

Administration of Immunizations in Louisiana

REPORT PREPARED IN RESPONSE TO SENATE RESOLUTION 122 (SR
122) OF THE 2011 REGULAR SESSION

February 2012

This report provides the information requested by Senate Resolution 122 of the 2011 Regular Session. The working group includes representatives from the Louisiana Department of Health and Hospitals, the Louisiana State Board of Medical Examiners, the Louisiana Board of Pharmacy, and other stakeholder groups.

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Executive Summary

Immunizations when used appropriately can make serious diseases disappear for individuals and protect communities. This decreases the pain and suffering from contagious illnesses in individuals, and significantly reduces the burden to the health care system.

Despite many successes, immunization has a long way to go nationally and in Louisiana, especially in some subgroups. There are many barriers which prevent optimal vaccination rates, including access to a provider who gives certain vaccines. Although trained and credentialed pharmacists are currently allowed to administer vaccinations with a written physician prescription in Louisiana, Senate Bill 60 of the 2011 Regular Session tried to address one of these barriers by enhancing access to adult vaccines by expanding the pharmacy practice act. Senate Bill 60 sought to increase the number of vaccines which could be administered by a pharmacist using standard national protocol rather than a prescription. This legislation did not seek to limit the practice of any other healthcare providers in the state, but instead tried to enhance current pharmacist practice to the benefit of the citizens of Louisiana.

The effectiveness of the expanded roles for pharmacists was demonstrated by Louisiana Act 287 of the 2010 Regular Session, which allowed trained and credentialed pharmacists in Louisiana to administer influenza vaccines to qualified individuals without a physician prescription. This practice is now the “norm”, and has significantly improved the influenza vaccination rates in Louisiana.

Several objections to Senate Bill 60 were raised in the legislative session, including questioning the training of vaccinating pharmacists, reporting, handling of emergencies, and age range of those they were allowed to vaccinate. This report seeks to educate the Louisiana Senate and House Committees on Health and Welfare of the current practice of immunization service delivery in Louisiana, and across the country.

1. Senate Resolution 122 / Senate Bill 60

Vaccines have been highly effective in eliminating or significantly decreasing the occurrence of many once-common diseases. The provision of immunization services has traditionally been done at pediatric offices and public health units, as most vaccines were recommended only for children. Over time, however, the number, complexity, and age range of recommended vaccines has expanded. Now, not only are there numerous vaccines and combinations of vaccines for children, but increasing numbers of vaccines for adolescents, young adults, adults, and seniors. These adolescents and adults, however, tend not to access preventive health services at regular providers, instead seeking care primarily when ill.

Senate Resolution 122 of the 2011 session seeks to gain more information on alternative and non-traditional providers of vaccinations, most notably the community pharmacist. Pharmacists have long been trained to become vaccinators, and have served community physicians by providing immunizations by prescription. This report seeks to inform the Louisiana House and Senate Health and Welfare Committee members on vaccine delivery in Louisiana and other states where pharmacists are providers of vaccination services, under various scenarios.

Senate Bill 60 was presented in the 2011 legislative session, and sought to increase access to adult vaccinations by expanding the role of pharmacists as community vaccinators.

A. Senate Resolution 122

Regular Session, 2011
ENROLLED
SENATE RESOLUTION NO. 122
BY SENATOR MILLS

A RESOLUTION

To urge and request the Department of Health and Hospitals, the Louisiana State Board of Medical Examiners and the Louisiana Board of Pharmacy to jointly study certain aspects of the administration of immunizations and to jointly present their findings to the Senate and House committees on health and welfare.

WHEREAS, it is of the utmost importance to the citizens of Louisiana that access to care is maximized to the greatest degree possible while still ensuring the highest degree of quality and competence from health care providers; and

WHEREAS, the administration of immunizations is one area where it is beneficial for further study so that the Senate and House committees on health and welfare can make sound recommendations and decisions as to whether an expanded array of health care providers should be allowed to administer immunizations in this state.

