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**Witness Statement of Healthcare Lawyer Gregory J. Glaser**

I am the General Counsel for Physicians for Informed Consent (PIC), a 501(c)(3) nonprofit organization comprised of physicians, scientists, and attorneys whose mission is to safeguard informed consent in vaccination and educate the public.

As evidenced by my Curriculum Vitae, I have closely followed the legal evolution of California's mandatory vaccine law since 2015 when SB277 was enacted, through the present day. On a routine and regular basis since 2015, I have advised integrative physicians, including Dr. Kenneth Paul Stoller, of my legal opinions regarding same. I am providing this letter as a summary of my expected testimony, to the extent that any of it is deemed expert testimony by the court.

As an attorney, I believe I understand the limitations of expert testimony from attorneys about matters relating to the interpretations of statutes. However, the statutory analysis contained herein is what I shared with Dr. Stoller and many other integrative physicians since the passage of SB 277 privately in consultations and publicly at various seminars and events described below.

## A. The Evolution of California's Medical Exemption Law

The view which I shared with the integrative community is that California's medical exemption law has evolved considerably since 1995, whereby the statute originally utilized the word "contraindicate", but then for political reasons in 2015 the word "contraindicate" was replaced with "not considered safe". For what I have described to them as political reasons, meaning the outspoken opposition among California legislators to a strict medical exemption standard, SB277 bill author Senator Richard Pan was forced to amend his bill to eliminate the word "contraindication". I explained that this fact can be plainly seen on the record as the bill authors made statements such as:

> "...one of the things we've talked about over and over again is how important it is that there be a strong and robust medical exemption so that anybody who had a legitimate medical concern, genetic predisposition, some sort of immunological problem, they can go to a doctor anywhere in the state and get an exemption from that doctor."

SB277 co-author Ben Allen on the record during legislative hearing. See Exhibit A -- Assembly Health Committee Hearing transcript on SB277, June 9, 2015, page 15, lines 15 through 21.

"Rob Bonta: Thank you, Dr. Pan. And then finally, we have an amendment regarding the medical exemption and a physician's judgement. And I've heard from a number of constituents and Californians regarding concerns that a medical exemption is difficult to obtain or was difficult to obtain. I believe that current law states that a physician has complete, professional discretion over the writing of a medical exemption. However, I have asked the author to take an amendment to clarify that a medical exemption is entirely within the professional judgement of a physician and we have agreement on that amendment."

"SB277 bill author Richard Pan: Yes."

See Exhibit A - excerpt from Assembly Health Committee Hearing transcript on SB277, June 9, 2015, page 31, line 23 through page 32, line 10.

I pointed out to individuals and the group that Senator Pan made several unorthodox medical statements showing the clear intent for a medical exemption significantly broader than CDC standards:

"If the physician feels that there's a genetic association in a sibling, a cousin, some other relative, it's not safe for a vaccine, they can provide a medical exemption for that vaccine. There is no limitation on a physician from doing that other than their own professional judgment, their own knowledge and expertise about what they believe is safe for the patient.... we are trying to create the space to allow doctors and their patients and their parents to work together, hand in hand like it should be" [and] "We took amendment to absolutely clarify that point. Ad so what that means is is [sic] that if the physician feels that a sibling of a child, because the condition may be genetic, it may be family related, that therefore that child is also at increased risk even though that child has not yet suffered harm, then they can exercise to [sic] professional judgment to provide an exemption.... There's no requirement that you even have to go to a physician that you've seen multiple times in the past."

See Exhibit A -- excerpt from Assembly Health Committee Hearing transcript on SB277, June 9, 2015, page 129, lines 9 through 16; and page 131, line 25 through page 132 line 2; and page 116, line 22 through page 117 line 4; and page 117 lines 11-13.

The medical issues referenced in the above-cited legislative history, such as "genetic association... with a...cousin" cited by Senator Pan are not CDC listed contraindications (or even temporary precautions) to vaccination, nor are they within the scope of ACIP or AAP vaccination contraindication guidelines. Rather, they are only precautions to

vaccination recognized in different measure in various medical communities (i.e., integrative medical communities) to justify a medical exemption to vaccination.

I explained to Dr. Stoller the chronological evolution of this medical exemption as follows:

**1995-2015: Contraindication Standard**

**Exhibit B, Pre-SB277, cited as**
1995 Cal ALS 415, 1995 Cal SB 1360, 1995 Cal Stats. ch. 415, 1995 Cal ALS 415, 1995 Cal SB 1360, 1995 Cal Stats. ch. 415

§ 120370.
If the parent or guardian files with the governing authority a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances that **contraindicate** immunization, that person shall be exempt from the requirements of Chapter 1 (commencing with Section 120325, but excluding Section 120380) and Sections 120400, 120405, 120410, and 120415 to the extent indicated by the physician's statement. [emphasis added]

**2015-2019: Not Considered Safe Standard**

**Exhibit C, SB277, cited as**
2015 Cal ALS 35, 2015 Cal SB 277, 2015 Cal Stats. ch. 35, 2015 Cal ALS 35, 2015 Cal SB 277, 2015 Cal Stats. ch. 35
§ 120370. (A) If the parent or guardian files with the governing authority a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances ~~that contraindicate~~ , INCLUDING, BUT NOT LIMITED TO, FAMILY MEDICAL HISTORY, FOR WHICH THE PHYSICIAN DOES NOT RECOMMEND immunization, that ~~person~~ CHILD shall be exempt from the requirements of Chapter 1 (commencing with Section 120325, but excluding Section 120380) and Sections 120400, 120405, 120410, and 120415 to the extent indicated by the physician's statement.

My discussions with Dr. Stoller and other members of the group continued after SB 277 was amended in September 2019 as follows:

**Present Day: Contraindication Standard**

**Exhibit D, Post-SB277, cited as Cal. Health & Safety Code section 120370(a)**

(a) (1) Prior to January 1, 2021, if the parent or guardian files with the governing authority a written statement by a licensed physician and surgeon to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances, including, but not limited to, family medical history, for which the physician and surgeon does not recommend immunization, that child shall be exempt from the requirements of this chapter, except for Section 120380, and exempt from Sections 120400, 120405, 120410, and 120415 to the extent indicated by the physician and surgeon's statement.

(2) Commencing January 1, 2020, a child who has a medical exemption issued before January 1, 2020, shall be allowed continued enrollment to any public or private elementary or secondary school, child care center, day nursery, nursery school, family day care home, or developmental center within the state until the child enrolls in the next grade span. For purposes of this subdivision, "grade span" means each of the following:

(A) Birth to preschool, inclusive.

(B) Kindergarten and grades 1 to 6, inclusive, including transitional kindergarten.

(C) Grades 7 to 12, inclusive.

(3) Except as provided in this subdivision, on and after July 1, 2021, the governing authority shall not unconditionally admit or readmit to any of those institutions specified in this subdivision, or admit or advance any pupil to 7th grade level, unless the pupil has been immunized pursuant to Section 120335 or the parent or guardian files a medical exemption form that complies with Section 120372.

...

(d)(3) (A) **The department shall identify those medical exemption forms that do not meet applicable CDC, ACIP, or AAP criteria for appropriate medical exemptions**. The department may contact the primary care physician and surgeon or issuing physician and surgeon to request additional information to support the medical exemption.

(B) Notwithstanding subparagraph (A), the department, based on the medical discretion of the clinically trained immunization staff member, may accept a medical exemption that is based on **other contraindications or precautions**, including consideration of family medical history, if the issuing physician and surgeon provides written documentation to support the medical exemption that is consistent with the relevant standard of care.

As part of my attempts to educate myself so I could inform the integrative medical community regarding medical exemptions and its ability to write exemptions broader than CDC / ACIP

guidelines, I did online professional legal searches. As evidenced by the attached Lexis-Nexis Shepards results (Exhibit E), there is no case law interpreting California's medical exemption laws. In particular, I looked at every California case law precedent (see Exhibit E), and there is nothing interpreting the meaning of "not considered safe" in Cal. Health & Safety code section 120370. The most that can be said is that in 2010, one California court case (*Brown v. Shasta*) referred in their unpublished dicta to the pre-SB277 standard ("contraindicate") as follows "Health & Saf. Code, § 120370 [dangerous due to medical or physical condition].)" *Brown v. Shasta Union High Sch. Dist.*, No. C061972, 2010 Cal. App. Unpub. LEXIS 7051, at *25 (Sep. 2, 2010)

**B. Historical Perspective -- Integrative Physician Community Response to SB277**

I have personal knowledge that the California Integrative Physician community, of which Dr. Stoller is a member, was shocked by SB277 in the year 2015. After the bill passed, this minority group discussed the ambiguity of the law as written with tremendous confusion and uncertainty. But in the meantime, regular and routine patient appointments were ongoing, so in the face of uncertainty, it was still necessary for the physicians to move forward and continue seeing their patients. For better or worse, this respectable minority of physicians took Senator Pan at his word and believed they had discretion to write medical exemptions in areas where the emerging data proved or suggested that vaccination was not considered safe. In a nutshell, the physicians were engaged in risk assessment in their discretion.

PIC organized a conference for physicians at our earliest opportunity (March 2017), where we hosted a private closed-door session exclusively for physicians and lawyers to discuss SB277. There was a vibrant scientific discussion among the physicians regarding the medical criteria and factors that appeared to be opened under SB277 ("not considered safe") that had previously been closed under the pre-SB277 law ("contraindicate"). Some of the physicians, like Dr. Stoller, emphasized the importance of genetic testing in this emerging field. There was also, for example, a significant discussion regarding autoimmune disorders in a family member. The consensus among the group was that the new law granted physicians the ability to write permanent medical exemptions from all vaccines (due to common ingredients in vaccines, and due to the uncertainty of knowing which vaccine was the culprit of adverse events) without going through a contraindication analysis vaccine by vaccine (like the way a contraindication analysis is done in the CDC contraindication table), because SB277 used words that were expressly different from contraindication from each vaccine. This minority community essentially decided together as a group that the actual words in the statute mattered, and the legislative history especially empowered them to be cautious against adverse events.

Overall, PIC's March 2017 meeting with the physicians and lawyers was somber, and the group was unable to resolve the inherent uncertainty in the law, especially given the absence of any case law precedent. Indeed, certain physicians among this respectable minority had already contacted the California Medical Board for guidance on the applicable or relevant standards of care for integrative physicians, and the Medical Board simply replied "it is up to you, as the treating physician, to determine what an appropriate medical exemption is". See Exhibit F that

integrative physician Dr. [redacted] received, and which is information I shared with his colleague Dr. Stoller. The medical board provided precisely zero medical or legal authority for its position ("it is up to you") on SB277.

The only thing that was certain after the March 2017 meeting was that this respectable minority community of California integrative physicians was determined to stand up for their patients' rights to integrative care, even if it meant possible disciplinary action and the need to assert the CAM defense of Cal. Business & Professions Code section 2234.1 (which was discussed at length during our meeting). Personally, I was inspired by their bravery, and I proudly stand with Dr. Stoller today. Indeed, as part of my legal consultation to this respectable minority of California physicians, I provide them a copy of the CAM defense requirements. See Exhibit G.

**C. It is impossible to ignore the respectable minority of physicians who are extra cautious about vaccine adverse events. Just as vaccine recommendations vary among nations, likewise there is more than one community of California physicians and more than one standard of care in vaccine administration, medical exemption, immune system support, and immune system education.**

Attached as Exhibit H is the written paper (Best Practices for Physicians Recommending a Medical Exemption to Vaccination) that Toni Bark, MD and I presented to PIC Physicians on March 17, 2019 at our medical conference in California. Dr. Stoller was in attendance and I personally observed him participate actively to engage with his integrative physician colleagues.

Exhibit H represents the medical citations and methods that California physicians were recognizing prior to 2019, and in many cases prior to SB277. It is a helpful summary of my prior oral advice and discussion with Dr. Stoller and other PIC physicians since 2015. In other words, Exhibit H represents the culmination of my work from 2015-2019.

The express goal of the presentation was, "the participant will be able to meet the following four learning objectives:

1. Understand the difference between vaccine warnings, precautions, and contraindications to vaccination, and the medicolegal definition of a medical exemption.
2. Become familiar with vaccine warnings and precautions described in vaccine package inserts (PIs), contraindications and precautions recognized by the Centers for Disease Control and Prevention (CDC), vaccine injuries listed in the National Vaccine Injury Compensation Program's (VICP) Vaccine Injury Table, and other known and emerging vaccine adverse events.[1-3]
3. Recognize current medical problems, personal medical histories, family medical histories, and other circumstances that may increase the risk of vaccine adverse events.

4. Consider the administrative procedures and best practices involved in writing a medical exemption.

In regards to routine vaccine administration, California medical exemptions, immune system support, and immune system education, I have observed this minority group of California integrative physicians (of which Dr. Stoller is a member) practices a different standard of care than the majority of California physicians. That alternative standard of care is well-represented by Exhibit H, representing my professional opinion to Dr. Stoller and the integrative medical community; in particular see:

> "A medical exemption to vaccination is a medicolegal document that is required specifically for school attendance when a patient is at increased risk of harm from any state-mandated vaccine. It is important to recognize that a medical exemption must be based on one or more medical issues, such as contraindication, precaution, warning, or perceived risk of an adverse event from the physician's point of view.
>
> "In California, for example, a medical exemption is "a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe." [footnote omitted] Thus, in California, licensed physicians are allowed by law to make individualized and up-to-date recommendations for at-risk children, after weighing the benefits versus the risks of a vaccine."

