



# **Liability Protection For Children's Immunization Providers**

**Texas Department of State Health Services  
April 2005**

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## **LIABILITY PROTECTION FOR CHILDREN'S IMMUNIZATION PROVIDERS**

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This introduction is for individual providers, while some of the following material is aimed at business and government entities.

The malpractice risks for health care providers who immunize children are low. In traditional and non-traditional settings (outside the private physicians office), the provider is protected by a strong set of legal provisions. However, no law provides absolute protection to the individual nor, in fairness, should it.

Although the legal risk to the individual practitioner is infinitesimally small, attorneys are trained to avoid speaking in absolutes, such as “never” or “no conceivable circumstances.” Most of the laws have potentially weak spots or exploitable ambiguities, but, given the layers of such laws, a practitioner’s legal risk is very low. The single best defense against malpractice is well-trained health care providers who perform their duties in a professional, competent manner. The root cause of successful medical malpractice suits almost always is negligence of the provider. The primary questions of a personal injury attorney considering a lawsuit against anyone must be: “Can I prove negligence?” and, if so, “Can I prove damages to my client?”

A practitioner may disagree, but Texas law generally disfavors medical malpractice lawsuits. A 1992 study by the Texas Medical Association, the Texas Hospital Association, and the Texas Trial Lawyers Association indicated the economic impact of medical malpractice claims is low nationally (0.74% of medical costs) and even lower in Texas (0.62%). The Medical Liability and Insurance Improvement Act requires plaintiffs in malpractice claims to jump through a number of procedural hoops that do not apply in other types of tort claims. Amendments in 1993 add procedure intended to screen out frivolous health liability claims.

Because the private and public health care system always has provided immunizations to most Texas children, much of the concern about increased liability is directed toward the class of patients that has not been immunized in the past. Many providers think poor or indigent patients are more litigious than other patients. The Journal of the American Medical Association (October 13, 1993) published a study, the most thorough of its kind, which indicates just the opposite is true. As an accompanying editorial states: “It is time to put to rest the myth that poor patients are litigious.”

Providing immunizations should be fairly low risk, if all medical procedures were ranked by their risk of causing litigation against the health care professional. Additionally, the professional is protected from personal liability by an extraordinary set of statutes. The provider, in a non-traditional setting, should be covered by at least one of the statutes below. In many instances the provider is covered by two or more of the statutes.

The most important of these laws, which covers most of the routine vaccines and vaccine-related injuries, is the National Vaccine Injury Compensation Program (VICP). VICP requires anyone who alleges that they have suffered an injury from the administration of a covered vaccine to file a claim as specified in the law. This “no fault” claim is designed to demonstrate that the injury is serious enough to deserve compensation and is related to the vaccine. If this can be proved, the claimant will be awarded damages from a federal fund set up for this purpose.

From the perspective of the plaintiff's attorney, this process is simple and stream-lined.

While VICP does not provide for extraordinary or punitive damages, its awards generally are fair and include attorneys' fees. Claims result in an award of damages to the claimant or a determination that the injury is not vaccine-related. Though the claimant can reject the determination or award and proceed to file a traditional tort lawsuit, most attorneys familiar with the VICP believe this should rarely occur. Because a neutral magistrate already has made an adverse determination, the attorney must assume the odds are against him. Also, the expense of litigation is high in this type of case and, as shown below, a formidable array of defenses must be overcome. Finally, if a client has received any award, the attorney will receive a generous hourly fee.

A shortcoming of this legislation is the apparent exclusion of injuries not "vaccine-related." Although the text of the law implies Congress intended to cover all injuries "associated with the administration of a vaccine," the claimant must show the injury was vaccine-related. This appears to exclude the risk of injuries associated with the direct injection of any type of substance: namely infection such as staphylococcus, hepatitis, HIV, etc. However, all other types of injury should be covered.

After VICP, the most comprehensive and vaccine specific liability protection is provided by the Texas Health and Safety Code (§ 81.007):

A private individual performing duties in compliance with orders or instruction of the [Texas]department [of Health] or a health authority issued under this chapter [81] is not liable for the death of or injury to a person or for damage to property, except in the case of willful misconduct or gross negligence.

The exception for "willful misconduct or gross negligence" is common to most statutes cited here and is inserted for obvious reasons. Otherwise, this statute provides broad and complete protection. The only major problem relates to the definition of a "private individual," which is not defined in the statute. Individuals employed by the Texas Department of State Health Services and local health authorities assumably are not considered "private individuals" during their working hours.

But consider the following situations: Might a Texas Department of State Health Services or local public health nurse become a private individual if they volunteer to do immunization work? What about employees of other governmental bodies, such as school districts or publicly owned hospitals, when they are working in an official capacity or off duty? Or private physicians and their employees? Ultimately, only a court can clarify the meaning of this term. Given the importance of the public policy involved, it has every incentive to define the term broadly.

A more narrow legal issue deals with the meaning of "instruction of the department under this chapter." Another provision of the Health and Safety Code (§ 161.001) seems to provide broad exemption from liability. But because it does not cover "a negligent act in administering the vaccine," it provides more coverage for the vaccine manufacturer than the provider who administers the shot. A court test is needed to determine whether this statute provides protection other than that already afforded by VICP. Arguably, it limits liability, especially to those who might be liable under theories of negligent delegation or supervision, because their negligence

was not in the “act of administering the vaccine.” This statute has the same shortcoming as VICP because it does not cover infections.

The remaining statutes, along with those above, are covered in the chart on the page 6. These statutes cover more particular situations. Some apply to volunteers and others to governmental employees or participants in federal or state-sponsored care for certain indigent groups. These statutes are not mutually exclusive of each other or with the statutes discussed above. For example, assume that a volunteer nurse providing immunizations for a local nonprofit organization administers an inappropriately large dose of vaccine to a child. Further assume provable damages occur and that the attorney retained by the child’s parents believes the nurse can be proved “negligent” as defined by Texas law. Of course, this is the worst-case scenario, and many mistakes made in the course of administering the immunizations will not be attended by these facts.

The attorney must go through the procedure provided by VICP, where negligence will not be an issue. The majority of injured claimants will obtain satisfaction at the end of this process, but for the sake of our hypothetical example, assume this did not occur and the attorney files suit in state court. The attorney for the nurse will immediately seek to have the suit dismissed because the nurse was acting as a private individual performing duties in compliance with the Texas Department of State Health Services (§ 81.007) and “the injury was caused by the vaccine or immunizing agent” as quoted in the Health and Safety Code (§ 161.001).

In the unlikely event these defenses fail, the nurse would seek to have the suit dismissed on the grounds that he or she was serving as a direct service volunteer of a charitable organization and therefore, not subject to liability (Chapter 84 of the Texas Civil Practice and Remedies Code). Even this list of statutory defenses may not be exhaustive, but it serves to illustrate why it is extremely unlikely that an attorney will reject the award of the VICP proceeding to pursue the expensive and difficult litigation in state court where the award of damages might prove extremely elusive.

If a similar situation developed as a result of an immunization administered by a government employee, the employee could not claim as many absolute bars to the suit but probably could claim a right to both legal representation and indemnification from the employer, but again, only if award under VICP failed to satisfy the injured party. The more likely course of action for the plaintiff would be to sue the government entity directly under the Texas Tort Claims Act.