THEREFORE, BE IT RESOLVED that the Senate of the Legislature of Louisiana does hereby urge and request the Department of Health and Hospitals, the Louisiana State Board of Medical Examiners, and the Louisiana Board of Pharmacy to study certain aspects of the administration of immunizations and to jointly present their findings to the Senate and House committees on health and welfare.

BE IT FURTHER RESOLVED that the study shall include, but not be limited to, the following:

(1) The scope and rate of CDC-recommended immunizations proactively administered by all health care providers, including specially trained pharmacists, in Louisiana. This shall be identified by provider type and by health care setting.

(2) A comprehensive list of allowable CDC-recommended immunizations administered in other states by various provider types.

(3) A comparison of immunization rates where pharmacists are able to administer such immunizations, comparing rates when a physician's prescription is required and where the same immunization may be administered under CDC protocol.

(4) A comprehensive review of accessibility issues in obtaining immunizations in various health care settings.

(5) A comprehensive review of the training which is available and its adequacy for non-physician immunizers.

BE IT FURTHER RESOLVED that the Department of Health and Hospitals, the Louisiana State Board of Medical Examiners, and the Louisiana Board of Pharmacy study certain aspects of the administration of immunizations and jointly present their findings to the Senate and House committees on health and welfare no later than February 1, 2012.

BE IT FURTHER RESOLVED that a copy of this Resolution be transmitted to the secretary of the Department of Health and Hospitals, the Louisiana State Board of Medical Examiners, and the Louisiana Board of Pharmacy.

B. Senate Bill 60

DIGEST

Mills (SB 60)

Present law allows a pharmacist to administer the influenza vaccination to any person seven years of age or older.

Proposed law retains present law but expands the types of vaccinations which can be administered by a pharmacist to persons 18 years of age or older to include the following:

(1) Pneumococcal

(2) Zoster

(3) Tetanus and Diphtheria Toxoids Adsorbed for Adult Use (Td)

(4) Tetanus Toxoids, Reduced Diphtheria Toxoids and Acellular Pertussis Vaccine Adsorbed (**Tdap**) (Tdap)

Effective upon final adoption of certain rules and regulations promulgated in accordance with the APA by the La. Board of Pharmacy pursuant to the proposed law.

(Amends R.S. 37:1218)

Summary of Amendments Adopted by Senate

Committee Amendments Proposed by Senate Committee on Health and Welfare to the original bill.

1. Adds provision which requires the administration of immunizations by a pharmacist to be in conformance with guidance published in the Louisiana State Immunization Policies and Procedures Manual.
2. Changes the age, at which the pharmacist may administer a vaccine for Pneumococcal, Zoster, Tetanus and Diphtheria Toxoids Adsorbed for Adult Use (Td), and Tetanus Toxoids, Reduced Diphtheria Toxoids and Acellular Pertussis Vaccine Adsorbed (Tdap) to a person without prescription or medical order from 7 to 18 years of age.
3. Technical amendments

2. Vaccines

Vaccine preventable disease levels are at or near record lows. Most infants and toddlers have received all recommended vaccines by age 2. However, many adolescents and adults are under-immunized, missing opportunities to protect themselves against diseases such as shingles, pertussis, influenza, and pneumococcal disease. The Centers for Disease Control and Prevention (CDC) work closely with public health agencies and private partners to improve and sustain immunization coverage and to monitor the safety of vaccines.