Exhibit H advises integrative physicians of the majority standard of care on pages 4-14, including for example, "As defined by the CDC, a vaccine contraindication is a condition that 'increases the risk of a serious adverse reaction,' and when such condition is present, a vaccine should not be administered. [footnote omitted]

And then on pages 15-18, Exhibit H advises integrative physicians of the minority standard of care that recognizes "Emerging Data for Risk Assessment Regarding Vaccine Adverse Events". In this minority standard of care section, published peer-reviewed evidence is explored regarding the increased risk of vaccine adverse event and:

- "Autoimmune Disorders
- "Asthma/Allergy/Atopic Disorders
- "Neurological Disorders
- "Inflammatory Bowel Disorders
- "Developmental or Learning Disorders
- "Psychiatric or Mental Health Disorders
- "Genetic Susceptibility That May Increase the Risk of Vaccine Adverse Events"

To emphasize the distinction between the two standards of care, Exhibit H plainly distinguishes between:

(1) Pages 4-14 -- CDC contraindications and precautions (which are federal public health terms primarily employed by drug companies in package inserts, federal agencies, and adopted by various consensus entities like the ACIP and professional organizations like the AAP and embodied in the Red book which is colloquially viewed as the 'bible' of conventional pediatricians.

and

(2) Pages 15-18 -- Emerging data for risk assessment regarding vaccine adverse events, representing the type of published, peer-reviewed studies that Dr. Stoller discusses with his patients and is found in his risk assessment report given to patients.

Once again, this document is largely a written version of information and advice I have shared with Dr. Stoller and other members of the integrative medical community concerning my views on allowable exemptions under SB 277. Neither the document nor this letter nor my testimony is intended to render expert opinion on meaning or interpretation of the statutes, which I understand is solely the province of the court.

**Conclusion**

It was and still is my professional opinion that t the CAM defense should protect Dr. Stoller, and that SB 277 by the terms of the statute as explained by the statements of the bill's authors as related above created the statutory authorization for Dr. Stoller and other integrative physicians to write medical exemptions beyond the CDC / ACIP contraindications and precautions, and I have so advised Dr. Stoller and many other physicians in private and public since 2015.

Greg Glaser _____ February 10, 2020

Greg Glaser Date

# Exhibit A

TRANSCRIPTION OF RECORDED MEETING

OF

ASSEMBLY HEALTH COMMITTEE

JUNE 9, 2015

State Assembly Members Present:

Member Rob Bonta, Chairman

Member Brian Maienschein, Vice Chairman

Member David Chiu

Member Jimmy Gomez

Member Lorena Gonzalez

Member Jim Patterson

Member Miguel Santiago

Member Marc Steinorth

Member Marie Waldron

Member Jim Wood

Transcribed by: Gita Barrett

Foothill Transcription Company

October 10, 2016

Elk Grove, California

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**Chairman Bonta:** Good afternoon everyone. I'm calling to order the Assembly Health Committee meeting of June 9th. We only have one item on our agenda today, SB-277. I want to thank Senators Pan and Allen for bringing this important measure forward. I look forward to a robust discussion today. I want to make a couple quick points on our process.

Given the heightened interest in this bill and to ensure a robust debate today, I'm allowing additional testimony beyond our normal committee rules. We will allow 25 minutes for expert witnesses on each side.

After we hear from witnesses on each side we will allow time for members to ask questions while the expert testimony is fresh in their minds and after members have asked questions directly of authors and witnesses we will open the microphones for public testimony.

All additional witnesses after the expert witnesses speak are to state only their name, organization or city and their position and I'm going to need to hold everyone to that because we have a lot of speakers who want to speak today and in order to let everybody speak we must commit to the same rules for everybody. Name, organization or city and position.

The sergeants will be directing members of the

ourselves -- that we are going to be a risk of diseases that exist in other places if we don't take the steps necessary to protect ourselves here. I think what -- essentially I am someone who has a strong civil liberties streak in me.

I do think that at the end of the day, though, government has a role to play when one's beliefs, one's actions founded even upon sincerely felt beliefs start to impact other people and that's, I think, what we have here and that's why I've been involved with this bill. Now, as you know, the committee has offered several amendments that we're very happy to accept.

Glaser Note: Senator Pan speaking

They mainly relate to expanding the medical exemption and that's something that I'm very interested in and one of the things we've talked about over and over again is how important it is that there be a strong and robust medical exemption so that anybody who had a legitimate medical concern -- genetic predisposition, some sort of immunological problem -- they can go to a doctor anywhere in the state and get an exemption from that doctor. That's very important to me and I'm glad that the committee, I think, pointed out some weaknesses in the earlier bill and took some steps necessary to expand exemption and I'm certainly happy to talk further about that if you like as well.

amendment. As was discussed in the Senate Judiciary Committee, clarification is needed to address the status of students currently enrolled with an existing PBE. Amendment language clarifies that a student who had a PBE filed anywhere in California before January 1, 2016 will have their PBE stay in effect until they enroll into the next grade span. Currently, schools are required to check the immunization status of every student at kindergarten and seventh grade. It would be unnecessarily burdensome to require schools to check the immunization status of every student at every grade upon the enactment of this bill.

The amendment aligns the language with current practice so that schools are only required to verify a student's immunization status upon enrollment in kindergarten and upon advancement to the seventh grade and this includes transfer students.

**Senator Pan:** Okay. Yes.

**Chairman Bonta:** So that's the part that's slightly different. So okay. We have confirmation on that amendment?

**Senator Pan:** Yes.

**Chairman Bonta:** Thank you, Dr. Pan. And then finally, we have an amendment regarding the medical exemption in a physician's judgment. And I've heard from a number of

constituents and Californians regarding concerns that a medical exemption is difficult to obtain or was difficult to obtain. I believe that current law states that a physician has complete professional discretion over the writing of a medical exemption.

However, I have asked the author to take an amendment to clarify that a medical exemption is entirely within the professional judgment of a physician. And we have agreement on that amendment?

**Senator Pan:** Yes.

**Chairman Bonta:** Okay. Thank you. So at this time, we're going to go to -- you have eight minutes left. You don't have to use the eight minutes. Is there any desire to address further issues or for witnesses to speak? I want to make sure you're aware of your allotted time and how much you have left. We're going to -- the plan next is to go to witnesses in opposition and then to member questions.

**Senator Pan:** Okay.

**Chairman Bonta:** But you have more time if you wish to use it.

**Senator Pan:** No, I think -- we'll save time for the committee. We're good.

**Chairman Bonta:** Okay. Thank you. Thank you very much, Dr. Pan, expert witnesses in support. We will now invite

**Senator Pan:** Yes.

**Member Burke:** Thank you.

**Chairman Bonta:** Thank you, Assembly Member Burke. Assembly Member Nazarian.

**Member Nazarian:** First and foremost, thank you, Senators Pan and Allen, for bringing this important measure. Obviously, it stirred up a lot of emotion and interest. I just want to be clear about the medical exemption. This is something that I've discussed the matter with you previously and I'm happy to be a co-author. Yet, this area concerns me somewhat only because I want to know, given if we lose the opportunity to have personal beliefs not available, in the case of the gentleman who was talking about his daughter, who's perfectly healthy, if the first child has a reaction would there be a medical exemption for the second child?

**Senator Pan:** So the medical exemption --

**Member Nazarian:** Does it clearly allow that?

**Senator Pan:** So the -- what the -- what the law --the bill and the law clearly states is is that the medical exemption is at the professional judgment of the physician. We took amendment to absolutely clarify that point. And so what that means is is that if the physician feels that a sibling of a child, because the condition may be genetic, it may be family related, that

therefore that child is also at increased risk even though that child has not yet suffered harm, then they can exercise to professional judgment to provide an exemption. That is -- it's the professional judgment of the physician in term of what they believe that if the risk of the immunization is going to be such that it's going to put that child at certain or near -- you know, basically at increased harm then they can provide that exemption. And so that's to the judgment of the -- of actually any licensed physician in the state of California. There's no requirement that you even have to go to a physician that you've seen multiple times in the past. The law clearly states that any licensed physician in the state of California can provide a medical exemption. What they have to do is document the reason. They document the duration, which can -- and there's no limitation. That could be indefinite. And they have to sign it, of course, saying that they're -- as a licensed physician and you get a medical exemption.

**Member Nazarian:** Okay. So Mr. Chair, if you'll allow me to just follow up on a couple of these questions.

**Chairman Bonta:** Please do, Assembly Member Nazarian.

**Member Nazarian:** So okay. So then if the parent -- let's say the decision of the physician is to not allow.

**Senator Pan:** Uh-huh.

vaccine causes autism. There have been more than seven well-done studies involving hundreds of thousands of children and there is no evidence. There is no evidence specifically that thimerosal is associated with autism in African Americans and in fact if you look at vaccine-preventable diseases they -- some vaccine-preventable diseases do tend to affect racial and ethnic minorities disproportionately and higher vaccination rates erases those disproportional diseases.

**Member Thurmond:** Thank you, Mr. Chair, and thank you for your answers. Mr. Chair, thank you for obliging me. I just figured with all these wonderful experts and all this expertise I wanted each side to have an opportunity to speak to the things that we've heard and what science they have to defend their assertions. Thank you, Mr. Chair.

**Chairman Bonta:** Assembly Member Nazarian.

**Member Nazarian:** Thank you again, Mr. Chair. I guess I want to just conclude by asking you if you would consider -- I've grappled with this and I'm a co-author. I want to support this. I ask you if you would consider putting in language not limited to but for the exemptions to be offered in instances when a sibling or a family members has had an adverse reaction and if there's a -- I know there isn't a very good test for it but if there are any

genetic dispositions that --

**Senator Pan:** So I would say -- first of all, there's no restrictions in both current law or in the bill that prevents a physician from doing that. There are none. There are none. So now what we're doing is you're -- my concern is we're now adding language to tell a physician to do something that may not be necessary. If a physician feels that a test is necessary to perform to be sure that a vaccine is safe they can perform that test. If a physician feels that there's a genetic association in a sibling, a cousin, some other relative, it's not safe for a vaccine, they can provide a medical exemption for that vaccine. There is no limitation on a physician from doing that other than their own professional judgment, their own knowledge and expertise about what they believe is safe for the patient. I think that when we craft our laws it's best that we try not to direct, unless we have strong scientific evidence and we believe -- direct the physician that they now must do something that they have the ability to already do. So I appreciate what you're saying. I also want to just be sure -- reassure you there is nothing in the bill or the existing law, and I would ask you to point it out if you feel there is because then yes, I would be willing to look at an amendment. That actually prevents the physician from

doing exactly what you're asking them -- asking to do.

**Member Nazarian:** This will be my last comment. But Senator Pan, all due respect, there are three doctors sitting at the desk and you're not all agreeing and that's what gives me some concern.

**Senator Pan:** So --

**Member Nazarian:** Naturally, not everyone needs to -- there shouldn't be 100 percent agreement. But this is a very, at some point, critical issue that I think we're intervening between a parent and a child and if there is documented -- if there is a sibling or if there's a family relationship or if there's genetic potential opportunity for there to be something else happening I would feel more comfortable.

**Senator Pan:** So let me just say that actually we've worked with the Health Committee staff. We've worked with the chair of this very, very specific issue. All right. There are some assertions that made -- that people have made that they think doctors won't do things or will do things or something. But we are dealing with the bill and the law, right. We're dealing with what the law says and what the bill will say what physicians and parents can -- you know, cannot do in schools. And so what this bill has been crafted, working with the chair and the staff, looking at what the bill actually says,

not what people would like to assert it says -- what it actually says, how it will be interpreted, we have left that discretion to licensed physicians in the state of California including either to your own physician, the specialist you're seeing, another physician, we have left that discretion open. We -- physicians -- there's no limitation in the law. We've just heard from the medical board. There -- we are not aware of any physician who's been disciplined and investigated because they provided a medical exemption. So there's no cloud hanging over them to be able to do this. Certainly, they have to look at their own expertise and conscience and knowledge and be sure that they're fulfilling their oath to do the best they can for their patient. That is what we expect of our licensed physicians. But there is no legal barrier if they believe that a sibling that needs to have an exemption that they will -- can not grant that exemption. There is no legal barrier at all.

So no matter what we put into the law, unless we want to force physicians and say you must, that's a whole different discussion. But there's nothing in the law that says that they cannot. They are perfectly free to do that and physicians have done that before. And so I hope that, you know -- I think that that is what, you know, we are trying to create the space to allow doctors

and their patients and their parents to work together hand in hand like it should be -- working hand in hand to try to do what's best for the patient and also to protect all the children who are attending their school -- be sure that we protect all our communities and that we keep people safe from contagious diseases including children who cannot be immunized because they -- and who are at risk of these diseases. But in the end, the medical exemptions between that health care professional doctor and that child and their parents or guardian and that's where that decision will be made.

**Chairman Bonta:** Thank you, Mr. Nazarian. And let me just jump in on that point. This is an issue that we worked very closely with the office on. This -- the amendments that we took -- one of the four amendments that we took and we went over together earlier today was specifically designed to address this issue, to make it clear that the physician can act within his or her professionals judgment and discretion based on all sorts of medical factors without limitation including family history. And when we were discussing this amendment we specifically discussed the scenarios of a parent or an older sibling who had an adverse reaction to a vaccine and if that could be an appropriate factor to lead to the decision by a doctor to provide a medical exemption. And

TRANSCRIBER'S CERTIFICATE

STATE OF CALIFORNIA )
) ss.
COUNTY OF SACRAMENTO )

This is to certify that I transcribed the foregoing pages 1 to 236 to the best of my ability from an audio recording provided to me by California State Assembly.

I have subscribed this certificate at Elk Grove, California, this 16th day of November, 2016.