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*This article and accompanying chart provide an overview of the statutes associated with immunizing children. Many of the statutes are complex and have exceptions and provisos not mentioned here and other attorneys may interpret some of these provisions differently. Institutions and individuals should obtain more details on these statutes before making personal or policy decisions based upon them. This information can be provided by your attorney. The accompanying chart provides summaries of the statutes consulted and enough information to allow an attorney to find them. The information was believed to be accurate at the time produced. However, it does not cover every topic and should not be considered legal advice. Any specific questions should be addressed by your attorney.*



## STATUTES REGARDING IMMUNIZING CHILDREN

STATUTE	COVERAGE	FEATURES	LIMITATIONS
National Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-10 <i>et. seq.</i>	All who manufacture or administer vaccines listed in the statute.	Forbids civil action for “damages arising from a vaccine-related injury or death associated with the administration of a vaccine” until plaintiff exhausts opportunities under the act.	1) Does not cover injuries unrelated to vaccine itself (e.g., infection). 2) Lawsuit still possible if injured party dissatisfied with outcome of federal proceeding.
Communicable Disease Prevention and Control Act, § 81.007 of the Texas Health and Safety Code	“A private individual performing duties in compliance with orders or instruction of the [Texas Department of State Health Services (DSHS)].”	Provides complete immunity “except in a case of willful misconduct or gross negligence.”	1) No definition of a “private individual.” 2) Needs “orders or instructions” of DSHS or local health authority to be triggered.
Charitable Immunity and Liability Act, Chapter 84 of Texas Civil Practice and Remedies Code	Anyone who is serving as a direct service volunteer of a charitable organization.	Provides immunity from civil liability for any act or omission resulting in death, damage, or injury if the volunteer was acting in good faith and in the course and scope of duty within the organization.	1) Does not cover intentional, willful, or wantonly negligent acts. 2) Organization itself may still be liable and should have insurance coverage.
Section 161.001 of the Texas Health and Safety Code	“Person who administers or authorizes vaccine.”	No liability “for an injury caused by the vaccine or immunizing agent” if the vaccine is required by law.	Doesn’t apply to a “negligent act in administering the vaccine.”
Chapter 22, Subchapter B of the Texas Health and Safety Code	Volunteers and professional employees of school districts.	No liability for any act within the scope of the duties of employment or volunteer services rendered on school premises.	Ambiguous language in § 21.912(b); not clear whether “negligence resulting in bodily injury to students” is covered in non-disciplinary situations.
Chapters 104 and 108 of the Texas Civil Practice and Remedies Code	State officers and employees and contract physicians.	Provides for the state to indemnify the covered individual up to specified limits and to provide defense by the attorney general.	1) Once statutory limits are surpassed, individual may be personally liable. 2) Willful or wrongful acts or acts of gross negligence are not covered.
Chapter 101 of the Texas Civil Practice and Remedies Code	Employees of “governmental units” acting within their “scope of employment.”	Provides that governmental units are responsible for the negligent acts of their employees. Provides for caps on damages. Requires plaintiff to follow special procedures. Provides for representation by attorney general (or local government).	Provides waiver of absolute sovereign immunity to allow tort suit against government.
Chapter 110 of the Texas Civil Practice and Remedies Code	Doctors, advanced nurse practitioners, certified nurse midwives, and physician assistants providing services under various indigent care programs.	Provides for state indemnification up to specified limits, reduction in malpractice premium because of this.	1) Requires that professionals have malpractice insurance. 2) \$25,000 cap on most immunization claims.
Title 42 U.S. Code § 233	Officers, employees, or contractors of public or non-profit private entities receiving funds under any of four federal community health services programs.	Covered individuals are deemed public health service employees for purposes of bringing them under the Federal Tort Claims Act. Claims are defended by the U.S. Attorney General and paid by federal government as provided in the act.	The secretary of HHS or the attorney general may exclude the facility or the individual from the coverage of the act for reasons listed there.

## QUESTIONS AND ANSWERS ABOUT IMMUNIZATION LIABILITY

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**Q1:** What is the National Vaccine Injury Compensation Program (VICP)?

**A.** The National Childhood Vaccine Injury Act of 1986 established the VICP. The VICP is a federal program designed to provide no-fault-insurance to persons unavoidably injured by vaccines. The law was enacted to combat the perceived “vaccine liability crisis” of the mid-1980s.<sup>1</sup> Vaccine manufacturers and administrators were becoming increasingly concerned about rising liability for unavoidable injuries linked to vaccinations, which occurred following state-mandated vaccinations. It was feared that they might leave the vaccination market to avoid these increasing costs. The VICP is intended to provide compensation to persons who may have been unavoidably injured by vaccines rather than passing the costs on to vaccine manufacturers and administrators, who provide much-needed services to the state, which, after all, requires them to provide such services. Forcing them to pay for unavoidable damages resulting from this public good was considered unfair.

**Q2:** Who does the VICP protect?

**A.** The VICP protects vaccine manufacturers and administrators by requiring injured persons to pursue their tort claims exceeding \$1,000 in the VICP before going to state courts.<sup>2</sup> Because the VICP pays compensation to valid claims, vaccine manufacturers and administrators are protected from having to pay for unavoidable vaccination injuries. Injured persons also are protected because their claims are paid by the federal government rather than potentially adversarial insurance companies, vaccine manufacturers, or physicians. If a petitioner accepts an award under the VICP, the claim cannot be brought subsequently to the tort system.

**Q3:** What vaccines are covered?

**A.** Diphtheria, tetanus, pertussis (DTP, DTaP, DT, TT, or Td); measles, mumps, and rubella (MMR or any components); and polio (IPV and OPV)<sup>3</sup> were initially covered by VICP. Any vaccine administered at the same time as a covered vaccine. Effective August 6, 1997, *Haemophilus influenzae* type b, hepatitis B, and varicella (chickenpox) were added for coverage, and pneumococcal conjugate vaccine was added in December 18, 1999. All covered vaccines are listed in the Vaccine Injury Table.

**Q4:** Who can file a claim?

**A.** Claims may be filed in the federal system by injured persons, parents or their legal representatives, or the legal representatives of persons who have died as the result of the administration of a covered vaccine.<sup>4</sup> Injuries may include, but are not limited to: anaphylaxis, paralytic polio, and encephalopathy.