A. Vaccine Recommendations

The charts as Appendices A, B and C depict the recommended vaccines and schedules for children, adolescents, and adults in the United States according to the Advisory Committee on Immunization Practice (ACIP) and the State of Louisiana. The full vaccine abbreviations and a listing of all vaccines are included as Appendix D. The following is a brief list of some of the adolescent and adult vaccinations and the diseases they prevent:

Tdap	Combined Tetanus, Diphtheria, Tetanus
Td	Adult Tetanus and Diphtheria
HPV	Human Papillomavirus (cervical cancer)
MCV	Meningococcal (meningitis)
Influenza	Influenza (the flu)
PPSV	Pneumococcal (pneumonia)
HepA HAV	Hepatitis A
HepB HBV	Hepatitis B
IPV	Polio
MMR	Measles, Mumps, Rubella
Zoster	Shingles

B. Side Effects of Vaccines

Any vaccine can cause side effects. For the most part these are minor (for example, a sore arm or low-grade fever) and go away within a few days. More serious side effects are rare, and potentially life-threatening side effects (allergic reactions) are extremely rare. Listed in Appendix E are vaccines licensed in the United States and side effects that have been associated with each of them. This information is copied directly from CDC's Vaccine Information Statements, which in turn is derived from the Advisory Committee on Immunization Practices (ACIP) recommendations for each vaccine.

Vaccines are continually monitored for safety, and like any medication, vaccines can cause side effects. However, a decision not to immunize also involves risk, and could put the person and others who come into contact with him or her at risk of contracting a potentially deadly disease.

Summary points:

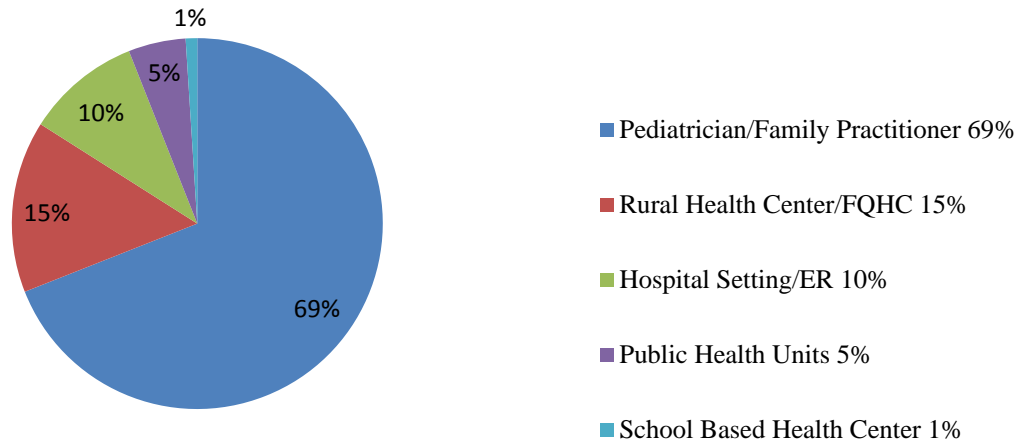
- Any vaccine can cause side effects, most of which are minor, such as sore arm or low grade fever, and go away within a day or so.
- More moderate side effects do occur, such as fever >105, but occur rarely (>1:15,000) and mostly resolve without intervention.

- Severe life-threatening reactions occur, but are very rare (1:1,000,000), and usually occur within minutes of receiving the injection.
- Any side-effect or suspected adverse event following vaccination (<24hrs) needs to be immediately reported to the Vaccine Adverse Event Reporting System (VAERS).

3. Vaccine Delivery by Location/Provider Types

A. Vaccines for the Child (VFC) Population in Louisiana

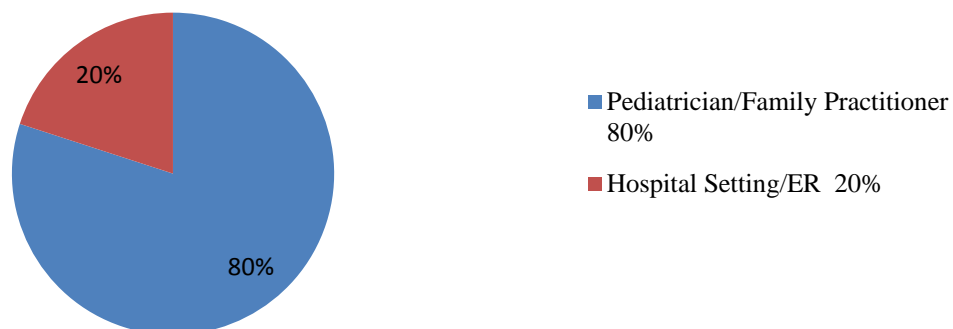
VFC Children in LA, place of vaccination



Vaccine for Children is a federal program which provides vaccines at no cost to children from birth through age 18 years of age that are Medicaid eligible, uninsured or under-insured, or American Indians/Alaskan Native. The above data represents the VFC population in Louisiana and where VFC vaccines are received. This data is from the Louisiana Immunization Registry for Kids Statewide (LINKS) in 2010.

