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7/1/19 Post Assembly Health Committee
SB276 Amendment Concerns/Questions

SB276's current wording still removes the doctor-patient relationship and puts a state bureaucrat, who will never interact with the patient, in charge of reviewing and revoking vaccine medical exemptions.

The bill does not provide a clear process for the submission of medical exemptions, the appeals process, the database usage or criteria for the medical exemption to be used, among other things.

The bill seems to grandfather in existing medical exemptions but they then come under the same scrutiny as medical exemptions moving forward.

The bill penalizes the child, as well as the physician if their medical exemption has issues.

The bill leaves many questions unanswered which need to be resolved before the bill moves forward, specifically:

- Initially, the bill referred to "a database" that would be created, then it was changed with the 6/17/19 amendments that the CAIR database would be used. In the 7/1/19 amendments, Section 123072(a)(1) refers to CAIR, Section 123072(c)(2) has CAIR crossed out and replaced by "a database" and Section 123072(d)(7) refers to CAIR or database. When will a database would be used and when will CAIR be used? What are the two different upload processes and places where this information is stored, depending on when and who is filing the exemption?
- What upgrades are required to the CAIR2 database and the databases for the 9 counties that are not currently part of CAIR2 (Section 120372 (a) (1)) to be able to integrate the provisions set forth in this bill and at what cost?
- Who are the end users of the California Immunization Registry (CAIR) database (Section 120372 (a) (1)) and any other databases created and who will have access to vaccine medical exemption form and records and to what degree? Will personal medical history, such as Hep B or HIV status given as part of the medical exemption form be accessible to end users? CAIR has an opt out option for sharing of information. Will this apply to all Medical Exemptions as well?
- The bill states a physician cannot bill for filling out the medical exemption form or an examination related to a temporary exemption renewal (120372 (a) (3)). Is this against B&P Fair Businesses Code?
- The bill creates a standardized system to monitor immunizations levels in schools and institutions (120372 (c) 1). The department already has a system in place that monitors immunization levels in schools per Section 120375. https://www.shotsforschool.org/k-12/reporting-data/ How is the system referred to in this section different from what is currently done?
- It seems medical exemptions given prior to January 2021 will be grandfathered in so long as they are uploaded to a database (120372 (c) 2 (A) and they meet the revised restricted criteria. Is this for all grades or just the check point grades? What is the purpose of this database (other than a having a significant financial impact)? How will it be used? Can information from this database be used to target children or their physicians? Will the medical exemptions from this database be counted towards the review trigger count? They were submitted lawfully and it is unusual for a law to retroactively apply. If applied retroactively, this will cause a huge amount of work for physicians and the state to implement.

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- Currently schools enter immunization information at the kindergarten and 7th grade checkpoints. This bill states department will review schools immunization records at minimum annually (120372 (d) (1)). Will this review be just for these two check points, as they currently do, because the rest of the relevant statute is not affected, or will schools now have to enter immunization records for all 13 grades annually?
- A review will be prompted if a physician submits 5+ exemptions in a calendar year (120372 (d) (2) (B)). Physicians, who are specialists, such as oncologists, immunologists or experts in adversonomics, will write significantly more than 5 exemptions per calendar year. When will be physician be reviewed – at the 5 trigger point? And for what time period will they be reviewed – continuously or will just the first 5 medical exemptions be reviewed or will a random subset of exemptions be reviewed? Will these specialists be reviewed every year or just in the first year they write 5 or more exemptions?
- "The department" is referred to numerous times in the capacity of review and determination, but no specific position is identified. Who will this be reviewing the medical exemptions, school information and physician information – the clinically trained immunization staff member (120372 (d) 3 (B)) or someone else in the department?
- Bill refers to CDC, ACIP and AAP **criteria** for appropriate medical exemptions (Section 120372 (d) (3) (C)). These organizations do not have criteria for appropriate medical exemptions. The CDC, ACIP and AAP have guidelines for vaccinations. However, ACIP and AAP refer 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 how are these criteria defined?
- What is the definition of a physician whose "practice is contributing to a risk to public health" (120372 (d) 6 (A)) and how do they prove they no longer are contributing such risk or appeal this determination? Why are they barred from writing medical exemptions for 2+ years even if they are found not to pose a public health risk or "fix" the issue prior to that time? And why are their patients penalized in the meantime? What if one of their patient's needs a medical exemption, including a temporary one. Do they now have to go find a new physician to treat them?
- Why is the state worried about public transparency of contracts (120372 (h))?
- Why is the child whose child's medical exemption is revoked by the state public health officer and denied in appeal (120372.05), penalized for their doctor's incompetence?
- The evidence suggests that there should be NO physician giving vaccinations that does not write medical exemptions. Physicians need to be better trained in how to recognize vulnerable patients, medically exempt them, and to recognize/report vaccine injuries in shared professional responsibility. If this were occurring, there would not be a small cluster of doctors with expertise in this area, but a diligent medical profession doing its collective job. How can we ensure this is happening?
- Insurance should pay for the time it takes to do such evaluations rather than being made to stick to the 7 minutes allotted per patient by insurance billing procedures. Can the medical exemption evaluation process be given its own ICD10 code so doctors can adequately bill for the time it takes to do the evaluation?
- Who assumes liability for the child whose medical exemption is revoked, appeal denied, is vaccinated against their doctor's recommendation and has a severe adverse reaction? The parents cannot sue the vaccine manufacturer or the doctor. They may no longer be able to apply to vaccine court because they have gone against medical advice. What liability coverage is CDPH going to have to cover vaccine injury?