**Q5:** What is the time frame in which to file a claim?

**A.** For injuries resulting from a vaccine administered on or after October 1, 1988, claims must be filed within 36 months after the first symptom or manifestation of onset or

significant aggravation of the vaccine-related injury,<sup>5</sup> or within 24 months of a vaccine-related death.<sup>6</sup> The effects of the injury must have lasted at least 6 months after the vaccine administration or the injury must have resulted in inpatient hospitalization and surgical intervention. If there is a vaccine-related death, the claim also must be filed within 48 months of the occurrence of the first symptom, manifestation of onset, or significant aggravation of the injury from which the death resulted.<sup>7</sup> As of 2/1/1991, the time for filing claims for injuries resulting from vaccines administered prior to October 1, 1988, has expired. A claim may be filed if the first symptom, manifestation of onset, or significant aggravation of the injury occurs within a certain time after the administration of the vaccine.<sup>8</sup> The VICP uses a Vaccine Injury Table to determine these times, which usually range from 24 hours to three days, depending on injury and vaccine.<sup>9</sup> For example, encephalopathy occurring after DTP vaccine must have manifested itself within three days of the administration of the vaccine or a claim will not be paid.<sup>10</sup>

**Q6:** Under what circumstances may a vaccine administrator or manufacturer be sued?

**A.** If damages sought are more than \$1,000, a vaccine administrator or manufacturer may be sued only if and when the injured person is not awarded or rejects compensation awarded from the VICP.<sup>11</sup> The injured person is encouraged to accept compensation from the VICP to avoid delay in receiving compensation and because of the surety of the award. The VICP may not protect vaccine administrators when a vaccination is performed negligently.<sup>12</sup> The VICP may not compensate for negligent vaccinations, so persons injured by such vaccinations may reject the VICP's "award" of zero and sue the physician. A vaccine administrator or manufacturer may also be sued if vaccine used is not covered under the VICP.

**Q7:** How does the VICP work?

**A.** No one may sue in state or federal court for vaccination injuries of more than \$1,000 before going through the VICP. Claims must be filed in the United States Court of Federal Claims.<sup>13</sup> A special master, an appointee of the court, resolves the claim in proceedings intended to be less adversarial and more informal than a court setting.<sup>14</sup> Decisions of the special masters may be reviewed by the Court of Federal Claims upon motion<sup>15</sup> and may be appealed to Federal Circuit Courts of Appeals.<sup>16</sup> Only after all appeals can an injured party sue the manufacturer or administrator of the vaccine in state court.

Compensation claims paid on vaccines administered prior to October 1, 1988 came from Federal tax dollars allocated by Congress at \$110 million per year, and have since been paid from the Vaccine Injury Compensation Trust Fund that is funded by an excise tax on vaccine purchased.

**Q8:** How is eligibility for compensation determined?

**A.** Special masters may require the submission of reasonable and necessary evidence and information, testimony of persons, and production of documents and must allow any interested person to submit relevant information. A special master may engage in discovery.<sup>17</sup> The special master uses this information to determine compensation.

Compensation for vaccine-related deaths are limited to \$250,000 plus attorney's fees & costs.<sup>18</sup> No maximum compensation exists for vaccine-related injuries except that the maximum award for pain, suffering, and emotional distress caused by the injury is \$250,000.<sup>19</sup> No punitive or exemplary damages may be awarded.<sup>20</sup> Compensation to recover attorneys' fees must be reasonable.<sup>21</sup>

**Q9:** How many claims have been received and adjudicated by the VICP? How many have been found eligible for compensation? What is the average award given for compensable claims?

**A.** As of May 31, 2003, the VICP reported 8,813 petitions filed for compensation. At that time, 5,674 claims had been adjudicated. Of the adjudicated claims, 1,806 were found compensable, and 3,868 were dismissed.<sup>22</sup> For fiscal year 2002 the average amounts of award for claims filed prior to October 1, 1988 and on or after October 1, 1988, were \$932,988 and \$772,675 respectively.<sup>23</sup>

**Q10:** Whom can I contact for more information about the program?

**A.** The VICP Internet Home Page can be found at <http://www.hrsa.gov/osp/vicp/>. For further information you can call the VICP at 1-800-338-2382 or write them at: National Vaccine Injury Compensation Program, Parklawn Building, Room 16C-17, 5600 Fishers Lane, Rockville, MD 20857.

**Q11:** Is the VICP effective?

**A.** The "vaccine-liability crisis" no longer is front-page news. Whether this was caused by the VICP is debatable, but the main purpose of the VICP was to combat the crisis. The VICP has paid hundreds of millions of dollars that otherwise would have been paid by vaccine manufacturers and administrators, so it has lessened liability of vaccine providers, a goal of the VICP. The VICP is effective in lowering the dollar amount of liability of physicians and other providers.

The VICP has greatly reduced the number of lawsuits against vaccine manufacturers, according to federal sources. The number dropped from 255 in 1986 (before the VICP) to 18 in 1991.<sup>24</sup> Lawsuits against physicians who administer vaccines are rare in Texas. According to one large medical liability carrier, only eight closed claims have occurred against physicians involving the administration of vaccines (one was closed before 1986), and two were closed with payment. Both claims closed with payment of \$1,000, the maximum amount an injured party can sue for before utilizing the VICP. The VICP probably resulted in these claims being settled for \$1,000 given the large potential damages for these types of claims.

**Q12:** How is the VICP funded?

**A.** The VICP is run by the federal government and thus, can have its funding increased, decreased, or cut off at any time, making this question difficult to answer. The program is supported by excise taxes applied to the cost of the vaccine.<sup>25</sup> Funding of vaccine claims depends on the date of vaccination: for vaccines administered prior to October 1, 1988, awards are compensated from Federal tax dollars allocated by Congress at \$110 million

per year; for vaccines administered on or after October 1, 1988, awards are paid from the Vaccine Injury Compensation Trust Fund, funded from an excise tax of .75¢ on every dose of covered vaccine that is purchased.

**Q13:** What protection do I have from lawsuits for adverse reactions to vaccines if I participate in the Texas Vaccines for Children program, Community Immunization Campaign, or any other immunization activities coordinated or sponsored by the Texas Department of State Health Services or local health departments?

**A.** The VICP does not prevent an injured person from rejecting compensation awarded by the VICP and suing the manufacturer or administrator for damages, although it does reduce the number of such suits. However, Texas offers additional protection. Physicians will not be liable for adverse reactions to vaccines if they are administering vaccines as required by state law, unless administered in a “negligent manner.”<sup>26</sup>

**Q14:** What is “negligence?”

**A.** “Negligence” is the breach of a duty of care. If you administer a vaccination, you are required to administer it carefully and reasonably. If you do not, you may be sued for negligence. Some examples of negligence in the immunization context include the use of a dirty needle, the damaging of a nerve by a needle, the administering of the wrong vaccine, and the administering of a medically contraindicated vaccine.

**Q15:** Can a physician be held liable for not administering an immunization?

**A.** No. Texas law specifically states that any person who fails to comply with a statewide immunization plan is not liable or responsible for that failure.<sup>27</sup>

**Q16:** Would a letter from the local health authority relieve a physician or nurse from liability?

**A.** No. Such a letter would have no effect on liability.

**Q17:** What does the practicing physician need to know about standing delegation orders with regard to immunization?

**A.** Physicians need to ensure their standing delegation orders comply with general requirements of the Texas State Board of Medical Examiners. In particular, physicians need to set out the requirement that vaccines be administered only to a recipient who is free of any condition for which the immunization is contraindicated. The standing delegation orders also must take into account the proper procedure for the care of a recipient of the immunization who has or suffers an adverse reaction.

