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SB276 Key Amendment Requests
Post Assembly Health Committee

Ensure a State Bureaucrat does not come between the Doctor-Patient Relationship

While the latest amendments to SB276 address some of the doctor patient relationship issues, they still give final oversight of reviewing and revoking medical exemptions to a state bureaucrat who will never meet the patient. This also penalizes the child who is an innocent party, if a doctor is incompetent in writing medical exemptions. The process should focus on the doctors, not the children. Also the majority of physician oversight for medical exemptions falls under the CDPH rather than the medical boards, whereas per the California Medical Board's own concerns, they should the organization with jurisdiction over physicians.

- SB276 needs to be amended to remove the medical exemption revocation process. Any medical exemption reviewed, and found questionable, should be referred to the Medical Board of California and the Osteopathic Board of California to allow them to determine if it warrants further investigation.

Truly Grandfather in Medical Exemptions written prior to SB276 going into effect

While the latest amendments seem to grandfather in medical exemptions lawfully written under the broader SB277 criteria, they are still subject to review and revocation based on SB276's stricter criteria if written by a doctor who writes more than 4 exemptions or if the school does not meet 95% overall vaccination rates. They were submitted lawfully and it is unusual for a law to retroactively apply.

- SB276 needs to be amended to remove the review and revocation process for medical exemptions written and submitted prior to January, 1 2021.
- The bill needs to clarify that permanent medical exemptions written and submitted prior to January, 1 2021, are valid until the child graduates from high school, regardless of grade or school transfers.

Apply valid Medical Exemption criteria reference points, to be expanded to include full family history and consistently applied at every step of the review and appeal process

SB276 supposedly expanded the reasons medical exemption could be written to include not only the CDC, but also ACIP and AAP "criteria for appropriate medical exemptions". However none of these organizations have **criteria** for appropriate medical exemptions. They do have guidelines for vaccinations, although ACIP and AAP's guidelines refer back to the CDC guidelines for vaccinations, so they are one and the same. None of these organizations have criteria or guidelines for appropriate medical exemptions, so the bill refers to something that is non-existent.

- SB276 needs to be amended to remove reference to the non-existent CDC, ACIP and AAP criteria for medical exemptions and replace all references to the criteria with "CDC Contraindications and Precautions, information from the CDC Vaccine Information Statements, adverse reactions from the manufacturer vaccine package insert, the HRSA National Vaccine Injury table information, family medical history, genetics and other documentation supported by relevant research."

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Clarify the criteria for physicians that trigger a review

According to the Harvard Lazarus study, vaccine reactions are expected in 2.6% of the population being vaccination (https://healthit.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system). If a physician has 500 patients they would expect to see 13 patients who may require a medical exemption from one or more vaccines.

- SB276 needs to be amended to prompt review based on 2.5% of the physician's practice size rather than an arbitrary number.

Medical exemptions are currently given for a variety of reasons where the patient should be counted as vaccinated, immune or conditional rather than as medically exempt.

- SB276 needs to be amended so that the review trigger only applies to permanent medical exemptions, not temporary medical exemptions which indicate the child will be vaccinated in the future.
- SB276 needs to be amended so that the review trigger does not apply to a child who has had the disease evidenced by doctor confirmation, or has conferred immunity from the disease or a previous vaccine evidenced by laboratory titer testing. These should be counted as vaccinated/immune for that disease rather than requiring a medical exemption. If it remains that these situations require a medical exemption then the medical exemptions should not be counted towards those that trigger a review.

Currently SB276 states a review will be prompted if a physician submits 5+ exemptions in a calendar year. Physicians, who are specialists, such as oncologists, immunologists or experts in adversonomics, will write significantly more than 5 exemptions per calendar year. They will also likely continue to write 5+ exemptions year over year.

- SB276 needs to be amended to clarify what will be reviewed – just the first 5 exemptions that triggered the review or a random subset in a particular time period or continuously for the remainder of the year.
- SB276 needs to be amended that a physician that is reviewed one year is not reviewed in subsequent years, or once every 5 years.

The bill refers to a physician having a "pending accusation", but does not define it. There are many online pro-vax trolls who pride themselves in filing medical board complaints about physicians who they believe are writing too many medical exemptions. It takes 1-2 years for the medical board to take a complaint to resolution. A doctor is guilty until proven innocent under this clause, as they cannot write another medical exemption until they are cleared.