B. Non-VFC Children in Louisiana

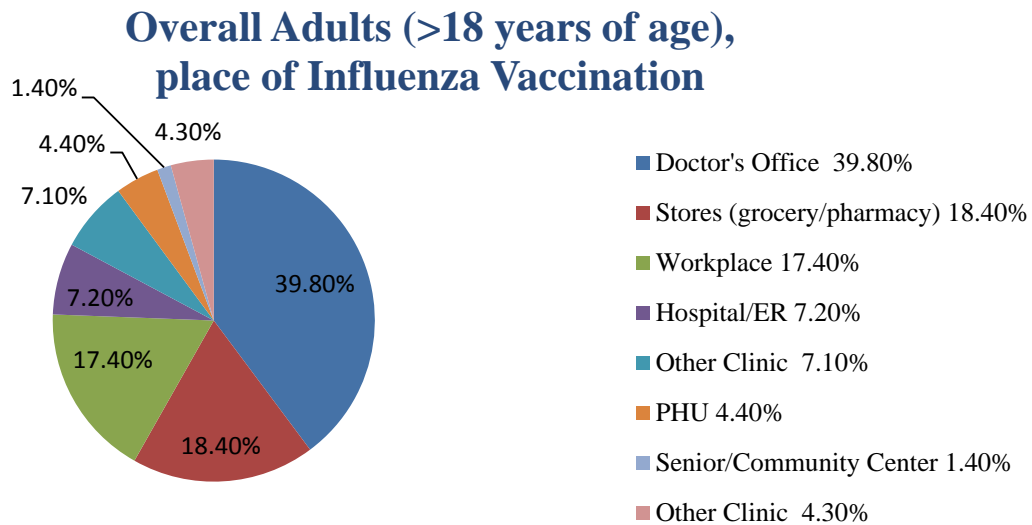
Non VFC children to age 18 years of age, place of vaccination (estimate from LINKS)



Non-VFC children are children 0 to 18 years of age that have insurance coverage for vaccinations, or choose to pay for vaccinations out of pocket. This data is estimated from the data in the Louisiana Immunization Network for Kids Statewide (LINKS) system, 2010.

C. Adults

Data on where adults receive vaccinations is very limited, due to multiple factors. These factors include lack of a reporting system, vaccinations that have been recommended for just a few years, and lack of research. This does not hold, however, for influenza vaccination in adults which has been widely researched in the past few years.



This data is a compilation of national research on where adults over 18 years of age received their influenza vaccinations from 2007-2010.

4. Other States Allowing Pharmacists Vaccinators

A. States and Current Vaccination Practices in Regard to Pharmacists

- Every state permits pharmacists to administer influenza vaccine by protocol with age limitations.
- There are 30 states that currently allow pharmacists to administer all CDC recommended vaccines by protocol with age limitations.
- There are an additional 10 states that allow pharmacists to administer influenza plus at least one other vaccine with age limitations.