**Q18:** Who may give informed consent for a child to receive immunizations?

**A.** The child’s biological parent, managing conservator, guardian, or person with consent authority under another state’s laws may give informed consent for the child to receive immunizations.<sup>28</sup> If such a person is not available and has not denied consent, the child’s grandparent, adult brother or sister, adult uncle or aunt, or stepparent may consent for the

grandparent, adult brother or sister, adult uncle or aunt, or stepparent may consent for the minor.<sup>29</sup> Those parties also may consent for the minor if such a person listed above delegates the authority to them.<sup>30</sup>

A school may consent for the minor if such a person listed above cannot be contacted and has provided written authorization.<sup>31</sup> An adult who declares himself as the primary caregiver of the minor can consent for the immunization of the minor without written authorization from the parent. Adults not listed above but who have care and control of the minor may consent for the minor if they have written authorization to consent from anyone listed above, whether such a person can be contacted or not.<sup>32</sup> Also, a court may be able to give consent for a minor or authorize another adult to give consent if the adult reasonably believes the minor needs immunization.<sup>33</sup> The Texas Youth Commission may consent for the immunization of a committed minor without written authorization if a parent has been contacted, refuses to consent, or fails to carry out consent for the minor or does not expressly deny to the Texas Youth Commission the authority to consent.

**Q19:** Can adolescents consent to their own immunization?

**A.** Usually, no. Minors must be 18 years old to consent to their own immunization, unless they are in the Armed Forces, are 16 or older living apart from their parents and managing their own financial affairs. Unmarried, pregnant adolescents can consent to immunizations related to their pregnancies.<sup>34</sup>

**Q20:** When is a child exempt from the law requiring immunizations?

**A.** If the parent, managing conservator or guardian files an affidavit making a claim that the immunization is being declined for reasons of conscience, including a religious belief,<sup>35</sup> or if the immunization is medically contraindicated based on a licensed physician's examination.<sup>36</sup>

**Q21:** Would a local coalition set up for a Community Immunization Campaign be considered a "charitable organization" for purposes of the Charitable Immunity and Liability Act?

**A.** Yes, if a local coalition is a tax-exempt organization under Section 501(a) of the Internal Revenue Code of 1986 by being listed as an exempt organization in Section 501(c)(3) or 501(c)(4). These organizations are formed and operated exclusively for charitable, religious or educational purposes or for the promotion of social welfare.<sup>37</sup>

Direct service volunteers are immune for civil liability for any act resulting in death, damage or injury if the volunteer was acting in good faith and in the course of duties or functions within the organization.<sup>38</sup> A volunteer is a person rendering services for a charitable organization who does not receive compensation in excess of reimbursement for expenses. This can include persons who are directors, officers, trustees or direct service volunteers.<sup>39</sup> Physician direct service volunteers are liable if they act intentionally or are willfully or wantonly negligent.<sup>40</sup>

**Q22:** If I practice in a group that offers a special immunization clinic, what liability does the group, as an employer, share?

A. Employers are liable for the negligence of its employees. Therefore, employers are liable for negligent immunizations by employees. The employer has the same protection as an individual vaccine administrator.

**Q23:** Will professionals administering vaccines be covered under an existing liability insurance system such as the city-county health department or school districts?

A. Coverage depends on the local liability insurance system. Check with your local government.

**Q24:** Will service sites be leased temporarily by local city/county or state health departments and will this suffice as a legal liability umbrella?

A. If the city, state, or county health department is leasing and operating sites under the Charitable Immunity and Liability Act with physician volunteers, then physicians will have only service volunteer liability (see above). Whether the city, state, or county health departments will do this is up to them.

**Q25:** Which are the vaccines that federal regulations require physicians to provide information about the risks and benefits of vaccines administered to children?

A. The vaccines are diphtheria, tetanus, pertussis (DTP, DTaP, DT, TT, Td); measles, mumps and rubella (MMR or any components); polio (OPV or IPV), *Haemophilus influenzae* type b, hepatitis A, hepatitis B, varicella (chickenpox), and pneumococcal conjugate vaccine.<sup>41</sup> In addition to these are also any other vaccines recommended for inclusion in the U.S. Recommended Schedule by the Advisory Committee on Immunization Practices (ACIP) of the CDC.

**Q26:** What information is to be provided?

A. The National Childhood Vaccine Injury Act requires all administrators of covered vaccines to use CDC developed Vaccine Information Statements (VISs) that contain the following information:

1. The frequency, severity, and potentially long-term effects of the disease to be prevented by the vaccine;
2. Symptoms or reactions to the vaccine that should be brought to the physician's attention immediately;
3. Measures patients can take to reduce the risk of major adverse reactions;
4. Early warning signs to major adverse reactions that patients should be aware of;
5. How parents should "monitor" adverse reactions, including forms to record such events;

6. When, how, and to whom parents should report adverse reactions;
7. Contraindications to administration of the vaccine;
8. Groups of potential vaccine recipients who may be at risk of adverse reactions;
9. A summary of relevant federal recommendations about a complete schedule of childhood immunizations and the availability of the National Vaccine Injury Compensation Program; and,
10. Other relevant information as the government determines.<sup>42</sup>

**Q27:** Where can I obtain this information for my patients?

**A.** The CDC and Texas Department of State Health Services offer VISs that satisfy the criteria for vaccines. For questions about the regulations and forms, contact the Texas Department of State Health Services, Immunization Branch at 512-458-7284.

**Q28:** Will CDC send me a free VIS for each parent to whom I have to give this information?

**A.** No. The Texas Department of State Health Services will send VISs to every physician licensed in Texas, but the physician must copy these materials and provide them to parents. Public sector clinics and physicians who receive state-supplied vaccine, however, will be provided free VISs for parents.

**Q29:** I have seen one of these VISs. The last page is titled “Addendum to (name of vaccine) Information Statement” and is scored to be torn off. How should I use this form?

**A.** This is a two-part form. The first two pages are the CDC-developed Vaccine Information Statement to be reviewed by the parent. The last page is the addendum. There is space to record information about the child and his parents, and a witness signature. It also has space to record the location of the office, vaccination date, vaccine manufacturer, vaccine lot number, injection site, and information on the vaccine administrator.

**Q30:** Will patients really read and understand this material?

**A.** The VISs were developed jointly by a number of advocacy groups that have an interest in vaccine injury litigation such as the Children’s Defense Fund and Dissatisfied Parents Together to Stop Hurting Our Tots (“DPT SHOT”). As a result, some believe the VIS is too long, too detailed, and overly legalistic. Efforts have been made and will continue to be made to shorten the VISs and make them user friendly.<sup>43</sup>

**Q31:** Are the VISs available in languages other than English?

**A.** Yes. They are available upon request in Spanish, Vietnamese, Chinese, French, and over 25 other languages.

**Q32:** What documentation are vaccine administrators required to keep?



- A.** Each health care provider is required to keep permanent records of covered vaccinations. These records must contain:
1. The date of the administration of the vaccine;
  2. The vaccine manufacturer and lot number of vaccine;
  3. The name and address and, if appropriate, the title of the health care provider administering the vaccine;
  4. Edition (date of publication) of Centers for Disease Control and Prevention (CDC) Vaccine Information Statement (VIS) provided and date provided; and
  5. Any other identifying information on the vaccine required pursuant to government regulations.<sup>44</sup>

**Q33:** What adverse events are health care providers required to report?

- A.** Any covered event that occurs within seven days of administration of the vaccine (or longer if specified on the Vaccine Injury Table) must be reported.<sup>45</sup> Any contraindicating reaction to a vaccine specified in the manufacturer's package insert occurring in the same time period must be reported.<sup>46</sup> Reports must include the time periods after the administration of the vaccine, which vaccine-related illnesses, disabilities, injuries, conditions, or deaths occur, plus the name of the manufacturer and lot number of the vaccine.<sup>47</sup>

**Q34:** Are health care providers protected if the procedures regarding record documentation and reporting of adverse events are not followed?