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Gita Barrett

Foothill Transcription Company

# Exhibit B

# *1995 Cal SB 1360*

Enacted, August 11, 1995

**Reporter**
1995 Cal ALS 415; 1995 Cal SB 1360; 1995 Cal Stats. ch. 415

**DEERING'S CALIFORNIA ADVANCE LEGISLATIVE SERVICE > 1995 REGULAR SESSION > CHAPTER 415 > (Senate Bill No. 1360)**

## Notice

Urgency legislation is effective immediately, Non-urgency legislation will become effective January 1, 1996

**[A>** Uppercase text within these symbols is added **<A]**
* * * indicates deleted text

## Digest

SB 1360, Committee on Health and Human Services. Reorganization of the Health and Safety Code: public health. Existing law sets forth in the Health and Safety Code various provisions relating to health and safety. Existing law requires the State Director of Health Services to conduct a comprehensive review of the statutes governing the protection of the public health as principally embodied in that code. This bill would repeal existing provisions of the Health and Safety Code relating to public health and reenact those provisions into 7 new divisions in the Health and Safety Code for the purpose of reorganizing the public health component of the Health and Safety Code and would make other technical changes. This bill would state the intent of the Legislature to reorganize and clarify portions of the Health and Safety Code and thereby facilitate its administration. It would further state the Legislature's intent that the changes made to the Health and Safety Code, as reorganized by this bill, have only technical and nonsubstantive effect. This bill would state the finding of the Legislature that the reorganization of the Health and Safety Code pursuant to this bill, in view of the nonsubstantive statutory changes made, will not result in new or additional costs to local agencies. This bill would provide that any section of any act, other than the code maintenance act (SB 975), enacted in 1995 that takes effect on or before January 1, 1996, and that amends, amends and renumbers, adds, repeals and adds, or repeals a section that is amended, amended and renumbered, added, repealed and added, or repealed by this act, shall prevail over the amendment, amendment and renumbering, addition, repeal and addition, or repeal of that section by this act.

## Synopsis

An act to amend Section 1290 of, to add Section 27 to, to add Division 101 (commencing with Section 100100), Division 102 (commencing with Section 102100), Division 103 (commencing with Section 104100), Division 104 (commencing with Section 106500), Division 105 (commencing with Section 120100), Division 106 (commencing with Section 123100), and Division 107 (commencing with Section 127000) to, to repeal Sections 26, 850, 1250.9, 1250.10, and 1260 of, to repeal Article 1 (commencing with Section 200), Article 1.5 (commencing with Section 225), Article 1.7 (commencing with Section 230), Article 1.7 (commencing with Section 235), Article 1.8

§ 120340.

A person who has not been fully immunized against one or more of the diseases listed in Section 120335 may be admitted by the governing authority on condition that within time periods designated by regulation of the department he or she presents evidence that he or she has been fully immunized against all of these diseases.

§ 120345.

The immunizations required by Chapter 1 (commencing with Section 120325, but excluding Section 120380) and required by Sections 120400, 120405, 120410, and 120415 may be obtained from any private or public source desired if the immunization is administered and records are made in accordance with regulations of the department.

§ 120350.

The county health officer of each county shall organize and maintain a program to make immunizations available to all persons required by Chapter 1 (commencing with Section 120325, but excluding Section 120380) and required by Sections 120400, 120405, 120410, and 120415 to be immunized. The county health officer shall also determine how the cost of the program is to be recovered. To the extent that the cost to the county is in excess of that sum recovered from persons immunized, the cost shall be paid by the county in the same manner as other expenses of the county are paid.

§ 120355.

Any person or organization administering immunizations shall furnish each person immunized, or his or her parent or guardian, with a written record of immunization given in a form prescribed by the department.

§ 120360.

The requirements of Chapter 1 (commencing with Section 120325, but excluding Section 120380) and of Sections 120400, 120405, 120410, and 120415 shall not apply to any person 18 years of age or older, or to any person seeking admission to a community college.

§ 120365.

Immunization of a person shall not be required for admission to a school or other institution listed in Section 120335 if the parent or guardian or adult who has assumed responsibility for his or her care and custody in the case of a minor, or the person seeking admission if an emancipated minor, files with the governing authority a letter or affidavit stating that the immunization is contrary to his or her beliefs. However, whenever there is good cause to believe that the person has been exposed to one of the communicable diseases listed in subdivision (a) of Section 120325, that person may be temporarily excluded from the school or institution until the local health officer is satisfied that the person is no longer at risk of developing the disease.

§ 120370.

If the parent or guardian files with the governing authority a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances that contraindicate immunization, that person shall be exempt from the requirements of Chapter 1 (commencing with Section 120325, but excluding Section 120380) and Sections 120400, 120405, 120410, and 120415 to the extent indicated by the physician's statement.

§ 120375.

(a) The governing authority of each school or institution included in Section 120335 shall require documentary proof of each entrant's immunization status. The governing authority shall record the immunizations of each new entrant in the entrant's permanent enrollment and scholarship record on a form provided by the department. The immunization record of each new entrant admitted conditionally shall be reviewed periodically by the governing authority to ensure that within the time periods designated by regulation of the department he or she has been fully immunized against all of the diseases listed in Section 120335, and immunizations received subsequent to entry shall be added to the pupil's immunization record.

(b) The governing authority of each school or institution included in Section 120335 shall prohibit from further attendance any pupil admitted conditionally who failed to obtain the required immunizations within the time limits allowed in the regulations of the department, unless the pupil is exempted under Section 120365 or 120370, until that pupil has been fully immunized against all of the diseases listed in Section 120335.

# Exhibit C

# *2015 Cal SB 277*

Enacted, June 30, 2015

**Reporter**
2015 Cal ALS 35; 2015 Cal SB 277; 2015 Cal Stats. ch. 35

**CALIFORNIA ADVANCE LEGISLATIVE SERVICE > 2015 REGULAR SESSION > CHAPTER 35 > (SENATE BILL NO. 277)**

## Notice

**Added:** Text highlighted in green
**Deleted:** ~~Red text with a strikethrough~~

## Digest

**Public health: vaccinations.**

Existing law prohibits the governing authority of a school or other institution from unconditionally admitting any person as a pupil of any public or private elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center, unless prior to his or her admission to that institution he or she has been fully immunized against various diseases, including measles, mumps, and pertussis, subject to any specific age criteria. Existing law authorizes an exemption from those provisions for medical reasons or because of personal beliefs, if specified forms are submitted to the governing authority. Existing law requires the governing authority of a school or other institution to require documentary proof of each entrant's immunization status. Existing law authorizes the governing authority of a school or other institution to temporarily exclude a child from the school or institution if the authority has good cause to believe that the child has been exposed to one of those diseases, as specified.

This bill would eliminate the exemption from existing specified immunization requirements based upon personal beliefs, but would allow exemption from future immunization requirements deemed appropriate by the State Department of Public Health for either medical reasons or personal beliefs. The bill would exempt pupils in a home-based private school and students enrolled in an independent study program and who do not receive classroom-based instruction, pursuant to specified law from the prohibition described above. The bill would allow pupils who, prior to January 1, 2016, have a letter or affidavit on file at a private or public elementary or secondary school, child day care center, day nursery, nursery school, family day care home, or development center stating beliefs opposed to immunization, to be enrolled in any private or public elementary or secondary school, child day care center, day nursery, nursery school, family day care home, or development center within the state until the pupil enrolls in the next grade span, as defined. Except as under the circumstances described above, on and after July 1, 2016, the bill would prohibit a governing authority from unconditionally admitting to any of those institutions for the first time or admitting or advancing any pupil to the 7th grade level, unless the pupil has been immunized as required by the bill. The bill would specify that its provisions do not prohibit a pupil who qualifies for an individualized education program, pursuant to specified laws, from accessing any special education and related services required by his or

her individualized education program. The bill would narrow the authorization for temporary exclusion from a school or other institution to make it applicable only to a child who has been exposed to a specified disease and whose documentary proof of immunization status does not show proof of immunization against one of the diseases described above. The bill would make conforming changes to related provisions.

## Synopsis

An act to amend Sections 120325, 120335, 120370, and 120375 of, to add Section 120338 to, and to repeal Section 120365 of, the Health and Safety Code, relating to public health.

## Text

*The people of the State of California do enact as follows:*

**SECTION 1.**

Section 120325 of the Health and Safety Code is amended to read:

§ 120325.

In enacting this chapter, but excluding Section 120380, and in enacting Sections 120400, 120405, 120410, and 120415, it is the intent of the Legislature to provide:

**(a)** A means for the eventual achievement of total immunization of appropriate age groups against the following childhood diseases:

**(1)** Diphtheria.

**(2)** Hepatitis B.

**(3)** Haemophilus influenzae type b.

**(4)** Measles.

**(5)** Mumps.

**(6)** Pertussis (whooping cough).

**(7)** Poliomyelitis.

**(8)** Rubella.

**(9)** Tetanus.

**(10)** Varicella (chickenpox).

**(11)** Any other disease deemed appropriate by the department, taking into consideration the recommendations of the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, the American Academy of Pediatrics, and the American Academy of Family Physicians.

**(b)** That the persons required to be immunized be allowed to obtain immunizations from whatever medical source they so desire, subject only to the condition that the immunization be performed in accordance with the regulations of the department and that a record of the immunization is made in accordance with the regulations.

**(c)** Exemptions from immunization for medical reasons~~or because of personal beliefs~~.

**(d)** For the keeping of adequate records of immunization so that health departments, schools, and other institutions, parents or guardians, and the persons immunized will be able to ascertain that a child is fully or only partially immunized, and so that appropriate public agencies will be able to ascertain the immunization needs of groups of children in schools or other institutions.

**(e)** Incentives to public health authorities to design innovative and creative programs that will promote and achieve full and timely immunization of children.

**SEC. 2.**

Section 120335 of the Health and Safety Code is amended to read:

§ 120335.

**(a)** As used in this chapter, "governing authority" means the governing board of each school district or the authority of each other private or public institution responsible for the operation and control of the institution or the principal or administrator of each school or institution.

**(b)** The governing authority shall not unconditionally admit any person as a pupil of any private or public elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center, unless, prior to his or her first admission to that institution, he or she has been fully immunized. The following are the diseases for which immunizations shall be documented:

**(1)** Diphtheria.

**(2)** Haemophilus influenzae type b.

**(3)** Measles.

**(4)** Mumps.

**(5)** Pertussis (whooping cough).

**(6)** Poliomyelitis.

**(7)** Rubella.

**(8)** Tetanus.

**(9)** Hepatitis B.

**(10)** Varicella (chickenpox).

**(11)** Any other disease deemed appropriate by the department, taking into consideration the recommendations of the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, the American Academy of Pediatrics, and the American Academy of Family Physicians.

**(c)** Notwithstanding subdivision (b), full immunization against hepatitis B shall not be a condition by which the governing authority shall admit or advance any pupil to the 7th grade level of any private or public elementary or secondary school.

**(d)** The governing authority shall not unconditionally admit or advance any pupil to the 7th grade level of any private or public elementary or secondary school unless the pupil has been fully immunized against pertussis, including all pertussis boosters appropriate for the pupil's age.

**(e)** The department may specify the immunizing agents that may be utilized and the manner in which immunizations are administered.

**(f)** This section ~~shall become operative on July 1, 2012~~ DOES NOT APPLY TO A PUPIL IN A HOME-BASED PRIVATE SCHOOL OR A PUPIL WHO IS ENROLLED IN AN INDEPENDENT STUDY

PROGRAM PURSUANT TO ARTICLE 5.5 (COMMENCING WITH SECTION 51745) OF CHAPTER 5 OF PART 28 OF THE EDUCATION CODE AND DOES NOT RECEIVE CLASSROOM-BASED INSTRUCTION .

(g) (1) A PUPIL WHO, PRIOR TO JANUARY 1, 2016, SUBMITTED A LETTER OR AFFIDAVIT ON FILE AT A PRIVATE OR PUBLIC ELEMENTARY OR SECONDARY SCHOOL, CHILD DAY CARE CENTER, DAY NURSERY, NURSERY SCHOOL, FAMILY DAY CARE HOME, OR DEVELOPMENT CENTER STATING BELIEFS OPPOSED TO IMMUNIZATION SHALL BE ALLOWED ENROLLMENT TO ANY PRIVATE OR PUBLIC ELEMENTARY OR SECONDARY SCHOOL, CHILD DAY CARE CENTER, DAY NURSERY, NURSERY SCHOOL, FAMILY DAY CARE HOME, OR DEVELOPMENT CENTER WITHIN THE STATE UNTIL THE PUPIL ENROLLS IN THE NEXT GRADE SPAN.

(2) FOR PURPOSES OF THIS SUBDIVISION, “GRADE SPAN” MEANS EACH OF THE FOLLOWING:

(A) BIRTH TO PRESCHOOL.

(B) KINDERGARTEN AND GRADES 1 TO 6, INCLUSIVE, INCLUDING TRANSITIONAL KINDERGARTEN.

(C) GRADES 7 TO 12, INCLUSIVE.

(3) EXCEPT AS PROVIDED IN THIS SUBDIVISION, ON AND AFTER JULY 1, 2016, THE GOVERNING AUTHORITY SHALL NOT UNCONDITIONALLY ADMIT TO ANY OF THOSE INSTITUTIONS SPECIFIED IN THIS SUBDIVISION FOR THE FIRST TIME, OR ADMIT OR ADVANCE ANY PUPIL TO 7TH GRADE LEVEL, UNLESS THE PUPIL HAS BEEN IMMUNIZED FOR HIS OR HER AGE AS REQUIRED BY THIS SECTION.

(H) THIS SECTION DOES NOT PROHIBIT A PUPIL WHO QUALIFIES FOR AN INDIVIDUALIZED EDUCATION PROGRAM, PURSUANT TO FEDERAL LAW AND SECTION 56026 OF THE EDUCATION CODE, FROM ACCESSING ANY SPECIAL EDUCATION AND RELATED SERVICES REQUIRED BY HIS OR HER INDIVIDUALIZED EDUCATION PROGRAM.