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The answers to the above questions will likely result in further amendments. However, there are a number of areas of the current bill wording that do not need clarification, but do need to be amended, specifically:

- Section 123070 (a) (1) states "that child shall be exempt from the requirements of this chapter, except for Section 120380,..." This was an error left in during SB277 but which results in allowing school nurses to override a valid medical exemption. The "except for Section 120380" should be removed from that section.
- Section 123070 (a) (1) needs to be amended 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 school transfers.
- Who is giving the authorization of the release of records related to the medical exemption – the physician or the parent or both (120372 (a) 2 (H))? This bill should be amended to have the parent agree to release their child's medical records.
- 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 (Section 120372 (a) (2) (H) and Section 12440). The bill should 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 has been revoked.
- A review will be prompted if a school/institution has an overall immunization rate below 95%. How is this defined (120372 (d) (2) (A))? If it is defined by AVR 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%. Why is this not just for communicable diseases based on the rate of individual vaccinations? Herd immunity (the need for 95% vaccination) does not apply to tetanus, Hepatitis B and other non-infectious diseases. The bill should be amended to prompt a review if a school's MMR, Varicella and/or Pertussis vaccinations rates are below 95%.
- A review will be prompted if a physician submits 5+ exemptions in a calendar year (120372 (d) (2) (B)). 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. The bill should be amended to prompt review based on 2.5% of the physician's practice size rather than an arbitrary number.
- Does this bill apply to temporary medical exemptions which are required to be renewed annually? For children that are too sick to get the vaccine on schedule (included in the CDC precautions), they would be given a temporary medical exemption, so they can remain in school, until they have recovered and can schedule another doctor's appointment. This may be days, weeks or months. If these temporary medical exemptions are counted towards the 5 before a physician gets reviewed (120372 (d) (2) (B)), the physician will likely go against their judgement and just vaccinate the child, which puts the child at

increased harm, but not the physician because they have no liability for injury after vaccination. The bill should be amended so that the review trigger only applies to permanent medical exemptions.

- A child who has had the disease or conferred immunity from a previous vaccine evidenced by titer testing, currently has to get a medical exemption to attend school. The bill should be amended so that 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 should be counted as vaccinated for that disease rather than requiring a medical exemption or if these situations require a medical exemption then the medical exemptions should not be counted towards the 5 that trigger a review (120372 (d) (2) (B)).
- A child who is vaccinated in a different country currently has to get a re-vaccinated or a medical exemption to attend school. The bill should be amended so that a child who has proof of vaccination from a different country should be counted as vaccinated for that disease rather than requiring a medical exemption or vaccination and if these situations require a medical exemption then the medical exemptions should not be counted towards the 5 that trigger a review (120372 (d) (2) (B)).
- It seems medical exemptions given prior to January 2021 will be grandfathered in so long as they are uploaded to a database (120372 (c) 2 (A)). However, they will be reviewed if they fall into a school that is below 95% or not reporting or from a physician who has written 5+ exemptions that year (120372 (d) 2). If they are reviewed they will then be subject to the new stricter exemption criteria in review ((120372 (d) 3 (A, B, C)). The bill needs to be amended so that existing exemptions are removed from (120372 (d) 1).
- When a medical exemption does not comply with the non-existent CDC, ACIP and AAP criteria for medical exemptions, CDPH can consider family history as long as it complies with relevant standard of care, which would circle back to the CDC guidelines and be extremely narrow (120372 (d) (3) (B)). The bill should be amended that at all times a medical exemption is reviewed the possible criteria for a medical exemption should include 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.
- What is the definition of "relevant" standard of care (120372 (d) (3) (B))? Relevant to what? It takes 17 years for research to get into a doctor's practice (http://ajcc.aacnjournals.org/content/25/3/194.full). The bill should be amended to replace "relevant standard of care" to "relevant research" so doctors can be using the most current information with regard to vaccination injury triggers, genetics, etc.
- The clinically trained immunization staff member has the ability to **accept** a medical exemption (120372 (d) 3 (B)) but everywhere else in the bill the state health officer can only revoke a medical exemption. This section of the bill should be amended to read "The department will review additional supporting evidence for a medical exemption based on other contraindications or precautions, including but not limited to consideration of family medical history, genetics, information on the CDC Vaccine Information Statements, information listed on the manufacturer package insert." The following section then refers to what happens after this review.
- What is the definition of a "pending accusation" and from whom does such an accusation need to stem (120372 (d) 6 (B))? 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. The bill should 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"

- Why is this bill subverting the regulation process (120372 (i) and 120372 (j)) completely and 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. The bill should be amended to remove these sections.
- During the appeal process the parent/guardian can provide additional information (120372.05 (a)). The bill should be amended so that the physician is also be allowed to provide additional information, as well as amended so that the physician and parent should also be given the opportunity to meet and confer with the appeal panel.
- The appeals process is left very open ended. California already has a vetted appeals process in The Knox-Keene Act. This bill should be amended to define the appeals process in a similar way:

  HHS Panel Review:
  First, the board is required to consider any relevant individual characteristics of the child involved.
  Second, the board must consider any relevant characteristics of the other children or the staff at the school that the child with the disease would attend.
  Third, the board must consider the degree of certainty and unanimity among medical experts regarding the risk that the disease could be spread by casual contact.
  Fourth, the board is required to consider whether there are less restrictive alternatives than excluding the child that could reduce the risk of contagion
  https://www.cahealthwellness.com/content/dam/centene/cahealthwellness/pdfs/imr_E1.pdf

  Referring to evidence allowed and considered by the appeals process:
  https://www.dmhc.ca.gov/Portals/0/Docs/OLS/KKA_2019.pdf
  (d) For the purposes of subdivision (b), "medical and scientific evidence" means 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:

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(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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- Why is the majority of the physician oversight falling under the CDPH rather than the medical board, when the medical board is the organization with jurisdiction over physicians? The bill should be amended to remove all physician oversite from CDPH and put it in the hands of the medical board.

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