- A.** Yes. The VICP applies to all vaccine-related injuries whether or not the procedures are followed. However, the usual sanctions for failure to keep proper medical records still apply.

## NOTES

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1. See Randall B. Keiser, “Deja Vu All Over Again? The National Childhood Vaccine Injury Compensation Act of 1986,” 47 Food and Drug L.J. 15 (1992); Theodore H. Davis, Jr., and Catherine B. Bowman, “No Fault Compensation for Unavoidable Injuries: Evaluating the National Childhood Vaccine Injury Compensation System,” 16 U. Dayton L.R.227 (1991).
2. 42 U.S.C. § 300aa-11(a)(2)(A).
3. 42 U.S.C. § 300aa-11(c)(1); 42 U.S.C. § 300aa-14(a).
4. 42 U.S.C. § 300aa-11(b)(1)(A).
5. 42 U.S.C. § 300aa-16(a)(2).
6. 42 U.S.C. § 300aa-16(a)(3)
7. Id.
8. 42 U.S.C. § 300aa-11(c)(1)(C)(i).
9. 42 U.S.C. § 300aa-14(a).
10. Id.
11. 42 U.S.C. § 300aa-11(a)(2)(B).
12. Monty Waters, Office of General Counsel, Texas Department of State Health Services, has written that “to file a claim, the injury must be one on the Vaccine Injury Table’ (42 U.S.C. § 300aa-11(c)(1)(C)(i)), or ‘caused by a vaccine referred to in’ the act (42 U.S.C. § 300aa-11(c)(1)(C)(ii)). Thus, the law would not cover most types of infection caused by negligent administration of the vaccine, e.g., bacterial infection, hepatitis or HIV, because these are not listed in the Vaccine Injury Table’, nor are they caused by the vaccine.” Waters, “Legal Concerns Associated with the Vaccine Immunization Drive: The Public Health Perspective,” Oct. 6, 1993. The same analysis also applies to nerve damage caused by the negligent administration of a vaccine.
13. 42 U.S.C. § 300aa-11(a)(1).
14. 42 U.S.C. § 300aa-12(d)(2)(A).
15. 42 U.S.C. § 300aa-12(e)(1).
16. 42 U.S.C. § 300aa-12(f).
17. 42 U.S.C. § 300aa-12(d)(3)(B).
18. 42 U.S.C. § 300aa-15(a)(2).

19. 42 U.S.C. § 300aa-12(a)(4).
20. 42 U.S.C. § 300aa-15(d)(1).
21. 42 U.S.C. § 300aa-15(e)(1)(A).
22. National Vaccine Injury Compensation Program, “Monthly Statistics Report for March 7, 2000.”
23. Financial Review Subcommittee of the Advisory Commission on Childhood Vaccines, “Analysis of Vaccine Excise Tax Levels: An Update, June 7, 1993.”
24. Date from George Sharp, Austin Project.
25. Financial Review Subcommittee of the Advisory Commission on Childhood Vaccines, “Analysis of Vaccine Excise Tax Levels: An Update, June 7, 1993.”
26. Texas Health and Safety Code Annotated § 161.001(a) (Vernon Supp 1993).
27. Texas Health and Safety Code Annotated § 161.001(c) (Vernon Supp 1993).
28. Texas Family Code Annotated § 12.04(6) (Vernon 1986).
29. Texas Family Code Annotated § 35.011(a) (Vernon 1993).
30. Texas Family Code Annotated § 35.012(a) (Vernon 1993).
31. Texas Family Code Annotated § 35.011(a)(5).
32. Texas Family Code Annotated § 35.011(a)(6), 35.012(a)(5).
33. Texas Family Code Annotated § 35.011(a)(7)-(9).
34. Texas Family Code Annotated § 35.03(a) (Vernon Supp 1993).
35. Texas Health and Safety Code Annotated § 161.004(d)(1) (Vernon Supp 1993).
36. Texas Health and Safety Code Annotated § 161.004(d)(2) (Vernon Supp 1993).
37. Texas Civil Practice and Remedies Code Annotated § 84.003(1) (Vernon Supp 1991).
38. Texas Civil Practice and Remedies Code Annotated § 84.004(b) (Vernon Supp 1993).
39. Texas Civil Practice and Remedies Code Annotated § 84.003(2) (Vernon Supp 1993).
40. Texas Civil Practice and Remedies Code Annotated § 84.007(a) (Vernon Supp 1993).
41. 42 U.S.C. § 300aa-26(a), 42 U.S.C. § 300aa-14(a).

42. 42 U.S.C. § 300aa-26(c).
43. “Vaccine Information Pamphlets Here, But Some Physicians React Strongly,” JAMA 1992;267:2005.
44. 42 U.S.C. § 300aa-25(a).
45. 42 U.S.C. § 300aa-25(b)(1)(A).
46. 42 U.S.C. § 300aa-25(b)(1)(B).
47. 42 U.S.C. § 300aa-25(b)(2).



## **BUSINESS LIABILITY**

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- Q:** Do private businesses subject themselves to increased liability by allowing their premises to be used for immunizations?
- A:** No. This memorandum ignores any protection which may be afforded by the National Childhood Vaccine Injury Act, 42 U.S.C.A. § 300aa-1 through § 300aa-34 (West Supp. 1993). Briefly, this act establishes a no-fault system, which compensates individuals who have been injured by vaccines given by both the private and the public sector. Claimants may bypass the act and file suit in local courts but, by and large, have not. The number of claims filed in court has decreased significantly since the act was passed. Because this act is the primary source of protection for those sued due to harm caused by the immunization itself, this memorandum confines itself to liability of premises owners for incidents allegedly caused by some defect of the premises.

### **Texas Law**

Under general Texas negligence law, property owners owe a duty to three classes of persons: trespassers, licensees, and invitees. Most assuredly, children — and their guardians — seeking immunizations at malls or grocery stores would be classified as invitees, specifically business visitors, under Texas Premises Liability law.

For the duty property owners to business visitor invitees, Texas courts consistently quote the Restatement 2d of Torts which says, in part:

“A possessor of land is subject to liability for physical harm caused to his invitees by a condition on the land if, but only if, he (a) knows or by the exercise of reasonable care would discover the condition, and should realize it involves an unreasonable risk of harm to such invitees and... fails to exercise reasonable care to protect them against the danger” (at page 343) (Emphasis added).

As this duty extends beyond dangers property owners know about to those they should know about, the normal duty of property owners is the same with immunizations as with everyday business — to inspect the premises for defects or dangerous conditions, then correct those dangers or warn invitees about them. As stated in a 1988 case, Agricultural Warehouse, Inc. vs. Uvalde, “The owner has a duty to use reasonable care to keep the premises under his control in safe condition (at page 694).” Based on the cases in Texas, the nature of immunizations does not apply any more of a duty than “reasonable care” upon owners of malls or shopping centers who allow their premises to be used for immunizations.