**SEC. 3.**

Section 120338 is added to the Health and Safety Code, to read:

§ 120338.

Notwithstanding Sections 120325 and 120335, any immunizations deemed appropriate by the department pursuant to paragraph (11) of subdivision (a) of Section 120325 or paragraph (11) of subdivision (b) of Section 120335, may be mandated before a pupil’s first admission to any private or public elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center, only if exemptions are allowed for both medical reasons and personal beliefs.

**SEC. 4.**

Section 120365 of the Health and Safety Code is repealed.

**SEC. 5.**

Section 120370 of the Health and Safety Code is amended to read:

§ 120370. (A) If the parent or guardian files with the governing authority a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances ~~that contraindicate~~ , INCLUDING, BUT NOT LIMITED TO, FAMILY MEDICAL HISTORY, FOR WHICH THE PHYSICIAN DOES NOT RECOMMEND immunization, that ~~person~~ CHILD shall be exempt from the requirements of Chapter 1 (commencing with Section 120325, but excluding Section 120380) and Sections 120400, 120405, 120410, and 120415 to the extent indicated by the physician's statement.

(B) IF THERE IS GOOD CAUSE TO BELIEVE THAT A CHILD HAS BEEN EXPOSED TO A DISEASE LISTED IN SUBDIVISION (B) OF SECTION 120335 AND HIS OR HER DOCUMENTARY PROOF OF IMMUNIZATION STATUS DOES NOT SHOW PROOF OF IMMUNIZATION AGAINST THAT DISEASE, THAT CHILD MAY BE TEMPORARILY EXCLUDED FROM THE SCHOOL OR INSTITUTION UNTIL THE LOCAL HEALTH OFFICER IS SATISFIED THAT THE CHILD IS NO LONGER AT RISK OF DEVELOPING OR TRANSMITTING THE DISEASE.

**SEC. 6.**

Section 120375 of the Health and Safety Code is amended to read:

§ 120375.

**(a)** The governing authority of each school or institution included in Section 120335 shall require documentary proof of each entrant's immunization status. The governing authority shall record the immunizations of each new entrant in the entrant's permanent enrollment and scholarship record on a form provided by the department. The immunization record of each new entrant admitted conditionally shall be reviewed periodically by the governing authority to ensure that within the time periods designated by regulation of the department he or she has been fully immunized against all of the diseases listed in Section 120335, and immunizations received subsequent to entry shall be added to the pupil's immunization record.

**(b)** The governing authority of each school or institution included in Section 120335 shall prohibit from further attendance any pupil admitted conditionally who failed to obtain the required immunizations within the time limits allowed in the regulations of the department, unless the pupil is exempted under Section ~~120365 or~~ 120370, until that pupil has been fully immunized against all of the diseases listed in Section 120335.

**(c)** The governing authority shall file a written report on the immunization status of new entrants to the school or institution under their jurisdiction with the department and the local health department at times and on forms prescribed by the department. As provided in paragraph (4) of subdivision (a) of *Section 49076 of the Education Code*, the local health department shall have access to the complete health information as it relates to immunization of each student in the schools or other institutions listed in Section 120335 in order to determine immunization deficiencies.

**(d)** The governing authority shall cooperate with the county health officer in carrying out programs for the immunization of persons applying for admission to any school or institution under its jurisdiction. The governing board of any school district may use funds, property, and personnel of the district for that purpose. The governing authority of any school or other institution may permit any licensed physician or any qualified registered nurse as provided in *Section 2727.3 of the Business and Professions Code* to administer immunizing agents to any person seeking admission to any school or institution under its jurisdiction.

## History

GREGORY GLASER

Approved by Governor June 30, 2015

Filed with Secretary of State June 30, 2015



End of Document

# Exhibit D

# Senate Bill No. 714

## CHAPTER 281

An act to amend Sections 120370, 120372, and 120372.05 of the Health and Safety Code, relating to public health.

[Approved by Governor September 9, 2019. Filed with Secretary of State September 9, 2019.]

LEGISLATIVE COUNSEL'S DIGEST

SB 714, Pan. Immunizations.

Existing law generally prohibits the governing authority of a school or other institution from admitting for attendance any pupil who fails to obtain required immunizations within the time limits prescribed by the State Department of Public Health, except when the pupil has an exemption from this requirement. Existing law, as proposed by SB 276 of the 2019–20 Regular Session, requires the department, by January 1, 2021, to develop and make available for use by licensed physicians and surgeons an electronic, standardized, statewide medical exemption certification form that would be transmitted using the California Immunization Registry (CAIR), and which, commencing January 1, 2021, would be the only documentation of a medical exemption that a governing authority may accept. SB 276 also specifies the information to be included in the form, including a certification under penalty of perjury that the statements and information contained in the form are true, accurate, and complete. SB 276 requires a medical exemption authorized prior to the adoption of the form to be submitted by January 1, 2021, for inclusion in a statewide database to remain valid.

The bill would instead allow a child who has a medical exemption issued before January 1, 2020, to be allowed to continue enrollment until the child enrolls in the next grade span, as specified, and would prohibit, on and after July 1, 2021, a governing authority from unconditionally admitting or readmitting to these institutions, or admit or advance any pupil to 7th grade level, unless the pupil has been immunized or has a medical exemption through a procedure that includes the completion of a compliant statewide form. The bill would remove the requirement that the statewide form be signed under penalty of perjury. The bill would modify which physicians and surgeons are eligible to issue a medical exemption.

This bill would make its operation contingent on the enactment of SB 276 of the 2019–20 Regular Session.

*The people of the State of California do enact as follows:*

SECTION 1. Section 120370 of the Health and Safety Code, as proposed to be amended by SB 276 of the 2019–20 Regular Session, is amended to read:

120370. (a) (1) Prior to January 1, 2021, if the parent or guardian files with the governing authority a written statement by a licensed physician and surgeon to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances, including, but not limited to, family medical history, for which the physician and surgeon does not recommend immunization, that child shall be exempt from the requirements of this chapter, except for Section 120380, and exempt from Sections 120400, 120405, 120410, and 120415 to the extent indicated by the physician and surgeon's statement.

(2) Commencing January 1, 2020, a child who has a medical exemption issued before January 1, 2020, shall be allowed continued enrollment to any public or private elementary or secondary school, child care center, day nursery, nursery school, family day care home, or developmental center within the state until the child enrolls in the next grade span.

For purposes of this subdivision, "grade span" means each of the following:

(A) Birth to preschool, inclusive.

(B) Kindergarten and grades 1 to 6, inclusive, including transitional kindergarten.

(C) Grades 7 to 12, inclusive.

(3) Except as provided in this subdivision, on and after July 1, 2021, the governing authority shall not unconditionally admit or readmit to any of those institutions specified in this subdivision, or admit or advance any pupil to 7th grade level, unless the pupil has been immunized pursuant to Section 120335 or the parent or guardian files a medical exemption form that complies with Section 120372.

(b) If there is good cause to believe that a child has been exposed to a disease listed in subdivision (b) of Section 120335 and the child's documentary proof of immunization status does not show proof of immunization against that disease, that child may be temporarily excluded from the school or institution until the local health officer is satisfied that the child is no longer at risk of developing or transmitting the disease.

SEC. 2. Section 120372 of the Health and Safety Code, as proposed to be added by SB 276 of the 2019–20 Regular Session, is amended to read:

120372. (a) (1) By January 1, 2021, the department shall develop and make available for use by licensed physicians and surgeons an electronic, standardized, statewide medical exemption certification form that shall be transmitted directly to the department's California Immunization Registry (CAIR) established pursuant to Section 120440. Pursuant to Section 120375, the form shall be printed, signed, and submitted directly to the school or

institution at which the child will attend, submitted directly to the governing authority of the school or institution, or submitted to that governing authority through the CAIR where applicable. Notwithstanding Section 120370, commencing January 1, 2021, the standardized form shall be the only documentation of a medical exemption that the governing authority may accept.

(2) At a minimum, the form shall require all of the following information:

(A) The name, California medical license number, business address, and telephone number of the physician and surgeon who issued the medical exemption, and of the primary care physician of the child, if different from the physician and surgeon who issued the medical exemption.

(B) The name of the child for whom the exemption is sought, the name and address of the child's parent or guardian, and the name and address of the child's school or other institution.

(C) A statement certifying that the physician and surgeon has conducted a physical examination and evaluation of the child consistent with the relevant standard of care and complied with all applicable requirements of this section.

(D) Whether the physician and surgeon who issued the medical exemption is the child's primary care physician. If the issuing physician and surgeon is not the child's primary care physician, the issuing physician and surgeon shall also provide an explanation as to why the issuing physician and not the primary care physician is filling out the medical exemption form.

(E) How long the physician and surgeon has been treating the child.

(F) A description of the medical basis for which the exemption for each individual immunization is sought. Each specific immunization shall be listed separately and space on the form shall be provided to allow for the inclusion of descriptive information for each immunization for which the exemption is sought.

(G) Whether the medical exemption is permanent or temporary, including the date upon which a temporary medical exemption will expire. A temporary exemption shall not exceed one year. All medical exemptions shall not extend beyond the grade span, as defined in Section 120370.

(H) An authorization for the department to contact the issuing physician and surgeon for purposes of this section and for the release of records related to the medical exemption to the department, the Medical Board of California, and the Osteopathic Medical Board of California.

(I) A certification by the issuing physician and surgeon that the statements and information contained in the form are true, accurate, and complete.

(3) An issuing physician and surgeon shall not charge for either of the following:

(A) Filling out a medical exemption form pursuant to this section.

(B) A physical examination related to the renewal of a temporary medical exemption.

(b) Commencing January 1, 2021, if a parent or guardian requests a licensed physician and surgeon to submit a medical exemption for the parent's or guardian's child, the physician and surgeon shall inform the

parent or guardian of the requirements of this section. If the parent or guardian consents, the physician and surgeon shall examine the child and submit a completed medical exemption certification form to the department. A medical exemption certification form may be submitted to the department at any time.

(c) By January 1, 2021, the department shall create a standardized system to monitor immunization levels in schools and institutions as specified in Sections 120375 and 120440, and to monitor patterns of unusually high exemption form submissions by a particular physician and surgeon.

(d) (1) The department, at a minimum, shall annually review immunization reports from all schools and institutions in order to identify medical exemption forms submitted to the department and under this section that will be subject to paragraph (2).

(2) A clinically trained immunization department staff member, who is either a physician and surgeon or a registered nurse, shall review all medical exemptions from any of the following:

(A) Schools or institutions subject to Section 120375 with an overall immunization rate of less than 95 percent.

(B) Physicians and surgeons who have submitted five or more medical exemptions in a calendar year beginning January 1, 2020.

(C) Schools or institutions subject to Section 120375 that do not provide reports of vaccination rates to the department.

(3) (A) The department shall identify those medical exemption forms that do not meet applicable CDC, ACIP, or AAP criteria for appropriate medical exemptions. The department may contact the primary care physician and surgeon or issuing physician and surgeon to request additional information to support the medical exemption.

(B) Notwithstanding subparagraph (A), the department, based on the medical discretion of the clinically trained immunization staff member, may accept a medical exemption that is based on other contraindications or precautions, including consideration of family medical history, if the issuing physician and surgeon provides written documentation to support the medical exemption that is consistent with the relevant standard of care.

(C) A medical exemption that the reviewing immunization department staff member determines to be inappropriate or otherwise invalid under subparagraphs (A) and (B) shall also be reviewed by the State Public Health Officer or a physician and surgeon from the department's immunization program designated by the State Public Health Officer. Pursuant to this review, the State Public Health Officer or physician and surgeon designee may revoke the medical exemption.

(4) Medical exemptions issued prior to January 1, 2020, shall not be revoked unless the exemption was issued by a physician or surgeon that has been subject to disciplinary action by the Medical Board of California or the Osteopathic Medical Board of California.

(5) The department shall notify the parent or guardian, issuing physician and surgeon, the school or institution, and the local public health officer

with jurisdiction over the school or institution of a denial or revocation under this subdivision.

(6) If a medical exemption is revoked pursuant to this subdivision, the child shall continue in attendance. However, within 30 calendar days of the revocation, the child shall commence the immunization schedule required for conditional admittance under Chapter 4 (commencing with Section 6000) of Division 1 of Title 17 of the California Code of Regulations in order to remain in attendance, unless an appeal is filed pursuant to Section 120372.05 within that 30-day time period, in which case the child shall continue in attendance and shall not be required to otherwise comply with immunization requirements unless and until the revocation is upheld on appeal.

(7) (A) If the department determines that a physician's and surgeon's practice is contributing to a public health risk in one or more communities, the department shall report the physician and surgeon to the Medical Board of California or the Osteopathic Medical Board of California, as appropriate. The department shall not accept a medical exemption form from the physician and surgeon until the physician and surgeon demonstrates to the department that the public health risk no longer exists, but in no event shall the physician and surgeon be barred from submitting these forms for less than two years.

(B) If there is a pending accusation against a physician and surgeon with the Medical Board of California or the Osteopathic Medical Board of California relating to immunization standards of care, the department shall not accept a medical exemption form from the physician and surgeon unless and until the accusation is resolved in favor of the physician and surgeon.

(C) If a physician and surgeon licensed with the Medical Board of California or the Osteopathic Medical Board of California is on probation for action relating to immunization standards of care, the department and governing authority shall not accept a medical exemption form from the physician and surgeon unless and until the probation has been terminated.

(8) The department shall notify the Medical Board of California or the Osteopathic Medical Board of California, as appropriate, of any physician and surgeon who has five or more medical exemption forms in a calendar year that are revoked pursuant to this subdivision.

(9) Notwithstanding any other provision of this section, a clinically trained immunization program staff member who is a physician and surgeon or a registered nurse may review any exemption in the CAIR or other state database as necessary to protect public health.