State	Minimum Age Restrictions	Vaccines by Protocol	Vaccines by Rx Only
Alabama	7 years of age	Influenza	All CDC Recommended Vaccines
Alaska	7 years of age	All CDC Recommended Vaccines	
Arizona- Prescriptive Authority	Under Protocol: 7 years of age for Influenza and 18 years of age and older for all other vaccines allowed under protocol With RX: 7-17 years of age for Flu, Pneumonia, Td, Tdap, Hepatitis A and B, HPV, Meningitis, Polio, MMR, Varicella and Zoster; 18 years and older Japanese Encephalitis, Rabies, Typhoid (Live and Inactivated) and Yellow Fever	Influenza, Pneumonia, Td, Tdap, Hepatitis A and B, HPV, Meningitis, Polio, MMR, Varicella and Zoster	Designated Travel Vaccines- Japanese Encephalitis, Rabies, Typhoid (Live and Inactivated) and Yellow Fever
Arkansas	Under Protocol: 7 years and older for influenza, 18 years of age and older for all other immunizations With RX: 7-18 years of age all immunizations	All CDC Recommended Vaccines	
California	7 years of age	All CDC Recommended Vaccines	
Colorado	7 years of age	All CDC Recommended Vaccines	
Connecticut	18 years of age	Influenza, Pneumonia and Zostavax	
State	Minimum Age Restrictions	Vaccines by Protocol	Vaccines by Rx Only

Delaware	18 years of age and any person who will receive an adult dose	All CDC Recommended Vaccines	
District of Columbia	18 years of age	Influenza and Pneumonia	All CDC Recommended Vaccines
Florida	18 years of age	Influenza Only	
Georgia	13 years of age with inactivated flu	Influenza Only	Pneumonia and Zoster
Hawaii	18 years of age	All CDC Recommended Vaccines	
Idaho	7 years of age	All CDC Recommended Vaccines	
Illinois	14 years of age	All CDC Recommended Vaccines	
Indiana	14 years of age and 7 - 13 years of age with Rx	Influenza and Zostavax	All CDC Recommended Vaccines
Iowa	18 years of age and above	Influenza and Pneumonia	All CDC Recommended Vaccines
Kansas	7 years of age for Influenza and 18 years of age for all other Vaccines	All CDC Recommended Vaccines	
Kentucky	9 years and older for influenza under protocol, 14 years of age all other vaccines, 7-9 for flu and 7-14 for other immunizations by prescription	All CDC Recommended Vaccines	
Louisiana- Prescriptive Authority	7 years of age	Influenza Only	All CDC Recommended Vaccines
Maine	9 years of age for influenza and 18 years of age for Pneumonia, Zoster, Td and Tdap	Influenza, Zoster, Pneumonia, Td, Tdap,	
Maryland	9 years of age for influenza only, 18 years of age	Influenza	Pneumonia and Zoster
Massachusetts	18 years of age	Influenza	
Michigan	7 years of age	All CDC Recommended Vaccines	

State	Minimum Age Restrictions	Vaccines by Protocol	Vaccines by Rx Only
Minnesota	19 years of age	All CDC Recommended Vaccines	
Mississippi	7 years of age	All CDC Recommended Vaccines	
Missouri	12 years for protocol and 7 years of age with Rx	Influenza, Pneumonia, Zoster, Meningococcal	All CDC Recommended Vaccines
Montana	12 years of age for influenza only, 18 years of age	All CDC Recommended Vaccines	
Nebraska	7 years of age	All CDC Recommended Vaccines	
Nevada	7 years of age	All CDC Recommended Vaccines	
New Hampshire	7 years of age	Influenza, Pneumonia, and Zostavax	
New Jersey	18 years of age	All CDC Recommended Vaccines	
New Mexico- Prescriptive Authority	7 years of age	All CDC Recommended Vaccines	
New York	18 years of age	Influenza and Pneumonia	
North Carolina	14 years of age for Influenza Only, 18 years of age for all others	Influenza	Pneumonia and Zoster
North Dakota	7 years of age	All Vaccines	All Vaccines
Ohio	14 years of age for influenza, 18 years of age for all other vaccines listed	Influenza, Pneumonia, Hepatitis, Tdap, Td, Meningitis	Zostavax
Oklahoma	7 years of age	All CDC Recommended Vaccines	
Oregon- Prescriptive Authority	11 years of age	All CDC Recommended Vaccines	
Pennsylvania	18 years of age	All CDC Recommended Vaccines	
Puerto Rico- Prescriptive Authority	18 years of age	Influenza, Pneumonia, Td, Tdap	All CDC Recommended Vaccines
Rhode Island	9 years of age for influenza under protocol, 18 years of age all other vaccines	All CDC Recommended Vaccines	