According to one experienced insurance agent familiar with premises liability politics, private business would be covered under their standard commercial coverage for accidents caused by some conditions of the premises, which happened to persons on the premises for immunization. Each business should, of course, verify its coverage.

Some private businesses, such as grocery stores, that do not have a standard commercial policy may not be covered. Some grocery stores have policies written by surplus carriers which would not cover such “events” as an immunization drive on the store’s premises. In these cases,

businesses simply would need to pay a modest premium for additional coverage. A technician in the General Liability section of the Texas Department of Insurance confirmed standard commercial coverage would protect private business from premises liability during immunizations on their premises.

### **Conclusion**

The liability of premises owners for harm caused by a premises defect to persons on the premises for an immunization drive is the same as their liability to other business endeavors. Such losses are insured under most standard commercial liability policies and coverage can readily be obtained if it is not already included.

## LEGAL QUESTIONS RELATING TO REGISTERED NURSES (RNs) AND LICENSED VOCATIONAL NURSES (LVN's) ADMINISTERING VACCINES

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**Q1:** What is liability exposure for an RN or LVN who gives vaccines?

- A.** The liability exposure for RNs and LVNs is very small because of the extensive protections persons administering vaccines are afforded under federal and state laws. The federal Vaccine Injury Compensation Program provides no-fault protection for vaccine-related injuries and would cover most injuries from covered vaccines other than those caused by the RN's or LVN's negligence. State law affords additional protections that vary with the circumstances. Federal and state laws provide extensive liability protections for adverse reactions, usually the greatest source of liability concern, because of the potential seriousness of the injury and the inability to prevent the random adverse reaction. Some state laws even protect RNs and LVNs against allegations of negligence.

**Q2:** What specific liability protections are available to the RN or LVN who administers vaccines?

- A.** The RN's or LVN's liability protection is multi-layered protection. A basic layer of substantial protection is available in all circumstances and various additional layers of protection are available depending on the circumstances.

The first layer of protection is the federal Vaccine Injury Compensation Program. It provides no-fault liability protection for vaccine-related injuries associated with vaccines covered by the act. The federal law allows the petitioner to file a claim in civil court against the vaccine company and/or the vaccine administrator only after a claim with VICP has been rejected. The federal law also is not likely to apply if the injury is claimed to have resulted from the RN's or LVN's negligent administration of the vaccine (e.g., used a dirty needle, hit a nerve, failed to do any history or assessment of the patient, etc.). Even so, the act is likely to cover adverse reactions from covered vaccines.

If the federal law does not apply because negligence is alleged or because the injured person rejects the compensation awarded, the injured person would have to file suit in the state court against the LVN or RN. State law provides significant liability protections to the RN and LVN. Section §161.001 of the Texas Health and Safety Code provides for immunity from liability for persons administering immunizations unless the vaccine is administered negligently. This law covers all types of vaccines and applies to all circumstances in which vaccines are administered. Like the Vaccine Injury Compensation Act, Section § 161.001 covers adverse reactions. In addition, various other state laws provide additional protections, depending on the circumstances, under whose auspices the immunization program is conducted whether the RN or LVN is a volunteer, etc. Some of these would protect the RN or LVN even from allegations of negligence.

**Q3:** What is the RN's or LVN's protection when administering a vaccine not covered by the federal Vaccine Injury Compensation Act?

- A.** The RN or LVN would not be protected by the Vaccine Injury Compensation Act but would enjoy the protections available under state law. At a minimum, state law provides



immunity unless the vaccine was administered negligently. Additional protections would be available depending on the circumstances.

**Q4:** Where can I get more information about the Vaccine Injury Compensation Act and the state laws that might apply?

**A.** Both are discussed in detail under the sections addressing federal and state law. A number of questions in this section also provide more detailed information. The introduction to these materials also provides an overview of federal and state laws relating to the administration of vaccines.

**Q5:** How can an RN or LVN ensure the broadest possible liability protections when administering vaccines?

**A.** Frequently, immunization programs can be structured to maximize the application of various state laws providing immunity protections. Many programs probably could be structured such that administering the vaccine would be a duty performed in compliance with instructions of the Texas Department of State Health Services, and § 81.007 of the Health and Safety Code would protect against everything but gross negligence. Many programs could be set up under the auspices of a 501(c)(3) or (c)(4) tax-exempt organization, and the Texas Charitable Immunities Act would provide extensive immunity protections to RN and LVN volunteers. If a program is set up under the auspices of a school district, the special protections of the Educational Code should apply.

**Q6:** Could an RN or LVN be accountable to the Texas Board of Nurse Examiners (BNE) or Texas Board of Vocational Nurse Examiners (BVNE) respectively if a patient injury results from their administering a vaccine?

**A.** Yes, but no more so than in any other practice setting. Patient injury alone would not result in action by the BNE or BVNE. Rather, the RN or LVN would be subject to disciplinary action only for failure to comply with acceptable minimum standards of practice regardless whether patient injury occurs. Staff at the BNE and BVNE have indicated that minimum acceptable standards of practice would require:

- Properly assessing a client to determine if they are an appropriate candidate for the vaccine and the absence of contraindications;
- Appropriate teaching provided to patients;
- Ascertaining appropriate procedures to handle adverse reactions (EMS, medications to be administered, etc.);
- Appropriately responding to any adverse reactions.

**Q7:** What information, if any, must be provided to persons receiving a vaccine?

**A.** RNs and LVNs must provide the level of patient teaching and instruction required by safe nursing practice. The Vaccine Injury Compensation Act requires that certain information be provided about the risks and benefits of vaccines administered to children. The federal

government has prepared VISs (Vaccine Information Statements) providing this information. See section I, Q 26, 27, & 28 for the information to be provided under the federal act.

**Q8:** Should a physician issue an order for an RN or LVN to administer a vaccine?

**A:** Yes. Although the legal requirements for RNs and LVNs to administer vaccines are not entirely clear, certain aspects of any immunization program likely will require a physician's order. Having an appropriate physician order eliminates confusion whether legal requirements have been met.

**Q9:** If a vaccine is administered by an RN or LVN pursuant to a physician's order, is the physician liable if the RN or LVN administers negligently the vaccine?

**A:** Generally, no. When administering a vaccine ordered by a physician, RNs and LVNs are engaged in the practice of professional and vocational nursing respectively and are acting under the authority of their license. Physicians are not liable for RNs or LVNs who negligently practice nursing just as they are not liable for labs that negligently perform ordered tests.

Physicians can rely on RN or LVN licensure as assurance the nurse possesses a certain level of competency. Specifically, with respect to the administration of vaccines, physicians can rely on RN and LVN licensure as a reasonable basis for believing RNs and LVNs can administer vaccines competently. Of course, if a physician has reason to believe a particular RN or LVN lacks the competency to administer a vaccine, the physician could incur liability. However, the physician would not be liable for the negligence of the RN or LVN per se but rather for the physician's negligence in ordering a RN or LVN of questionable competency to give an immunization. Likewise, a physician employing the RN or LVN could incur liability, but that liability would be based on the employer-employee relationship and not on the physician-nurse relationship.