(e) The department, the Medical Board of California, and the Osteopathic Medical Board of California shall enter into a memorandum of understanding or similar agreement to ensure compliance with the requirements of this section.

(f) In administering this section, the department and the independent expert review panel created pursuant to Section 120372.05 shall comply with all applicable state and federal privacy and confidentiality laws. The department may disclose information submitted in the medical exemption form in accordance with Section 120440, and may disclose information

submitted pursuant to this chapter to the independent expert review panel for the purpose of evaluating appeals.

(g) The department shall establish the process and guidelines for review of medical exemptions pursuant to this section. The department shall communicate the process to providers and post this information on the department's website.

(h) If the department or the California Health and Human Services Agency determines that contracts are required to implement or administer this section, the department may award these contracts on a single-source or sole-source basis. The contracts are not subject to Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code, Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government Code, or Sections 4800 to 5180, inclusive, of the State Administrative Manual as they relate to approval of information technology projects or approval of increases in the duration or costs of information technology projects.

(i) Notwithstanding the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code), the department may implement and administer this section through provider bulletins, or similar instructions, without taking regulatory action.

(j) For purposes of administering this section, the department and the California Health and Human Services Agency appeals process shall be exempt from the rulemaking and administrative adjudication provisions in the Administrative Procedure Act Chapter 3.5 (commencing with Section 11340), and Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with 11400), and Chapter 5 (commencing with Section 11500) of, Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 3. Section 120372.05 of the Health and Safety Code, as proposed to be added by SB 276 of the 2019– 20 Regular Session, is amended to read:

120372.05. (a) A medical exemption revoked pursuant to Section 120372 may be appealed by a parent or guardian to the Secretary of California Health and Human Services. Parents, guardians, or the physician who issued the medical exemption may provide necessary information for purposes of the appeal.

(b) The secretary shall establish an independent expert review panel, consisting of three licensed physicians and surgeons who have relevant knowledge, training, and experience relating to primary care or immunization to review appeals. The agency shall establish the process and guidelines for the appeals process pursuant to this section, including the process for the panel to contact the issuing physician and surgeon, parent, or guardian. The agency shall post this information on the agency's internet website. The agency shall also establish requirements, including conflict-of-interest standards, consistent with the purposes of this chapter, that a physician and surgeon shall meet in order to qualify to serve on the panel.

(c) The independent expert review panel shall evaluate appeals consistent with the federal Centers for Disease Control and Prevention, federal Advisory

Committee on Immunization Practices, or American Academy of Pediatrics guidelines or the relevant standard of care, as applicable.

(d) The independent expert review panel shall submit its determination to the secretary. The secretary shall adopt the determination of the independent expert review panel and shall promptly issue a written decision to the child's parent or guardian. The decision shall not be subject to further administrative review.

(e) A child whose medical exemption revocation pursuant to subdivision (d) of Section 120372 is appealed under this section shall continue in attendance and shall not be required to commence the immunization required for conditional admittance under Chapter 4 (commencing with Section 6000) of Division 1 of Title 17 of the California Code of Regulations, provided that the appeal is filed within 30 calendar days of revocation of the medical exemption.

(f) For purposes for administering this section, the department and the California Health and Human Services Agency appeals process shall be exempt from the rulemaking and administrative adjudication provisions in the Administrative Procedure Act Chapter 3.5 (commencing with Section 11340), and Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with 11400), and Chapter 5 (commencing with Section 11500) of, Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 4. This act shall become operative only if Senate Bill 276 of the 2019–20 Regular Session is enacted and becomes effective.

O

# Exhibit E

LexisNexis®

# *Shepard's*®: Report Content

**History:**Requested

**Citing Decisions:**None Applied

**Other Citing Sources:**None Applied

***Shepard's®:*** Comprehensive Report for**Cal. Health & Safety Code sec. 120370**

## History (1)

1. Added Stats 1995 ch 415 § 7 (SB 1360). Amended Stats 2015 ch 35 § 5 (SB 277), effective January 1, 2016; Stats 2019 ch 278 § 2 (SB 276), effective January 1, 2020; Stats 2019 ch 281 § 1 (SB 714), effective January 1, 2020.

# Citing Decisions (8)

**Analysis:**Constitutional by (1), "Cited by" (7)

## California Courts of Appeal

1. Love v. State Dept. of Education, 29 Cal. App. 5th 980, 240 Cal. Rptr. 3d 861, 2018 Cal. App. LEXIS 1123, 2018 WL 6382089

   G **Constitutional by:** 29 Cal. App. 5th 980 p.986; 240 Cal. Rptr. 3d 861 p.865
   ... 120370 .) A student is exempt from the requirement if a licensed physician states in writing that "the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe." ( **§ 120370, subd. (a)** .) Additionally, vaccinations are not required for students in a home-based private school or independent study program who do not receive classroom-based instruction, or those in individualized education programs. ( § 120335, subds. ...
   **Court:** Cal. App. 3d Dist. | **Date:** November 20, 2018

2. Brown v. Smith, 24 Cal. App. 5th 1135, 235 Cal. Rptr. 3d 218, 2018 Cal. App. LEXIS 601, 2018 WL 3215780

   LB **Cited by:** 24 Cal. App. 5th 1135 p.1139; 235 Cal. Rptr. 3d 218 p.221
   ... condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances, including, but not limited to, family medical history, for which the physician does not recommend immunization, that child shall be exempt from the [immunization] requirements … to the extent indicated by the physician's statement." ( **Health & Saf. Code, § 120370, subd. (a)** ...
   **Court:** Cal. App. 2d Dist. | **Date:** July 2, 2018

## Unpublished California Appellate Decisions

3. Price v. Price (In re Price), 2019 Cal. App. Unpub. LEXIS 935, 2019 WL 458954

   LB **Cited by:** 2019 Cal. App. Unpub. LEXIS 935
   ... authority a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances, including, but not limited to, family medical history, for which the physician does not recommend immunization, that child shall be exempt . . . ." ( **Health & Saf. Code, § 120370, subd. (a)** ...
   **Court:** Cal. App. 4th Dist. | **Date:** February 6, 2019

4. Love v. Dep't of Educ., 2018 Cal. App. Unpub. LEXIS 7819, 2018 WL 6061180

   LB **Cited by:** 2018 Cal. App. Unpub. LEXIS 7819
   ... , 120335, subd. (b)(11) , 120338 .) or qualifies for an exemption recognized by statute. ( §§ 120335, subds. (b) & (g)(3) , **120370** .) A student is exempt from the requirement if a licensed physician states in writing that "the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe." ( § **120370**, subd. (a) .) Additionally, vaccinations are not required for students in a home-based private school or independent ...

**Court:** Cal. App. 3d Dist. | **Date:** November 20, 2018

5. Brown v. Shasta Union High Sch. Dist., 2010 Cal. App. Unpub. LEXIS 7051

**Cited by:**
... , however, not all students are subject to these examinations and vaccinations; parents may refuse to consent to a physical examination ( Ed. Code, § 49451 ) and may object to vaccinations on certain grounds ( Health & Saf. Code, § 120365 [contrary to religious beliefs]; **Health & Saf. Code, § 120370** [dangerous due to medical or physical condition].) The Hill court also found the student athlete's reasonable expectation of privacy diminished by the program's advance notice and the opportunity ...

**Court:** Cal. App. 3d Dist. | **Date:** September 2, 2010

## 9th Circuit - U.S. District Courts

6. Middleton v. Pan, 2017 U.S. Dist. LEXIS 216203

**Cited by:** 2017 U.S. Dist. LEXIS 216203
... exemptions to the vaccination requirements: (1) students who have on file "a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances, including, but not limited to, family medical history, for which the physician does not recommend immunization," Id. **§ 120370(a)** ...

**Court:** Central Dist. Cal. | **Date:** December 18, 2017

7. Middleton v. Pan, 2016 U.S. Dist. LEXIS 197627

**Cited by:**
... exemptions to the vaccination requirements: (1) students who have on file "a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances, including, but not limited to, family medical history, for which the physician does not recommend immunization," Id. **§ 120370(a)** ...

**Court:** Central Dist. Cal. | **Date:** December 15, 2016

8. Whitlow v. Cal. Dep't of Educ., 203 F. Supp. 3d 1079, 2016 U.S. Dist. LEXIS 185164, 2016 WL 6495512

**Cited by:** 203 F. Supp. 3d 1079 p.1083
... . Plaintiffs estimate there are 33,000 children that fall into this category, and are being denied enrollment as a result of SB 277. SB 277 provides three exemptions to the vaccination requirements at issue: One for medical reasons, **Cal. Health & Safety Code § 120370(a)** , one for children in a 'home-based private school or ... an independent study program[,]" Cal. Health & Safety Code § 120335(f) , and one for students who qualify for an individualized education program, or IEP. Cal. Health & ...

**Court:** Southern Dist. Cal. | **Date:** August 26, 2016

# Other Citing Sources: (20)

## Annotated Statutes

1. **Cal. Educ. Code @ 48216**

... SEC. 12. Sections 7, 8, 9, 10, and 11 of this act shall become operative on July 1, 1998. Cross References: Letter or affidavit stating beliefs opposed to immunization; Temporary exclusion from school: H & S C § 120365 . Statements by physician contraindicating immunization: **H & S C § 120370** . Treatises: Cal. Legal Forms, (Matthew Bender) § 100.21[1] . Hierarchy Notes: Cal Ed Code Title 2 Cal Ed Code Title 2, Div. 4 Cal Ed Code Title 2, Div. 4, Pt. 27, Ch. 2 Added Stats 1978 ch 325 § 2, as Ed ...

**Content:** Statutes

2. **Cal. Health & Safety Code @ 120372.05**

... ), Chapter 4.5 (commencing with 11400), and Chapter 5 (commencing with Section 11500) of, Part 1 of Division 3 of Title 2 of the Government Code . Editor's Notes— Amendments: Editor's Notes— For legislative findings and declarations, see 2019 note in **H & S C § 120370** . Amendments: 2019 Amendment (ch 281): Substituted “Parents, guardians, or the physician who issued the medical exemption” for “Parents or guardians” in the second sentence of (a); and added “, including the process for the panel ...

**Content:** Statutes

3. **Cal. Health & Safety Code @ 120372.05**

... ), Chapter 4.5 (commencing with 11400), and Chapter 5 (commencing with Section 11500) of, Part 1 of Division 3 of Title 2 of the Government Code . Editor's Notes— Amendments: Editor's Notes— For legislative findings and declarations, see 2019 note in **H & S C § 120370** . Amendments: 2019 Amendment (ch 281): Substituted “Parents, guardians, or the physician who issued the medical exemption” for “Parents or guardians” in the second sentence of (a); and added “, including the process for the panel ...

**Content:** Statutes

4. **Cal. Health & Safety Code @ 120372**

... **Section 120370** , commencing January 1, 2021, the standardized form shall be the only documentation of a medical exemption that the governing authority may accept. (2) At a minimum, the form shall require all of the following information: (A) The name, California medical license number, business address, and telephone number of the physician and surgeon who issued the medical exemption, and of the primary care physician of the child, if different from the physician and surgeon who issued the medical ...

**Content:** Statutes

5. **Cal. Health & Safety Code @ 120372**

... **Section 120370** , commencing January 1, 2021, the standardized form shall be the only documentation of a medical exemption that the governing authority may accept. (2) At a minimum, the form shall require all of the following information: (A) The name, California medical license number,

business address, and telephone number of the physician and surgeon who issued the medical exemption, and of the primary care physician of the child, if different from the physician and surgeon who issued the medical ...

**Content:** Statutes

6. **Cal Health & Saf Code @ 120375**

... shall prohibit from further attendance any pupil admitted conditionally who failed to obtain the required immunizations within the time limits allowed in the regulations of the department until that pupil has been fully immunized against all of the diseases listed in Section 120335 , unless the pupil is exempted under **Section 120370** or 120372 . (c) The governing authority shall file a written report, on at least an annual basis, on the immunization status of new entrants to the school or institution ...

**Content:** Statutes

7. **Cal. Health & Safety Code sec. 3386**

**Content:** Statutes

8. **Cal. Health & Safety Code sec. 3405**

**Content:** Statutes

## Law Reviews and Periodicals

9. CASE NOTE: A Bad Reaction: A Look at the Arkansas General Assembly's Response to McCarthy v. Boozman and Boone v. Boozman, 58 Ark. L. Rev. 251

**Content:** Law Reviews | **Date:** 2005

10. NOTE: RELIGION IN THE TIME OF MEASLES: PRESCRIPTIONS FOR MINIMIZING THE PUBLIC HEALTH THREATS ASSOCIATED WITH RELIGIOUS EXEMPTIONS FROM MANDATORY VACCINATIONS, 15 Cardozo Pub. L. Pol'y & Ethics J. 413

**Content:** Law Reviews | **Date:** 2017

11. FEATURE: HEALTH FIRST, 41 Los Angeles Lawyer 26

**Content:** Law Reviews | **Date:** June 1, 2018

12. ARTICLE: IN DEFENSE OF CALIFORNIA'S MANDATORY CHILD VACCINATION LAW: CALIFORNIA COURTS SHOULD NOT DEPART FROM ESTABLISHED PRECEDENT, 50 Loy. L.A. L. Rev. 391

**Content:** Law Reviews | **Date:** 2017

13. FEATURE: 2016 NEW STATE AND FEDERAL LAWS, 58 Orange County Lawyer 28

**Content:** Law Reviews | **Date:** April 1, 2016

14. REVIEW OF SELECTED 2019 CALIFORNIA LEGISLATION: HEALTH AND SAFETY: Dr. Bureaucrat@ Shifting Medical Immunization Exemptions from Doctors to Public Officials, 51 The U. Of Pac. L. Rev. 354

... ) (indicating that the herd immunity rate for measles vaccine is between ninety two and ninety five percent, making the current rate in California below the necessary herd immunity rate for measles). Presently, a doctor determines whether it is unsafe for a child to receive an immunization. 43 **CAL. HEALTH & SAFETY CODE § 120370(a)** (West 2019) (amended by Chapter 278). If a doctor deems administrating a vaccination to a child as unsafe, the issuance of an MBE is proper. ...