State	Minimum Age Restrictions	Vaccines by Protocol	Vaccines by Rx Only
South Dakota	18 years of age	Influenza	All CDC Recommended Vaccines
Tennessee	7 years of age	All CDC Recommended Vaccines	
Texas	Under Protocol: 7 years of age for Influenza, 14 years of age for all other Vaccines/ With Rx: 7 to 13 years of age for all other Vaccines	All CDC Recommended Vaccines	
Utah	7 years of age	All CDC Recommended Vaccines	
Vermont	18 years of age	All CDC Recommended Vaccines	
Virginia	7 years of age for Influenza and 18 years of age for all other Vaccines. Live Influenza Restriction - Pharmacists can administer to patients 7 years of age and older if no asthma/wheezing in the past 12 months	All CDC Recommended Vaccines	
Washington	7 years of age	All CDC Recommended Vaccines	
West Virginia- Prescriptive Authority	18 years of age	Influenza, Pneumonia	
Wisconsin	7 years of age	All CDC Recommended Vaccines	
Wyoming - Prescriptive Authority	19 years of age	Influenza, Pneumonia, Td, Tdap, MMR, Varicella, Hepatitis A and B, Meningitis, HPV, and Zoster	

B. Pharmacist Authority to Administer Vaccines in Neighboring States

Protocols vary by state. Listed below are a few examples of state protocols.

In Texas, a prescription is not required for a person 7 years of age and older for influenza vaccination. For persons 14 and older a written protocol from a physician is required for all other vaccinations. For

patients less than 14 years of age pharmacists may administer vaccinations upon a referral from a physician who has an established physician-patient relationship.¹

In Arkansas, general written protocol (not patient specific) is required for persons 18 and older. For influenza vaccination a general written protocol is required for persons over 7 years of age. For all other vaccinations in Arkansas, persons 7 to 18 require a patient specific order or prescription.² Vaccinations must be reported to the prescribing physician.³

In 1996 the Mississippi Pharmacists Association (MPhA) was asked by the Mississippi Department of Public Health to have pharmacists help with severe disparities in adult influenza and pneumococcal rates. MPhA contacted APhA for assistance, leading to the development of a national training program for pharmacists based on core competencies learned by public health nurses and military medics.^[12] Trained and credentialed pharmacists in Mississippi are allowed to administer all vaccines to all ages pursuant to a physician's prescription or written protocol.⁴

¹ Texas Administration Code Title 22 Part 15 chapter 295 rule 295.15
[http://info.sos.state.tx.us/pls/pub/readtac\\$ext.ViewTAC?tac_view=4andti=22andpt=15andch=295](http://info.sos.state.tx.us/pls/pub/readtac$ext.ViewTAC?tac_view=4andti=22andpt=15andch=295)

² Arkansas Senate Bill 130 <http://www.arkleg.state.ar.us/assembly/2011/2011R/Bills/SB130.pdf>

³ Arkansas 30 Medical Practices Act, § 17-95-201

⁴ Mississippi Pharmacy Practice Act Mississippi Code of 1972 as Amended Chapter 021 of Title 73

5. Comparable Immunization Rates from Other States Allowing Pharmacists to Vaccinate

SR 122 asks the workgroup to compare immunization rates in states that allow pharmacists to vaccinate versus rates in those that do not. Unfortunately, we could not locate valid comparisons of these rates for multiple reasons. First, most states only have very accurate rates for pediatric populations, whereas there are only a few states that allow pharmacists to vaccinate very young children.

