IDSA, PIDS, ASTHO
Require that exempted children be barred from school attendance and other group activities if there is an outbreak of a disease that is preventable by a vaccination from which they have been exempted. States that adopt provisions for personal belief exemptions should track exemption rates and periodically reassess the impact that exemptions may have on disease rates	Already in current statute		IDSA, PIDS, NACCHO
			IDSA, PIDS

Possible Recommendations

Annual Renewal of Exemption

- States that have enacted annual renewal:
 - Arkansas - 2003
 - Maine - 1986
 - Vermont - 2011
- Considerations:
 - Time/resources for both parents/guardians and administrative staff.
 - Arkansas saw no change in total percentage of exemptions (medical, religious and philosophical) immediately after implementation of the annual renewal process.
 - Maine's exemption rate increased from 3.9% in 2012 to 4.3% in 2013.

Medical Practitioner/Health Official Signature

- States that have enacted provider signature:
 - California - 2014
 - Oregon - 2013
 - Washington - 2011
- Considerations:
 - Definition of medical practitioner
 - Individuals without a medical home
 - Availability and time of medical practitioner
 - Finding a practitioner willing to sign the exemption
 - Washington has seen decrease in exemptions 5.9% in 2011 , 4.7% in 2012, 4.6% in 2013

Approval by Health Department

- States that have enacted approval by Health Department:
 - Arkansas - 2003
- Considerations:
 - Cost and time for staff at health department
 - Local and/or State approval

Signature of Notary

- States that have enacted the signature of a Notary
 - Arkansas - 2003
 - Minnesota - varies
 - Texas - 2004
- Considerations
 - Cost/access to get form notarized
 - In Arkansas Medical Exemptions fell from 21.3% annually to an average of 4.8% annually after the enactment of the 2003 changes (education, notary, annual renewal).

Required Education/Counseling Prior to Exemption/Information About the PBE

- States that have enacted:
 - Arkansas - 2003
 - California - 2014
 - Oregon - 2013
 - Texas - 2004
 - Vermont - 2011
 - Washington - 2011
- Considerations:
 - Who is creating and funding the education materials being developed
 - Who is providing the education (definition of provider)
 - Those without a medical home
 - Who monitors the implementation
 - How to ensure public understands the information

Informed Refusal

13

- States that have enacted informed consent:
 - Michigan - 1978
- Considerations:
 - How to ensure the public understands the information

Parent to Provide Reason for Exemption

14

- No States currently requires parents provide reason for exemption, however, Vermont currently has the parent inform the State as to which immunizations the child is exempting from
- Considerations
 - Privacy concerns

Separate Exemption Form

15

- States that have enacted separate exemption form:
 - Arizona, Arkansas, Idaho, Maine, Michigan, Ohio, Oklahoma, Oregon, Texas, Utah, Vermont, Washington.

Publically Available Publication of Immunization/Exemption Rates

16

- Vermont
- Oregon
- Washington
- Maine will begin in 2014
- California – by facility type and county
- Considerations:
 - Who is charged with collecting and publicizing the data?
 - Does it change behavior?

No Change to the PBE Policy

17

- States that require only a parent signature:
 - North Dakota
- Considerations:
 - Additional resources not needed
 - × Status quo in Colorado

Eliminate the Option of the Personal Belief Exemption

18

- 32 States currently do not have Personal Belief/Philosophical Exemptions
- Considerations
 - Individual choice vs. risk/health of community

Other Recommendations & Considerations

19

- **Recommendations**
 - Parents to submit in writing each year immunization exemption reason (no standard form)
 - ✦ Maine & Louisiana
- **Considerations**
 - Resources required to implement changes

Lessons Learned

20

- **Funding**
 - Some states passed legislation without identifying funding
 - ✦ Examples: OR did not fund education component
- **Leadership**
 - Differences in stakeholder leadership to change PBE led to different outcomes
 - ✦ Examples: CA led by coalition, VT led by legislator, WA led by local AAP
- **Clarity of statute**
 - Who can sign exemptions; who owns outcome; who provides education and what should it include; what data is reported and how is it used
- **Impact**
 - Differences in PBE rates among states have been noted after change implemented
 - ✦ Example: WA's PBE rate dropped significantly in one year but AR's did not