**Content:** Law Reviews | **Date:** 2020

15. ARTICLE: Externality Entrepreneurism, 50 U.C. Davis L. Rev. 321

**Content:** Law Reviews | **Date:** November 1, 2016

16. STUDENT NOTE: TAKING ONE FOR THE HERD: ELIMINATING NON-MEDICAL EXEMPTIONS TO COMPULSORY VACCINATION LAWS TO PROTECT IMMUNOCOMPROMISED CHILDREN, 119 W. Va. L. Rev. 749

**Content:** Law Reviews | **Date:** 2016

## Briefs

17. HILDEBRAND v. VECCIA, 2017 CA S. Ct. Briefs LEXIS 2765

**Content:** Court Documents | **Date:** October 19, 2017

18. DORRER-HILDEBRAND v. VECCIA, 2018 CA App. Ct. Briefs LEXIS 8315

**Content:** Court Documents | **Date:** December 3, 2018

19. PRICE, 2018 CA App. Ct. Briefs LEXIS 2486

**Content:** Court Documents | **Date:** April 25, 2018

20. BUCK v. SMITH, 2016 CA App. Ct. Briefs LEXIS 6459

**Content:** Court Documents | **Date:** December 20, 2016

## Legend

| | | | |
|---|---|---|---|
|  | Warning - Negative Treatment is Indicated | R | Red - Warning Level Phrase |
| Q | Questioned - Validity questioned by citing references | O | Orange - Questioned Level Phrase |
|  | Caution - Possible negative treatment | Y | Yellow - Caution Level Phrase |
|  | Positive - Positive treatment is indicated | G | Green - Positive Level Phrase |
|  | Analysis - Citing Refs. With Analysis Available | B | Blue - Neutral Level Phrase |
|  | Cited - Citation information available | LB | Light Blue - No Analysis Phrase |
|  | Warning - Negative case treatment is indicated for statute | | |

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# Exhibit F

Greg Glaser ATTORNEY AT LAW

# Best Practices for California Physicians Providing Complementary Health Care Methods

California law protects physicians who offer complementary health care methods, provided the physician ensures the following:

**1) Provide Informed Consent.** The patient has been provided with informed consent, including for example giving the patient information concerning conventional treatment.

**2) No Delay in Diagnosis.** The treatment or advice is provided for the patient's health or well-being. The treatment or advice should not delay or discourage traditional diagnosis of a condition of the patient.

**3) Describe Physician Background.** The physician describes his/her education, experience, and credentials related to the alternative or complementary medicine that the physician practices.

**4) Conduct a Physical Exam.** The physician conducts a good-faith examination of the patient.

**5) Do No Harm.** The treatment or advice does not cause death or serious bodily injury to the patient.

--

See California Business & Professions Code §2234.1

(a) A physician and surgeon shall not be subject to discipline pursuant to subdivision (b) , (c) , or (d) of Section 2234 solely on the basis that the treatment or advice he or she rendered to a patient is alternative or complementary medicine, including the treatment of persistent Lyme Disease, if that treatment or advice meets all of the following requirements:

(1) It is provided after informed consent and a good-faith prior examination of the patient, and medical indication exists for the treatment or advice, or it is provided for health or well-being.

(2) It is provided after the physician and surgeon has given the patient information concerning conventional treatment and describing the education, experience, and credentials of the physician and surgeon related to the alternative or complementary medicine that he or she practices.

(3) In the case of alternative or complementary medicine, it does not cause a delay in, or discourage traditional diagnosis of, a condition of the patient.

(4) It does not cause death or serious bodily injury to the patient.

(b) For purposes of this section, "alternative or complementary medicine," means those health care methods of diagnosis, treatment, or healing that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of the health care method.

(c) Since the National Institute of Medicine has reported that it can take up to 17 years for a new best practice to reach the average physician and surgeon, it is prudent to give attention to new developments not only in general medical care but in the actual treatment of specific diseases, particularly those that are not yet broadly recognized in California.

# Exhibit G

From: **Master, WEB@MBC** WebMaster@mbc.ca.gov
Subject: RE: Medical exemptions
Date: March 18, 2016 at 1:04 PM
To: [redacted]

Dear Dr. [redacted]

Thank you for contacting the Medical Board of California.

It is up to you, as the treating physician, to determine what an appropriate medical exemption is. The law states:

§ 120370. Statement by physicians contraindicating immunization

If the parent or guardian files with the governing authority a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances that contraindicate immunization, that person shall be exempt from the requirements of Chapter 1 (commencing with Section 120325, but excluding Section 120380) and Sections 120400, 120405, 120410, and 120415 to the extent indicated by the physician's statement.

Sincerely,

Christine Valine
Public Information Analyst
Medical Board of California

-----Original Message-----
From: [redacted]
Sent: Thursday, March 17, 2016 6:21 PM
To: Master, WEB@MBC
Subject: Medical exemptions

I am beginning to get calls from parents about medical exemption from mandated vaccines. So far I have granted for family history of anaphylaxis but I would like to know what legitimate medical contraindications are considered to be so I can be compliant with the law.

[redacted]

# Exhibit H


# Best Practices for Physicians Recommending a Medical Exemption to Vaccination

Toni Bark, M.D.

Gregory J. Glaser, Esq.

The goal of this presentation is to assist physicians and their staff with the evaluation of patients for medical exemption from vaccination. At the end of this presentation, the participant will be able to meet the following four learning objectives:

1. Understand the difference between vaccine warnings, precautions, and contraindications to vaccination, and the medicolegal definition of a medical exemption.
2. Become familiar with vaccine warnings and precautions described in vaccine package inserts (PIs), contraindications and precautions recognized by the Centers for Disease Control and Prevention (CDC), vaccine injuries listed in the National Vaccine Injury Compensation Program's (VICP) Vaccine Injury Table, and other known and emerging vaccine adverse events.[1-3]
3. Recognize current medical problems, personal medical histories, family medical histories, and other circumstances that may increase the risk of vaccine adverse events.
4. Consider the administrative procedures and best practices involved in writing a medical exemption.

In June 2015, California enacted a mandatory vaccination law (SB277) for both private and public-school attendance.[4] As personal belief exemptions and religious exemptions were no longer available to parents who had particular concerns about a vaccine's safety for their children, the law triggered a rapid increase in requests for physicians to evaluate potentially at-risk children for medical exemptions.[5] The new law revealed a population of chronically ill children whose parents had previously exercised a personal belief exemption for school attendance, as that was all that was required before SB277 was enacted into California law.

The new law emphasizes the need for physicians to understand the science of medical exemptions to vaccination. Most physicians understand that the risk of a vaccine side effect should always be weighed against the risk (e.g., severity and frequency of occurrence) of the corresponding infectious disease, since vaccination is intended as a preventative medical procedure. For example regarding the measles, a

pre-vaccination fatality rate of about 1 in 1,000 reported cases has been publicized by public health departments, even though in reality only 10% of cases were *reported* to public health departments, such as the Centers for Disease Control and Prevention (CDC).[97,98] Since nearly 90% of measles cases were not reported to the CDC, the result was a case-fatality rate of 1 in 10,000 for all measles cases,[97,98] which emphasizes the importance of reviewing available medical literature and data to measure disease risks based on *total* cases, not just the percentage of cases that are reported.

A similar analysis can be done on the risk of seizure. Measles surveillance between 1985 and 1992 showed that measles seizures are 3-times more common than measles deaths; therefore, about 3 in 10,000 (or 1 in 3,333) measles cases result in seizure.[97,98] In contrast, the risk of seizure from MMR has been measured to be 1 in 641, about 5 times greater than the seizure risk from measles.[8,17] In addition, studies show that pre-existing medical conditions significantly elevate the risk of suffering an adverse reaction from MMR. The risk of seizure from MMR in siblings of children with a history of febrile seizures is 1 in 252, and the risk of seizure from MMR in children with a personal history of febrile seizures is 1 in 51.[8,17]

In the United States, many physicians and their staff have not been trained or experienced with how to evaluate a patient for an increased risk of vaccine side effects, beyond general contraindications recognized by the CDC. The goal of this presentation is to fill the knowledge gap in physicians' training to evaluate a patient for a medical exemption to vaccination.

**WHAT IS A MEDICAL EXEMPTION TO VACCINATION?**

A medical exemption to vaccination is a medicolegal document that is required specifically for school attendance when a patient is at increased risk of harm from any state-mandated vaccine. It is important to recognize that a medical exemption must be based on one or more medical issues, such as contraindication, precaution, warning, or perceived risk of an adverse event from the physician's point of view.

In some states, a medical exemption must be based on specific contraindications or a state-determined standard. While in other states a medical exemption is not limited to contraindications or state-determined guidelines, but rather is based on a physician's professional recommendation to exempt a child from vaccination for school attendance for medical reasons. In California, for example, a medical exemption is "a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe." [4] Thus, in California, licensed physicians are allowed by law to make individualized and up-to-date recommendations for at-risk children, after weighing the benefits versus the risks of a vaccine.

The ethical implications of requiring a medical exemption, such as for school attendance, is beyond the scope of this presentation. Also beyond the scope of this presentation is the worldwide vaccine debate/conversation among medical professionals comparing, for example, the benefits of lifelong naturally-acquired immunity versus temporary pharmaceutical-based immunity.[46] The notion of a one-size-fits-all vaccination schedule has also recently come under scrutiny as potentially outdated science due to the known and unknown variety of immune system responses among diverse individuals.[92]

**WHAT ARE VACCINE CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, AND ADVERSE EVENTS?**

As defined by the CDC, a vaccine contraindication is a condition that "increases the risk of a serious adverse reaction," and when such condition is present, a vaccine should not be administered.[2] For example, a contraindication to any vaccine is a severe allergic reaction to a prior dose or hypersensitivity to a vaccine component.

The CDC defines vaccine precautions as conditions that "might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity," and therefore, when present, should also cause deferment of vaccine administration.[2] The CDC explains, "In general, vaccinations should be deferred when a precaution is present." Although the risk of a serious adverse reaction occurring in the presence of a precaution is considered to be smaller than that in the presence of a contraindication, the recommendation to vaccinate or not in the presence of a precaution "should be decided on a case-by-case basis" by the physician.[2] The latter requires weighing the necessity or urgency of administering the vaccine (e.g., the imminence of an outbreak or severity of disease) against the severity of a possible vaccine side effect. For example, a precaution to administering any vaccine is a "moderate or severe acute illness, with or without fever."[2]

In some cases, drug manufacturers' package inserts (PIs) identify certain conditions as contraindications, even though the CDC considers those conditions as precautions. Also, PIs include warnings to vaccination—situations where "due caution" should be exercised when determining the appropriateness of administering a vaccine.[1]

Vaccine adverse events (AEs) are side effects or health complications that occur after vaccination. AEs are identified during clinical trials and post-marketing surveillance and are usually listed in PIs in decreasing order of severity. For example, the measles, mumps, and rubella (MMR) vaccine PI lists panniculitis, vasculitis, pancreatitis, diabetes mellitus, thrombocytopenia, anaphylaxis, arthritis, encephalitis, and pneumonia amongst the most severe AEs.[7] Other severe adverse reactions include deafness, long-term seizures, coma, lowered consciousness, permanent brain damage, and death.[7,8]

In addition, the Vaccine Injury Table lists specific adverse events, including deaths, that are awarded compensation by the Vaccine Injury Compensation Program (VICP).[3] Notably, if an AE listed on the Vaccine Injury Table or a contraindication listed in a vaccine manufacturer's PI occurs, healthcare providers are required by law to report it to the Vaccine Adverse Event Reporting System (VAERS).[9]

Both the VICP and VAERS were enacted by the National Childhood Vaccine Injury Act of 1986 in order to provide a no-fault alternative to the traditional court system for resolving vaccine injury or death claims; and to conduct passive surveillance of adverse events occurring after vaccination, respectively.[10] With only limited exception, healthcare providers and vaccine manufacturers are not liable for damages from vaccines they produce or administer. And, generally, VICP claims of injury must be filed "within three years after the first symptom or manifestation of onset or of the significant aggravation of the injury," and within two years if the vaccination resulted in death.[11]

Select vaccine contraindications, warnings and precautions, and adverse events are tabulated in Table 1 provided with this presentation.

## MEDICAL CIRCUMSTANCES THAT INCREASE THE RISK OF VACCINE ADVERSE EVENTS

In evaluating a patient for a medical exemption to vaccination it is important that a physician consider medical circumstances that increase the risk of vaccine adverse events.

### Chief Complaint

If a patient is currently experiencing any of the following complaints, a medical exemption may be indicated for several months or longer until the problem is resolved:

- Any moderate or severe acute illness, with or without fever (See Table 1)
- Progressive neurologic disorder, until a treatment regimen is established, and the condition has stabilized—listed as a precaution in the PI of DTaP and on the CDC list of precautions (See Table 1)
- Cerebral injury or seizure disorder—listed as a contraindication in the PI of MMR and on the CDC list of precautions. (See Table 1)
- Severe immune deficiency states—listed as a contraindication in the PIs for live vaccines and on the CDC list of contraindications. (See Table 1)
- Prematurity in the early months—some PIs warn of the risk of apnea and other life-threatening events following intramuscular injections of premature infants (See Table 1)
- Developmental delay or regression[12]

In practice, a patient's current medical condition could deteriorate in response to vaccination. The physician must weigh the likelihood and consequences of worsening the patient's medical condition due to vaccination against the likelihood of acquiring and incurring permanent damage from the corresponding infectious disease(s).