- SB276 needs to be amended to read "If a physician and surgeon has been reprimanded by the Medical Board of California or the Osteopathic Medical Board of CA relating to medical exemptions, the department shall not accept a medical exemption form from the physician and surgeon unless and until the reprimand is resolved in favor of the physician and surgeon"

Clarify the criteria for schools that trigger a review

A review will be prompted if a school/institution has an overall immunization rate below 95%. Assuming the definition refers to the CDPH All Required Vaccines (ARV) rate (the https://www.shotsforschool.org/k-12/arv-rate/), an overall measure of fully-vaccinated students, a significant number of schools will fall below the 95% threshold even though their vaccination rates for each individual vaccine are above 95%. Herd immunity (the need for 95% vaccination) does not apply to tetanus, Hepatitis B and other non-infectious diseases.

- SB276 should be amended to prompt review for those schools/institutions whose MMR, Varicella and/or Pertussis vaccinations rates are below 95%.

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Define the Appeals Process

During the appeal process the parent/guardian can provide additional information.

- SB276 needs to be amended so that the physician is also be allowed to provide additional information
- SB276 needs to be amended so that the physician and parent are afforded the opportunity to meet and confer with the appeal panel.

The appeals process and the information that is admissible is left very open ended, especially if the regulations process will be circumvented. California already has a vetted healthcare appeals process in The Knox-Keene Act (§ 1370.6 KNOX-KEENE ACT 318).

- SB 276 should be amended to define the appeals process in a similar way to the Knox-Keene Act appeals process:

  The independent expert review panel shall evaluate appeals as follows:

  (1) The Panel is required to consider any relevant individual characteristics of the child involved.

  (2) The Panel must consider any relevant characteristics of the other children or the staff at the school that the child with the disease would attend.

  (3) The Panel must consider the degree of certainty and unanimity among medical experts regarding the risk that the disease could be spread by casual contact.

  (4) The Panel is required to consider whether there are less restrictive alternatives than excluding the child that could reduce the risk of contagion.

  Referring to medical and scientific evidence allowed and considered by the appeals process includes the following sources:

  (1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

  (2) Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS database of Health Services Technology Assessment Research (HSTAR).

  (3) Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act.

  (4) Either of the following reference compendia:

  (A) The American Hospital Formulary Service's Drug Information.
  (B) The American Dental Association Accepted Dental Therapeutics.

  (5) Any of the following reference compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

  (A) The Elsevier Gold Standard's Clinical Pharmacology.
  (B) The National Comprehensive Cancer Network Drug and Biologics Compendium.
  (C) The Thomson Micromedex DrugDex.

  (6) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Federal Agency for Health Care Policy and Re- search, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

  (7) Peer-reviewed abstracts accepted for presentation at major medical association meetings.

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Ensure medical privacy and limit who accesses the databases that will store medical exemptions and related medical records

The upgrades to the California Immunization Registry (CAIR) database to accommodate the medical exemption for all California is extensive, given 2 regions (9 counties) use different software from the main CAIR2 database. Either upgrades need to be made to the three individual databases or the CAIR2 integration of them needs to be fast-tracked. CAIR has numerous end users, but not limited to including federal, state and local assistance programs (such as WIC, CALWorks, foster care, schools), physicians, pharmacists and insurance companies. CAIR has an opt out option for sharing of information to third party users. SB276 does not clarify what information will be shared with whom.

- SB276 needs to be amended to clarify who will have access to the medical exemption information that is uploaded to CAIR and the other databases and what personal identifiable information and medical information and records will be shared with those querying.

The bill gives a blanket release of all medical records relating to vaccine medical exemptions to anyone who works at the CA Department of Health, the California Medical Board and the California Osteopathic Medical Board, not based on good cause or any other reason.

- SB276 needs to be amended so that only the clinically trained immunization staff member and the state health officer at CDPH and the investigations staff at the California Medical Board and the California Osteopathic Medical Board have access to patient medical records for a specific patient, if that patient's medical exemption is under review.

Remove Regulation Subversion

SB276 subverts the regulation process by completely removing administrative procedure. Such monumental legislation absolutely should allow public comment on the regulations for this bill. It will take at least 18 months to set up the form and upgrade the CAIR database, which gives plenty of time for public comment.

- SB276 should be amended to remove these sections and allow the regulatory process to prevail.

Require Liability Coverage for Vaccine Injury

This bill does not take into consideration who is liable for a child whose medical exemption is revoked and its appeal denied, who is then vaccinated against their doctor's recommendation and has a severe adverse reaction. Due to the 1986 federal Childhood Vaccine Injury Act, the parents cannot sue the vaccine manufacturer or the doctor. They may no longer be able to apply to vaccine court because they not adhered to their physician's medical advice.

- SB276 needs to be amended to require liability coverage for CDPH to cover vaccine injury legal costs.

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