Secondly, states that have allowed pharmacists to vaccinate using CDC/ACIP criteria have only done so for a short time, most not more than 5 years, whereas immunization rates take up to 3-4 years to assess. Additionally, data sources for older populations and new vaccines simply do not exist yet. There are a multitude of factors that go into an immunization “rate”, only one of which is access to the vaccinations. Even if valid comparisons existed, the differences could be due to any number of reasons, rather than simply if pharmacists could vaccinate by protocol or not. Therefore, we have included below a number of measures that we feel reflects the impact that allowing pharmacists to vaccinate can have.

The table below lists adult influenza vaccination rates pre and post legislation that allowed Louisiana pharmacists to administer influenza vaccinations without a physician prescription. Since allowing pharmacists to vaccinate against influenza, Louisiana’s influenza vaccination rate for those 18-49 years of age high risk increased by 18.4%, while the rest of the nation only improved by 3.9% during the same period. People over 50 in Louisiana have also increased their influenza vaccination rate when compared to the rest of the country.

	2008 18-49 High Risk	Others 18-49	All 50-64	≥65
US 2007	35.1	23.4	42	72.1
US current	39	30.5	44.5	66.6
% change	+3.9	+7.1	+2.5	-5.5
LA 2008	36.9	28.8	43.3	70.2
LA current	55.3	35.6	48.9	73.8
% change	+18.4	+6.8	+5.6	+3.6
LA vs. US	+14.5	-.3	+3.1	+9.1

Pharmacists have been allowed to vaccinate against influenza since 2009. During the 2009 H1N1 campaign, they vaccinated 27,544 persons, according to the LINKS registry, in which they were required to report all H1N1 vaccinations. For the first half of 2010, pharmacists were not required to report to LINKS, but when Act 287 was passed, they again began reporting. Therefore, the 2010 estimate of influenza vaccinations (although more than 40,000 reported) by pharmacists is an underestimate and does not reflect the actual total (estimated >200,000). During 2011, to date, pharmacists have vaccinated over 110,000 individuals this flu season.

6. Barriers to Vaccination

Vaccines have been highly effective in eliminating or significantly decreasing the occurrence of many once-common diseases. Barriers to immunization are a significant factor in low vaccination rates and the rising incidence rates of some vaccine-preventable diseases. Cost, reduced accessibility to immunizations, increasingly complex childhood and adolescent/adult immunization schedules, and increasing focus on the potential adverse effects of vaccines all contribute to difficulty in meeting national and state immunization goals.

The following table lists many of the common barriers to vaccination, listed by system, provider, and patient barriers.⁵

System Barriers	<ul style="list-style-type: none"> • Supplies of some vaccines have been inadequate, often due to manufacturing capacity • Vaccine distribution issues • Limited, inadequate or no insurance coverage for vaccines • Programs (such as VFC) lack provider participants
Provider Barriers	<ul style="list-style-type: none"> • Providers are unclear about vaccine indications and contraindications, due to number of vaccines, evolving recommendations and new combinations • Clinicians may be reluctant to administer multiple vaccines concurrently • Maintaining vaccines is not cost effective for clinicians • Clinicians may lack appropriate storage capacity • Limited access to a child’s previous vaccine records constrains clinicians • May miss immunization opportunities when children visit for other reasons • Lack of, or expense of using a reminder/recall system to inform both providers and parents when vaccines are due • Limited hours of operation at traditional health care providers such as PCP or Pediatrician

⁵ <http://www.pharmacytimes.com/publications/issue/2011/August2011/Removing-Barriers-to-Childhood-Immunization>

Patient/Parent Barriers	<ul style="list-style-type: none"> • Patients/parents may not understand that vaccines prevent disease, or the seriousness of the diseases • Perceived side effects from vaccinations • Pain or fear of pain of the shot • Parents/patients may have trouble understanding the complex immunization schedule • Parents may have logistical problems (limited providers in an area, transportation issues, inconvenient clinic hours or locations) • Unable to locate certain vaccines at their regular provider • Unable to get a timely appointment • Mistaken assumptions (adults don't need vaccines) • Personal physician doesn't recommend vaccinations • Adolescents/adults rarely make preventive health visits • Can't afford office visit • Don't have/think they need/can't afford PCP
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Health Professional Shortage Areas (HPSAs), formerly Health Manpower Shortage Areas, are based upon criteria set forth under Section 332 of the Public Health Service Act. These regulations, originally published in the November 17, 1980, Federal Register, are outlined below. Entities in these areas are eligible to apply for assignment of National Health Service Corps personnel and are eligible service areas for certain loan repayment, scholarship, and other public health service programs.