### Personal Medical History

If a patient's past medical history includes any of the following, a medical exemption may be indicated:

- History of previous vaccine adverse event (See Table 1)
- Latex allergy—listed as a precaution in some PIs (See Table 1)
- Mild to moderate (non-anaphylactic) egg allergy—listed as a precaution in the PI of the MMR and influenza vaccines (See Table 1)
- History of seizure disorder now resolved—listed as a warning in the PI of the MMR vaccine (See Table 1)
- History of significant neurodevelopmental regression requiring extensive therapy to resolve (See Table 1)
- History of inflammatory bowel disorder[14, 15]
- History of thrombocytopenia—listed as a warning in the PI of the MMR vaccine (See Table 1)
- History of severe immunodeficiency (See Table 1)
- History of intussusception (See Table 1)
- History of receipt of antibody-containing blood product within the past 11 months[2]

The physician must consider the possibility that a medical condition may be exacerbated as an adverse event to vaccination,[14,16,17] and weigh it against the likelihood of acquiring and incurring damage from the corresponding infectious disease(s).

**Table 1: Select Vaccine Contraindications, Warnings and Precautions, and Compensated Adverse Events**[1-3]

| **Vaccine** | **Contraindications** | **Warnings and Precautions** | **Adverse Events** From Vaccine Injury Compensation Program (VICP) |
|---|---|---|---|
| **Most vaccines** | Severe allergic reaction (e.g., anaphylaxis) after a prior dose or hypersensitivity to a vaccine component | Moderate or severe acute illness with or without a fever | Anaphylaxis<br>Shoulder injury related to vaccination<br>Vasovagal synope |
| **Inactivated Polio Vaccine** [o] | History of hypersensitivity to any component of the vaccine, including 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, and polymyxin B | Pregnancy<br>Immunodeficient patients or patients under immunosuppressive therapy may not develop a protective immune response against paralytic poliomyelitis after administration of IPV | Anaphylaxis<br>Shoulder injury related to vaccination<br>Vasovagal syncope |
| **Influenza (Inactivated)** [p] | Severe allergic reaction (e.g., anaphylaxis) after previous dose of influenza vaccine, to egg protein, or other vaccine component | GBS <6 weeks after previous dose of tetanus-toxoid-containing vaccine<br>Syncope warning<br>Egg allergy other than hives, e.g., angioedema, respiratory distress, lightheadedness, recurrent emesis; or required epinephrine or another emergency medical intervention (IIV may be administered in an inpatient or outpatient medical setting and under the | Guillain-Barré syndrome<br>Anaphylaxis<br>Shoulder injury related to vaccination<br>Vasovagal syncope |

| | | | |
|---|---|---|---|
| | | supervision of a health care provider who is able to recognize and manage severe allergic conditions) [2] | |

| | | | |
|---|---|---|---|
| **Diphtheria, tetanus and pertussis (DTaP)**[a,b,c,d,e] | Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP or DTaP<br><br>Progressive neurological disorders<br><br>Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any diphtheria-toxoid-, tetanus-toxoid-, or pertussis-containing vaccine, or any vaccine component<br><br>Severe allergic reaction to any component including neomycin and polymyxin[b] | Temperature of ≥105°F (≥40.5°C) within 48 hours after vaccination with a previous dose of a pertussis-containing vaccine<br><br>Collapse or shock-like state (i.e., hypotonic-hyporesponsive episode) within 48 hours after receiving a previous dose of a pertussis-containing vaccine<br><br>Seizure ≤3 days after receiving a previous dose of a pertussis-containing vaccine<br><br>Persistent, inconsolable crying lasting ≥3 hours within 48 hours after receiving a previous dose of a pertussis-containing vaccine<br><br>Guillain-Barré syndrome (GBS) <6 weeks after previous dose of tetanus-toxoid-containing vaccine<br><br>History of Arthus-type hypersensitivity reactions[2]<br><br>Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy<br><br>Premature infants (due to risk of apnea with intramuscular vaccines)<br><br>Latex sensitivity[a,b,c]<br><br>Immunocompromised persons may have a diminished response[d,e] | Encephalopathy or encephalitis<br><br>Brachial neuritis<br><br>Anaphylaxis<br><br>Shoulder injury related to vaccination<br><br>Vasovagal syncope |

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| ***Haemophilus influenza* type b (Hib)** [f,g,h] | Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any *H. influenzae* type b- or tetanus-toxoid-containing vaccine or any component of the vaccine [f,g]<br><br>Hypersensitivity to any component of the vaccine [f,g] or diluent [h] | Latex sensitivity [h]<br><br>Special care should be taken to ensure that the injection does not enter a blood vessel [h]<br><br>GBS <6 weeks after previous dose of tetanus-toxoid-containing vaccine [f,g]<br><br>Premature infants—risk of apnea with intramuscular vaccines [g]<br><br>Syncope warning [h]<br><br>Safety and effectiveness in immunosuppressed children have not been evaluated [g]<br><br>Immunocompromised persons may have a diminished response [f,h]<br><br>Cases of Hib disease may occur in the week after vaccination, prior to the onset of the protective effects of the vaccines [h] | Shoulder injury related to vaccination<br><br>Vasovagal syncope |

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| **Hepatitis A** [i] | A history of immediate and/or severe allergic or hypersensitivity reactions (e.g., anaphylaxis) after a previous dose of any hepatitis A vaccine or with an anaphylactic reaction to neomycin | Latex sensitivity<br>Vaccination may not prevent hepatitis A infection in individuals who have an unrecognized hepatitis A infection at the time of vaccination<br>Immunocompromised persons may have a diminished response | Shoulder injury related to vaccination<br>Vasovagal syncope |
| **Hepatitis B** [j,k,l] | Severe allergic or hypersensitivity reactions (e.g., anaphylaxis) after a<br>previous dose of any hepatitis B-containing vaccine, or to any vaccine<br>component including yeast. [j,k,l]<br>Hypersensitivity to yeast [j,k,l] | Latex sensitivity [j,k]<br>Syncope warning [k]<br>Premature infants—risk of apnea with intramuscular vaccines [j,k]<br>Vaccination may not prevent hepatitis A or hepatitis B infection in individuals who have an unrecognized hepatitis A or hepatitis B infection at the time of vaccination [j,k,l]<br>Immunocompromised persons—diminished response [k,l] | Anaphylaxis<br>Shoulder injury related to vaccination<br>Vasovagal syncope |
| **Human Papillomavirus (HPV)** [m,n] | Hypersensitivity, including severe allergic reactions to yeast [m] (a vaccine component) or after a previous dose [m,n] | Pregnancy [n]<br>Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity [m,n]<br>Latex warning sensitivity [n] | Anaphylaxis<br>Shoulder injury related to vaccination<br>Vasovagal syncope |

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| **Influenza**<br><br>**(Live, Intranasal)** [q] | Severe allergic reaction (e.g., anaphylaxis) after previous dose of influenza vaccine, to egg protein, or other vaccine component<br><br>Concomitant use of aspirin or aspirin-containing medication in children and adolescents<br><br>Should not be administered to persons who have taken influenza antiviral medications within the previous 48 hours<br><br>Pregnancy [2] | GBS <6 weeks after a previous dose of influenza vaccine<br><br>Asthma in persons aged 5 years old or older<br><br>Children younger than 5 years of age with recurrent wheezing and persons of any age with asthma may be at increased risk of wheezing<br><br>Medical conditions which might predispose to higher risk of complications attributable to influenza<br><br>The effectiveness has not been studied in immuno-compromised persons<br><br>May not protect all individuals receiving the vaccine | Guillain-Barré syndrome<br><br>Anaphylaxis<br><br>Vasovagal syncope |
| **Measles, mumps and rubella (MMR)**[r] | History of anaphylaxis to neomycin<br>Hypersensitivity to any component of the vaccine, including gelatin<br>Immunodeficiency states<br>Immunosuppressive therapy<br>Febrile illness (>101.3°F or 38.5°C)<br>Pregnancy<br>Family history of congenital or hereditary immunodeficiency<br>A parent, brother, or sister with a history of immune system problems [42] | Personal or family history of febrile seizures<br>Personal of family history of cerebral injury<br>History of anaphylaxis or hypersensitivity to eggs<br>Thrombocytopenia<br>History of thrombocytopenia or thrombocytopenic purpura<br>Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) [2]<br>Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing [2] | Encephalopathy or encephalitis<br><br>Chronic arthritis<br><br>Vaccine-strain measles viral disease in an immune-deficient recipient<br>Thrombocytopenic purpura<br><br>Anaphylaxis<br><br>Shoulder injury related to vaccination<br><br>Vasovagal syncope |

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| | | Any other vaccines in the past 4 weeks.[42] | |
| **Measles, mumps, rubella, and varicella (MMRV)** [s] | History of anaphylaxis to neomycin<br>Hypersensitivity to any component of the vaccine, including gelatin<br>Immunodeficiency states<br>Immunosuppressive therapy<br>Active untreated tuberculosis<br>Febrile illness (>101.3°F or 38.5°C)<br>Pregnancy<br>Family history of congenital or hereditary immunodeficiency<br>A parent, brother, or sister with a history of immune system problems [42] | Personal or family history of febrile seizures<br><br>Personal or family history of cerebral injury<br><br>History of anaphylaxis or hypersensitivity to eggs<br><br>Thrombocytopenia<br><br>The safety and efficacy for use after exposure to measles, mumps, rubella, or varicella have not been established<br><br>Any other vaccines in the past 4 weeks.[42] | Encephalopathy or encephalitis<br><br>Chronic arthritis<br><br>Vaccine-strain measles viral disease in an immune-deficient recipient<br><br>Thrombocytopenic purpura<br><br>Anaphylaxis<br><br>Shoulder injury related to vaccination<br><br>Vasovagal syncope |
| **Meningococcal** [t,u,v,w] | Severe allergic reaction (e.g., anaphylaxis) after a previous dose of or any component of this vaccine, or any other CRM197-, diphtheria-toxoid- or meningococcal-containing vaccine [t,u] | Premature infants may experience apnea [t]<br><br>Guillain-Barré syndrome [t,u]<br><br>Latex sensitivity [v,w]<br><br>Altered immunocompetence, safety and effectiveness have not been evaluated in immunocompromised persons [t,v,w]<br><br>Altered immunocompetence, immunosuppressant therapy, may have reduced immune responses [u,v,w] | Anaphylaxis<br><br>Shoulder injury related to vaccination<br><br>Vasovagal syncope |

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| **Pneumococcal** [x,y] | Severe allergic reaction (e.g., anaphylaxis) after a previous dose of PCV13 or any diphtheria-toxoid-containing vaccine or to a component of a vaccine (PCV13 or any diphtheria-toxoid-containing vaccine) [2,x] | Apnea following intramuscular vaccination has been observed in some infants born prematurely [x]<br><br>Individuals with altered immunocompetence, including those at higher risk for invasive pneumococcal disease (e.g., individuals with congenital or acquired splenic dysfunction, HIV infection, malignancy, hematopoietic stem cell transplant, nephrotic syndrome), may have reduced antibody responses to immunization [x]<br><br>Persons with severely compromised cardiovascular or pulmonary function [y]<br><br>Persons with chronic cerebrospinal fluid leakage [y]<br><br>Immunocompromised persons may have a diminished response [y] | Shoulder injury related to vaccination<br><br>Vasovagal syncope |
| **Rotavirus** [z] | Severe combined immunodeficiency (SCID)<br><br>History of intussusception<br><br>History of uncorrected congenital malformation of the gastrointestinal tract that would predispose to intussusception | Altered immunocompetence other than SCID (e.g., HIV/AIDS)<br><br>Delay administration in infants suffering from acute diarrhea or vomiting.<br><br>Chronic gastrointestinal disease [2,z]<br><br>Spina bifida or bladder exstrophy [2]<br><br>Latex sensitivity<br><br>Safety and effectiveness in infants with known primary or secondary immunodeficiencies have not been established | Intussusception |

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| | | Safety and effectiveness of ROTARIX when administered after exposure to rotavirus have not been evaluated.<br><br>Rotavirus shedding in stool occurs after vaccination with peak excretion occurring around Day 7 after Dose 1 | |
| **Tetanus, diphtheria, and pertussis (Tdap)** [aa] | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component<br><br>Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap [2] | GBS <6 weeks after a previous dose of tetanus-toxoid-containing vaccine<br><br>Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy [2]<br><br>History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid- or tetanus-toxoid-containing vaccine<br><br>Latex sensitivity<br><br>If vaccine is administered to immunocompromised persons, including persons receiving immunosuppressive therapy, the expected immune response may not be obtained. | Encephalopathy or encephalitis<br><br>Brachial neuritis<br><br>Anaphylaxis<br><br>Shoulder injury related to vaccination<br><br>Vasovagal syncope |

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| **Varicella** [bb] | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component including neomycin and gelatin.<br><br>Any febrile illness or active infection<br><br>Active, untreated tuberculosis<br><br>Pregnancy [2,bb]<br><br>Immunosuppressed states; immunodeficiency states<br><br>Family history of altered immunocompetence [2,bb]<br>A parent, brother, or sister with a history of immune system problems [42]<br>Immunoglobulins should not be given concomitantly<br><br>Blood or plasma transfusions, or administration of immune globulin(s) | Recent (≤11 months) receipt of antibody-containing blood product [2,bb]<br><br>Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) [2]<br><br>Use of aspirin or aspirin-containing products [2,bb]<br><br>Premature infants<br><br>Transmission of vaccine virus may occur between vaccinees and susceptible contacts<br>Any other vaccines in the past 4 weeks. [42] | Anaphylaxis<br><br>Shoulder injury related to vaccination<br><br>Vasovagal syncope<br><br>Disseminated varicella vaccine-strain viral disease<br><br>Varicella vaccine-strain viral reactivation |
| **Zoster** [cc] | Known severe immunodeficiency<br><br>Pregnancy<br><br>History of anaphylactic/anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine | Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) [2]<br><br>Transmission of vaccine virus may occur between vaccinees and susceptible contacts | |

The information in this table is extracted from the CDC Vaccine Recommendations and Guidelines of the ACIP on Contraindications and Precautions [2], Vaccine Information Statements,[42] manufacturers' package inserts (PI) current as of February 2019, and from the FDA's website.[1] To query whether a PI has been updated since this table was prepared, check the FDA's website.[1]

PIs referenced: [a] Infanrix, [b] Kinrix, [c] Pediarix, [d] Quadracel, [e] Pentacel, [f] ActHIB, [g] HIBERIX, [h]PedvaxHIB, [i] VAQTA, [j] Recombivax HB, [k] Engerix-B, [l] Hepislav B, [m] Gardasil 9, [n] Cervarix, [o] IPOL IPV, [p]Flulaval, [q] Flumist Quadrivalent, [r] MMR II, [s] Proquad, [t]MENVEO, [u] Menactra , [v]BEXSERO, [w]Menomune, [x] Prevnar 13, [y] PNEUMOVAX 13, [z] Rotarix oral suspension, [aa] TENIVAC, [bb] Varivax, [cc]Zostavax

## EMERGING DATA FOR RISK ASSESSMENT REGARDING VACCINE ADVERSE EVENTS

### Family Medical History

Emerging data is available on familial predispositions to adverse events to vaccination.[42] If a family has already experienced severe vaccine adverse events in several distant relatives, or a moderate to severe reaction in one or more close family members, a family member may express hesitation to receiving vaccines. The doctor should use discretion and judgment in weighing this factor in the consideration of a medical exemption.