21

SUPPORT FOR THIS PROCESS HAS BEEN MADE POSSIBLE THROUGH THE COLORADO TRUST'S CONVENING FOR COLORADO PROGRAM



IN PARTNERSHIP WITH



APPENDIX I: SLIDE PRESENTATION FROM THIRD STAKEHOLDER MEETING



1

**COLORADO'S PERSONAL BELIEF EXEMPTION
POLICY FOR IMMUNIZATIONS**

**FINAL STAKEHOLDER ENGAGEMENT MEETING
SEPTEMBER 12, 2013**

Agenda Review

2

Morning	Afternoon
<ul style="list-style-type: none"> Welcome & reflections from meeting #2 Review of scope & desired outcomes Review of outputs Review & discuss potential criteria for reviewing recommendations Review & discuss final potential recommendations 	<ul style="list-style-type: none"> Lunch <ul style="list-style-type: none"> Process survey Continued discussion of final potential recommendations Next Steps Adjourn

Scope Review

3

- Stakeholders will generate potential policy and/or rule changes to the **Personal Belief Exemption** system, if it is believed policy and/or rule changes are needed.
 - Narrowly focused on the Personal Belief Exemption Policy.
- Final recommendations on PBE will be formally submitted to the CDPHE in a written report outlining the process, deliberations and capturing the levels of agreement related to the recommendations.
- Recommendations should be **high level**.

Desired Outcomes

4

- Outcome 1:** Stakeholders will **gain a better understanding** of the current state of personal belief exemption attitudes and opinions in Colorado based on reviewing a background report developed from sector-specific focus groups of health care providers, parents, school administrators, school nurses and public health officials.
- Outcome 2:** Stakeholders will **meaningfully** participate in facilitated **in-depth discussions** on current personal belief exemption policies and practices in Colorado.
- Outcome 3:** Stakeholders will **generate potential policy and/or rule changes** to the personal belief exemption system.
- Outcome 4:** Stakeholders will make **final recommendations** on Colorado's personal belief exemption system to be formally submitted to the Colorado Department of Public Health and Environment in a written report.

Review of Outputs

5

- Recommendations should be **high level**

Recommendation # X

Considerations for implementation

- Striving for high levels of agreement
- Represent areas of divergent views

Example: Recommendation

6

- Example Recommendation:**
All children should be physically active each day
- Considerations:**
 - Type of activity: running, swimming, walking, basketball
 - Leader: Teacher, video, game system, online
 - Length of time

Criteria from Stakeholder Meeting #2

7

- Accountability
 - Evaluation/measurement
- Same level of effort/ease
 - Balance
- Simplicity
- Risk vs. benefit
- Freedom to vs. freedom from

- Reasonable/meaningful
- Informed consent
- Standards
- Resources
- Consistency

Polling Results from Stakeholder Meeting #2

8

- **Require education/counseling prior to exemption (16)**
 - Use VIS as the education (2)
- **Publically available publication of immunization/exemption rates by schools and child care centers (7)**
- **Medical practitioner or health official signature for exemption (6)**
- **Annual renewal of exemption (4)**
- **Mandatory acknowledgement of information about PBE (1)**
- **Exemption approved by health department (1)**
- **Informed refusal (1)**

Possible Recommendations

9

Possible Recommendation #1

10

Possible Recommendation #1

Require Education/counseling prior to exemption

↓

Considerations:

Type of Education:

- Online training (receive certificate upon completion)
- Counseling from health care provider/health department
- Use VIS as the education

Accepted signatures acknowledging education was provided:

- Health care provider
- Health Department

Other:

- Billing code or office visit fee

Possible Recommendation #2

11

Possible Recommendation #2

Publically available publication of immunization and exemption rates by schools and child care centers

↓

Considerations:

Data collection
Information dissemination
Resources

Possible Recommendation #3

12

Possible Recommendation #3

Medical practitioner or health official signature for exemption

↓

Considerations:

Accepted signatures
Required to sign
Billing code or office visit fee



16

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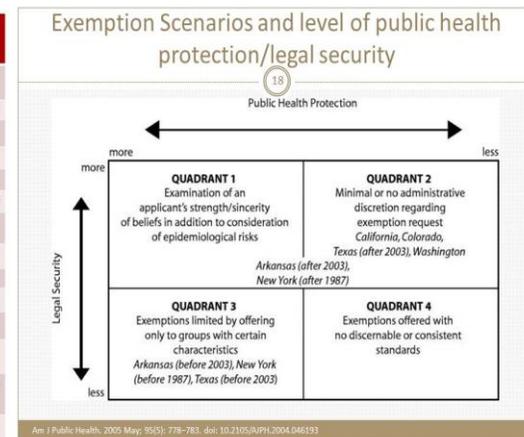
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