**Q10:** Can the physician's order be a standing order or protocol, i.e., for a patient population rather than a particular patient?

**A:** Yes. The order may need to describe the patient population unless a physician can reasonably assume an RN or LVN is knowledgeable about the population.

**Q11:** Should a physician's order or protocol for an RN or LVN to administer a vaccine follow a specific format?

**A:** Yes. The order should be in a format and contain information consistent with good medical and nursing practice. Standing orders or protocols for vaccines should:

1. Be signed and dated by the physician;
2. Identify the vaccines (including boosters) covered by the order;
3. Indicate that the patient should be assessed as an appropriate candidate to receive the vaccine, and for the absence of contraindications;

4. Indicate that appropriate procedures are in place for responding to any reactions to the vaccine; and

5. Order the administration of the specific medication or category of medication to be administered if a reaction occurs.

**Q12:** Must the physician know the RN or LVN who will administer the vaccine?

**A:** No. The physician can rely on the RN's or LVN's license as evidence that the RN or LVN is competent to administer a vaccine. See the response to Question 11 in this section for a more detailed discussion of the legal status of an RN or LVN administering a vaccine ordered by a physician.

**Q13:** Must the physician readily be available when the RN administers the vaccine or otherwise supervise the RN?

**A:** No. The actual administering of a vaccine ordered by a physician is a nursing act which RNs or LVNs perform under the authority of their license. A physician is not required to supervise an RN or LVN performing such a nursing act.

**Q14:** Should physicians delegate the administration of vaccines to RNs and LVNs?

**A:** The physician does not need to delegate to RNs or LVNs because they administer the vaccine under the authority of their licenses. See the response to Question 9 in this section for details of the legal status of RNs and LVNs administering vaccines ordered by a physician

**Q15:** Can an RN delegate the administration of a vaccine to an unlicensed person?

**A:** Yes, in certain circumstances. Since the administration of the vaccine is a professional nursing act, the RN can delegate it if permitted by the BNEs delegation rules. However, those rules currently don't permit such delegation.

**Q16:** What is the liability exposure for RNs if they delegate the administration of a vaccine to an unlicensed person and the patient is injured?

**A:** The delegation of the administration of a vaccine by an RN currently is not permitted. If the BNE amends its rules to permit such delegation, the RN's liability exposure would be the same as when the RN administers the vaccine. The RN could be found liable for the negligence of the unlicensed persons. Delegation can be analogized to "loaning ones license" because the delegated act is performed under the authority of the RN's license. The RN remains accountable for acts done under the authority of his or her license. If an RN delegates in compliance with the BNE rules, the RN would not be subject to disciplinary action by the BNE but would be liable to the patient for any injury. The RN also would have the same legal protections available as if he or she had administered the vaccine.

**Q17:** Can the RN authorize Emergency Medical Services (EMS) personnel, such as a paramedic, to administer a vaccine?

**A:** Texas law limits the certification of EMS personnel to pre-hospital transportation. EMS personnel administering vaccines would be considered unlicensed persons. The BNE delegation rules would apply, which currently do not permit RNs to delegate the administration of a vaccine.

**Q18:** Can LVNs delegate the administration of vaccines to unlicensed persons?

**A.** No, not without specific authorization from the Board of Vocational Nurse Examiners (BVNE). Currently, the BVNE has no rules that authorize LVNs to delegate the administration of a vaccine to an un-licensed person. Because the Vocational Nurse Act is a title act that regulates only the use of the title LVN and not the practice of vocational nursing, the BVNE may not have the authority to adopt such a rule. However, in the absence of such a rule, LVNs may not delegate the administration of a vaccine.

**Q19:** Should RNs or LVNs have professional insurance to participate in an immunization program?

**A.** Because of the low liability exposure in administering vaccines, the decision whether to purchase or not purchase professional liability insurance probably should be determined by the RN's or LVN's employer and not on the basis of his or her participation in an immunization program. However, RNs and LVNs should be aware that their employers liability insurance is unlikely to provide coverage outside of their employment setting. RNs and LVNs also should be aware that having coverage can help insure the availability of funds to cover an injured person's medical expenses.

**Q20:** How valid is a letter from a local health department that an RN or LVN will not incur liability exposure for participating in a Community Immunization Campaign?

**A.** A letter is not effective. The RN's or LVN's liability is determined by the extent of protections under federal and state law. However, as indicated, those protections are extensive.



## **OTHER STATE LAWS RELATING TO IMMUNIZATION LIABILITY PROTECTIONS**

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**Q1:** Does the Vaccine Injury Compensation Act provide all the liability protections needed for vaccine-related injuries?

**A.** The Vaccine Injury Compensation Act provides extensive protections. However, they would not apply in some situations. First, the act covers only vaccines for diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, Hib, Hepatitis B, and any vaccine administered at the same time as a covered vaccine. State law would cover injuries resulting from other vaccines. Second, the federal law covers only vaccine-related injuries such as adverse reactions. The law would not cover injuries caused by the negligent administration of the vaccine such as using a dirty needle or damaging a nerve. Finally, the act permits a person to reject the compensation awarded and file suit in state court. In these situations, protections afforded under state law to persons involved with immunization programs become determinative of liability exposure. Fortunately, state law grants extensive liability protections to persons participating in immunization programs, such as Community Immunization Campaigns.

**Q2:** What specific liability protections are available under state law to persons participating in immunization programs?

**A.** Depending on the circumstances, a number of different laws may apply, such as whether the program is conducted under the auspices of a school district or whether the person administering the vaccine is a volunteer. In many instances, more than one law may apply. The following is a brief overview of the main ones.

- Section § 161.001 of the Texas Health and Safety Code provides immunity from liability for anyone administering or authorizing the administration of a required vaccine. It does not cover the negligent administration of a vaccine. However, the law would cover adverse reactions, usually the greatest liability concern. This law applies to all circumstances in which vaccines are administered and to all types of vaccines. In short, this law protects anyone participating in an immunization program.

Various state laws provide additional protections depending on the circumstances. Some of these even provide protections against allegations of negligence.

- If the vaccine is administered as part of a program instructed by the Texas Department of State Health Services, Section § 81.007 of the Health and Safety Code provides private individuals with protection from any liability except for gross negligence. A private person is not defined but should be anyone other than a public/government employee.
- If the vaccine is administered under the auspices of an immunization program sponsored by a charitable or social welfare organization, i.e., a tax exempt organization or one that would qualify for exemption under 501(c)(3) or 501(c)(4) of the Internal Revenue Code, the Texas Charitable Immunity and Liability Act of

1987 (Chapter 84, Civil Practices and Remedies Code) provides for liability immunity for volunteers. The organization itself and its employees also are covered if the organization carries a certain level of insurance. Health care providers normally are not covered by the act except as volunteers.