A doctor must utilize clinical judgment and consider the health and well-being of children in families whose medical history includes numerous health problems. Health conditions in the immediate family (sibling, parent) may potentially have a bigger impact on the patient than conditions in more distant relatives.[17]

Medical conditions can be grouped into several categories, with an extensive body of medical research that has examined certain categories. In some, there are considerable data to support a possible link between vaccination and an acute or chronic medical condition; in others, the data are generally lacking.

Following are six categories of acute and chronic illnesses that physicians may encounter as they take familial medical histories of their patients, which could play a role in the consideration of medical exemption from vaccination. These are listed in a descending order of medical certitude (categories with the largest body of research are listed first). It is important to realize that medical research has not conclusively proven that these disorders increase the risk of a severe adverse reaction to vaccines (thus, they are not yet considered contraindications). However, an indicated relationship has been determined in some cases, which may be taken into account when evaluating a patient for a medical exemption.

1. **Autoimmune Disorders**[16,18-23]
    - Systemic lupus erythematosis[24-26]
    - Rheumatoid arthritis[24,26-28]
    - Hashimoto's thyroiditis[25]
    - Psoriasis[29-34]
    - Fibromyalgia/Chronic fatigue[35-38]

- Multiple sclerosis[24,39,40]
- Type 1 diabetes[41,43]
- Sjögren's syndrome[44]
- Vitiligo[35,47]
- Celiac disease[25]
- Addison's disease[25]
- Alopecia areata[24]
- Other autoimmune states[16]

2. **Asthma/Allergy/Atopic Disorders** [48-56]
   - Anaphylaxis[48,56]
   - Asthma and allergy [45,49,54-56]
   - Atopic disorders [50-52]
   - Eczema/Atopic dermatitis[57]
   - Severe food allergies[42,58,59]

3. **Neurological Disorders**[60,61]
   - Seizures or epilepsy[7,42,61,62]
   - Bell's palsy[63,64]
   - Alzheimer's disease[65,66]
   - Parkinson's disease[65,66]
   - Obsessive compulsive disorder/Tic disorder/Tourette's syndrome[67,68]
   - Mitochondrial dysfunction[12]
   - Guillain-Barré syndrome[69]
   - Demyelinating inflammatory disorders[70,71]
   - Other[24]

4. **Inflammatory Bowel Disorders**[14,15]
   - Crohn's disease[14]

- Ulcerative colitis[14]
- Celiac disease[25]

5. **Developmental or Learning Disorders**[73]
    - Autism[74]
    - Speech or language impairment[74]
    - Attention deficit disorder/Attention deficit and hyperactivity disorder[67,75 80, 94-96]
    - Learning disabilities[75]

6. **Psychiatric or Mental Health Disorders**[67]
    - Schizophrenia[76]
    - Depression[77-79]

**Genetic Susceptibility That May Increase the Risk of Vaccine Adverse Events**

Certain individuals are at a higher risk of having unique neurological, autoimmune, allergic, and inflammatory reactions to vaccine antigens and other ingredients. As part of the National Vaccine Injury Compensation Program (VICP) established in 1986, potential vaccine recipients "who may be at significantly higher risk of major adverse reactions" to vaccines were to be identified,[10] yet they remain unidentified because the population isn't being routinely screened. Certain genetic and immunological tests, some of which are highlighted below, are able to identify an increased risk of a vaccine adverse event based on personal genetic or immunological susceptibility. While more research is needed, preliminary data are available, and the growing body of literature is significant.[81-90]

The practice of performing genetic evaluations to determine the presence of increased risk to a vaccine adverse event has been named several terms, including genetic adversomics,[81] pharmacogenomics,[82,83] and vaccinomics.[84] Several gene polymorphisms (or SNPs) have been noted in the medical literature as having the potential to increase the risk of an adverse reaction to vaccination, for example, *MTHFR*,[85] *IRF1*,[85] *ICAM1*,[86] *IL4*,[87] *HLA-DBR1*,[88] *HLA-DQB1*,[88] and *SCN1A*.[89,90] Until further research is conducted, the degree to which these genetic variants increase vaccine risk cannot be claimed with certainty, but it is currently known that the risk is present. A physician may elect to perform a genetic evaluation for a patient and, for those with one or more genetic variants that are currently known to increase the risk of a vaccine adverse event over that in the general population, may follow the precautionary principle and issue a medical exemption.

The candidate genes noted to have the strongest association with adverse events following vaccination (AEs) include a metabolism gene previously associated with adverse reactions to a variety of pharmacologic agents*, MTHFR*, and an immunological transcription factor, *IRF1* gene. The statistical results from the medical literature carry strong biological plausibility and are in agreement with previous work on the immune response to poxviruses.[85]

Genetic polymorphisms related to inappropriate regulation of *IL4* expression and/or activity of IL-4 cytokine could be associated with altered brain function leading to the development of clinical AEs.[87]

Physicians need to be aware that in certain individuals, vaccinations can trigger serious and potentially disabling and even fatal autoimmune manifestations. These reactions are most often associated with the HLA class of genes. Individuals who carry certain genetic profiles are at increased risk.[16,88]

"Presence of the HLA class I allele A2 can result in heavy cytotoxic T-cell activation and vaccine/self-peptide presentation to immune cells. If HLA autoimmune susceptibility alleles/haplotypes are present that control other immune response components, the probability is elevated that these will activate cross-reactive immune cells; the cells, their inflammatory secretions and/or auto-antibodies may initiate adverse events reflecting those susceptibilities."[88]

The situation with HLA genes is very nuanced because the lack of *HLA-DRB1*13* is associated with being a vaccine non-responder but the presence of *HLA-DRB1*07* does as well.[72] Being a vaccine non-responder is not about calculating AE risk, but rather being able to assess risk versus benefit of a proposed vaccine.

The genetic variants of *IFI44L*, *CD46*, *SCN1A*, *SCN2A*, and *ANO3* are all related to seizure activity following the MMR vaccine.[89] The risk of developing febrile seizures from the MMR vaccine is five times greater than the risk of developing febrile seizures from the measles itself; it is estimated that there are 5,700 MMR-induced febrile seizures every year in the United States.[8] And a portion of febrile seizures have permanent sequelae, as shown for example in a large 2007 epidemiological study finding that 5% of febrile seizures resulted in epilepsy.[6,8]

## SUGGESTED POLICIES AND ADMINISTRATIVE PROCEDURES FOR DOCTORS WHO EVALUATE PATIENTS FOR MEDICAL EXEMPTION TO VACCINATION

The authors of this presentation hold the professional opinion that it is in the best interest of the patient for the physician to consider the factors below in a manner most protective of the current and future health and well-being of the individual patient.

1. An adverse event to one or more vaccines should factor into the recommendation regarding exemption to other and all vaccines, due to common vaccine ingredients and excipients.
2. There are no data establishing an age at which a child might outgrow a propensity to suffer a repeat vaccine adverse event, and a physician is justified in providing an exemption for any length of time which he or she decides is warranted in each clinical situation.
3. Extending an exemption beyond the patient's age in which a pediatrician practices medicine (age of 18 years) may not be within the scope of care of a pediatrician, but the severity of an adverse event or condition may be factored into this decision (e.g., a severe allergic reaction or neurological injury).

Best practices include the following:

1. **Asking patients to make a separate appointment for vaccine and immunity evaluation.** A thorough evaluation regarding vaccination and immunity takes time, and an ordinary checkup may not allow adequate time for full consideration of a patient's case. Alternatively, provide a longer appointment to cover both a checkup and an exemption evaluation. In certain cases, a patient's current medical provider may not provide such evaluations, or the patient may want to seek a second opinion.

2. **Providing pre-appointment personal and family history questionnaires so that all required information is available for the appointment.** A thorough personal and family history is most readily obtained if the patient has had adequate time beforehand to gather medical information and come to the appointment prepared with all necessary information written into a questionnaire. Where applicable, the patient should also bring documentation of previous vaccines, any medical records that substantiate a moderate to severe vaccine reaction in the patient history (if available), and medical records that document any past and current medical problems in the patient history (if available).

3. **Seeking to obtain informed consent from *both* parents/legal guardians.** It may generally be acceptable to consult with only one parent if both parents are known to a practice and if the parent who is present confirms that the other parent is in agreement. In the case of a difference of opinion, or (especially) if there is a current custody dispute, it is important to involve both parents in the evaluation process and, where appropriate, to obtain a written consent to the evaluation from both parents before providing an exemption. This respects the authority of both parents and avoids disruption of the doctor-parent relationship. Where one parent has full medical custody of a child, providing an evaluation and exemption irrespective of the consent of the absent parent is appropriate.

4. **Performing a complete physical exam.** It is standard practice to perform a complete physical exam during an evaluation for vaccination and immunity. For physicians who practice telemedicine, consult state laws regarding requirements for an in-person visit.

**Discussing the Implications of a Medical Exemption with Patients/Guardians**

If a patient is granted a medical exemption the key points that should be discussed with the patient and/or guardian are as follows:

• The medical exemption was granted because the risk of an adverse reaction may be higher for the patient than for the general population. The risks to vaccination outweigh the benefits.

• A medical exemption implies that the patient may attend school without receiving those vaccines.

• According to conventional medical opinion, being exempted from a vaccine or vaccines may leave the patient more susceptible to the associated disease and also more likely to be contagious. Conventional medical opinion also highlights that the patient may be more likely to contract a more severe form of the disease thus increasing the risk of harm or death.

• If necessary, ask the patient/guardian to return periodically or as needed for a re-evaluation of the patient's health and circumstances.

• In the event of an outbreak, a patient with a medical exemption may be requested or required to avoid entering certain areas until the increased risk has cleared.

**SUMMARY**

There are warnings, precautions, and contraindications associated with every vaccine. These are primarily described on the CDC website, PIs, and in the VICP Vaccine Injury Table. A vast body of medical literature further describes and clarifies the science of vaccination and immunity. To minimize the risk of an adverse event occurring, careful consideration should be given to a patient's personal medical history and family history.

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## Self-Assessment Test

### Best Practices for Physicians Recommending a Medical Exemption to Vaccination

**1. Which of the following is not listed amongst the most severe adverse events on the MMR package insert?**

a. Pancreatitis

b. Death

c. The common cold

d. Pneumonia

**2. Which of the following is a true statement about medical exemption to vaccination?**

a. All States have the same laws governing medical exemptions

b. Medical exemptions can only be written for an immunocompromised patient

c. In all States, a medical exemption must refer to a contraindication specified in the manufacturers' product insert

d. The physician's recommendation to vaccinate or not in the presence of a precaution should be decided on a case-by-case basis

**3. Which category of chronic health conditions has the largest body of medical literature indicating a possible link to vaccination?**

a. Psychiatric conditions

b. Allergic disorders

c. Autoimmune disorders

d. Inflammatory bowel disease

**4. Which of the following statements regarding making a recommendation for a medical exemption from vaccination is true?**

a. Family history of a vaccine reaction is not a factor

b. Contraindications are not the only considerations

c. Patients must provide written proof of a previous severe vaccine reaction in order for a doctor to consider it as a factor

d. A physical exam is not a factor in a medical exemption evaluation

**5. Once a medical exemption is provided, a patient is unable to receive any more vaccines, even in the event of an outbreak or epidemic.**

a. True

b. False

**6. What is the statute of limitations for reporting a death after vaccination to the Vaccine Injury Compensation Program?**

a. One year

b. Two years

c. Three years

d. Ten years

**7. Which of the following medical circumstances prior to vaccination is NOT a precaution to repeat vaccination according to the CDC?**

a. Seizure (with or without fever) within three days of a vaccine

b. Encephalitis (three or more hours of persistent, inconsolable crying)

c. Fever of 105 degrees F or higher

d. Hypotonic-hyporesponsive episode or shock-like state

e. None of the above (i.e., they are all precautions)

*Correct answers: 1:c, 2:d, 3:c, 4:b, 5:b, 6:b; 7:e*