- If the vaccine is administered under the auspices of a school district, employees and professional volunteers are provided immunity under Sections § 21.912 and § 21.935 of the Education Code. To help ensure that this law applies, the immunization program should be set up as a school district program and the administration of vaccines should be included as part of the professional employee's job description. In this situation, professional employees and volunteers would be physicians, RNs, LVNs, physician assistants, and other licensed or certified health care professionals. More complete information can be found in the following section.
- Physicians, RNs, LVNs, physicians assistants, and other persons employed by the Texas Department of State Health Services, local health department, or other government entity are entitled to certain governmental immunity protections.
- Physicians, advanced nurse practitioners, and physician assistants providing more than 10% charity care are entitled to indemnification under Chapter 110 of the Civil Practice and Remedies Code if they have professional liability insurance. That law has specific requirements about charity care, notice, etc. This law does not protect against liability but rather addresses payment issues if a suit is filed.

**Q3:** What constitutes negligence and gross negligence?

- A. Negligence is the breach of a duty of care. Health care professionals have a duty of care to administer vaccines in a careful and reasonable way. Examples of negligence in administering vaccines include using a dirty needle, reusing a needle, damaging a nerve, failing to take an appropriate history, administering the wrong vaccine, and administering a vaccine that is contraindicated.

**Q4:** How can I find out more about the state laws that might apply?

- A. The introduction to these materials includes a general discussion about liability protections and includes a table comparing the protections of the various laws.

**Q5:** What can be done to help ensure the broadest possible liability protections for persons participating in immunization programs?

- A. Immunization programs frequently can be structured to maximize the application of the various state laws providing immunity protections. Many programs probably could be structured such that administering vaccines would be a duty performed in compliance with instructions of the Texas Department of State Health Services, and § 81.007 of the Health and Safety Code would protect against everything but gross negligence. Many programs could be set up under the auspices of a 501(c)(3) or (c)(4) tax-exempt organization and the Texas Charitable Immunity and Liability Act of 1987 would provide

extensive immunity protections to volunteers. If a program were set up under the auspices of a school district, the special protections of the Education Code would apply.

**Q6:** Would a local coalition set up for a Community Immunization Campaign be considered a “charitable organization” for the purpose of the Charitable Immunity and Liability Act?

**A.** Yes, if a local coalition qualifies as a “charitable organization” as defined by the act. Generally, the act defines a “charitable organization” as one that is tax-exempt under sections 501(c)(3) or (c)(4) of the Internal Revenue Code or would qualify for such exemption because it is organized exclusively for charitable, educational, scientific, or religious purposes or for the promotion of social welfare. Promotion of social welfare is promotion of the common good and general welfare of the people in a community. A local coalition organized solely for the purpose of supporting a Community Immunization Campaign should meet the definition of a “charitable organization.”

Examples of organizations likely to be exempt under 501(c)(3) are churches, PTAs, colleges, nonprofit hospitals, and other charitable organizations. Volunteers would need to verify that the organizations listed are exempt under the indicated provisions, section 501(c)(63) or (c)(4).

**Q7:** Will professionals administering vaccines be covered under existing liability insurance such as the city-county or school districts?

**A.** Coverage depends on the local liability insurance policy. Persons should check with the local governmental entity or school district as to what coverage exists.

**Q8:** Does the Good Samaritan Act apply to vaccine administration?

**A.** No, the Good Samaritan Act applies only to emergencies and would appear not to apply to immunizations.





## IMMUNIZATION IN THE SCHOOLS

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- Q1:** What liability do school districts face when allowing school premises to be used for the administration of vaccines?
- A.** The Texas Tort Claims Act protects school districts from all liability for negligence unless it involves the use or operation of a motor vehicle (Texas Civil Practice and Remedies Code § 101.051). School districts risk little, if any, liability when they allow immunization drives on school grounds. School districts are protected from suit by governmental immunity.
- Q2:** If the school district allows school property to be used by an outside organization for giving vaccinations, does the school district have any liability for vaccinations administered by an outside organization?
- A.** Because school districts have the ability under the Education Code to lease or allow the use of their premises by outside parties and because school districts are almost always immune from suits for negligence, a suit of this type would likely be dismissed. See also Dillard v. Austin, ISD, 806 S. W. 2d 589 (Tex. App.-Austin 1991, writ denied).
- Q3:** What liability would a school district have if its employees were involved in the negligent administration of vaccines?
- A.** The Texas Tort Claims Act protects school districts in the case of an alleged negligent administration of vaccines.
- Q4:** How then is an individual school employee protected from liability when administering shots?
- A.** A school district employee will be shielded from liability for negligence if the employee is considered a “professional” acting within the scope of this duty.

For the purpose of determining individual liability for negligence, professional employees include “superintendents, principals, classroom teachers, supervisors, counselors, and any other person whose employment requires certification and an exercise of discretion” [Texas Education Code § 21.912(d)]. The requirement of certification has been interpreted liberally by the Texas Supreme Court to include certifications other than teaching certificates. In LeLeaux v. Hampshire-Fannett, ISD, 835 S. W.2d 49 (Texas 1992), a school bus driver was determined to be immune from suit for negligence because he fell within the definition of a “professional employee.” The Education Code requires bus drivers to be certified and the court viewed that professional license as sufficient to place the driver within the protection of Section § 21.912. Although the LeLeaux court offered no guidance as to what other licenses also might qualify an employee as “professional,” one can safely assume a registered nurse employed by a school district would fall within the definition. In fact, in two other cases, school nurses have received professional employee protection by the stipulation of the parties. See Duross v. Freeman, 831 W. W.2d 354 (Texas App.-San Antonio 1992) and

Hopkins v. Spring ISD, 736 S.W. 2d 617 (Texas 1987).

The Education Code provides that a professional employee will not be personally liable for any act involving the exercise of discretion which is incident to or performed within the scope of duty, except when he has used excessive force in the discipline of a student or negligence resulting in bodily harm to a student [Texas Education Code § 21.912(b)]. Although the last phrase of this statute appears to encompass a negligent vaccination, the Texas courts have read the statute to apply solely to discipline situations [Barr v. Bernhard, 562 S.W. 2d 844 (Texas 1978)]. As a result, a professional employee who negligently harms a student through a vaccination will not be liable.

In summary, employees whose employment requires certification or licensing and an exercise of discretion are protected from liability arising from the administration of immunizations.

- Q5:** What liability do volunteers risk when they assist in administering immunizations?
- A.** Volunteers are protected from liability for ordinary negligence in much the same way as school employees. Volunteers are defined in the Education Code as persons rendering services on behalf of a school district on school premises without compensation [Texas Education Code § 21.935(a)]. A volunteer is protected to the same extent as a professional employee under Education Code § 21.912(b). Volunteers will not be personally liable for any act within the scope of their duties, except an act involving the negligent disciplining of a student. Like professional employees covered by the same statute, volunteers can avoid liability by having immunizations specifically included in a description of duties. Volunteers will not be shielded from personal liability if their acts constitute gross negligence or intentional misconduct [Texas Education Code § 21.912(c)].

In conclusion, school districts, their volunteers, and employees appear well insulated from suits arising out of negligent vaccinations so long as they are acting within the scope of their duties and are not grossly negligent. Texas has an established policy of protecting schools and volunteers who perform this and other beneficial services. As a result, judgments against school districts and school personnel are nearly impossible to obtain. A well-informed plaintiff will choose to file under the National Childhood Vaccine Injury Compensation Fund instead of another remedy.



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