HPSAs are defined to include 1) urban and rural geographic areas, 2) population groups, and 3) facilities with shortages of health professionals. An area can obtain this designation if each of the following criteria is met.

1. The area must be a rational area for the delivery of primary medical care services. In determining "rational" areas, one of three conditions must be satisfied. The region must be comprised of:

- a) a county or a group of contiguous counties whose population centers are within 30 minutes travel time of each other,
- b) a portion of a county(s) whose population has limited access to contiguous area resources, as measured by a travel time greater than 30 minutes, and/or
- c) established neighborhoods and communities within metropolitan areas which display a strong self-identity, have limited interaction with contiguous areas, and have a minimum population of 20,000.

Distances corresponding to 30 minutes travel time are: 20 miles on U.S. Highways, 15 miles in mountainous terrain, state highways or county roads, and 25 miles in flat terrain or in areas connected by interstate highways.

2. One of the following two conditions must prevail within the area:

- a) A ratio of population to full-time-equivalent primary care physician of at least 3,500:1, or

- b) A ratio of population to full-time-equivalent primary care physician of less than 3,500:1 but greater than 3,000:1 and an unusually high need for primary care services or insufficient capacity of existing primary care providers.

All non-federal Doctors of Medicine (M.D.) and Doctors of Osteopathy (D.O.) providing direct patient care and who practice principally in one of the four primary care specialties - general or family practice, general internal medicine, pediatrics, and obstetrics/gynecology - will be counted. A 36-hour work week will be used as the standard for determining full-time equivalents (FTE). For practitioners working less than a 36-hour week, every four (4) hours (or 1/2 day) spent providing patient care, will be counted as 0.1 FTE and each physician providing patient care 36 or more hours a week will be counted as 1.0 FTE.

An area is considered having unusually high needs for primary health care services if there are:

- a) more than 100 births per year per 1,000 women age 15-44,
- b) more than 20 infant deaths per 1,000 live births, or
- c) more than 20% of the population (or of all households) with incomes below the poverty level.

3. Primary medical care professionals in contiguous areas must be over-utilized, excessively distant or inaccessible to the population of the area under consideration.

An over-utilized area is characterized by a population to full-time-equivalent primary care physician ratio in excess of 2,000:1. If primary care sources in contiguous areas are more than 30 minutes travel time from the population center of the area being considered for designation, the contiguous area is deemed excessively distant. Primary care in adjacent areas is considered inaccessible to the population if demographic barriers or economic access barriers exist.

The map below from the Health Resources and Services Administration identifies health professional shortage areas (HPSA) in Louisiana. Following established criteria and procedures geographic areas, population groups, medical facilities and other public facilities are designated as shortage areas. Generally, these areas have too few health professionals to serve the general, low income or Medicaid populations of the area, based on federal guidelines. Areas are evaluated in three main categories – primary care, dental and mental health. Each designation is based on the ratio of primary care physicians, dentists or psychiatrists to the population of a given area. Designation in the Federal Register qualifies areas for number of programs.

Louisiana's Health Professional Shortage Area (HPSA) Designations



7. Louisiana Board of Pharmacy Statute Review

A. Summary Points

Louisiana registered pharmacists providing vaccinations complete a comprehensive training course approved by the Louisiana Board of Pharmacy, maintain a current Basic Life Support certification, and complete continuing education annually which reinforces vaccine types, storage and handling, administration, and emergency event response. Pharmacists maintain records of each vaccine administered as well as notify the patient's primary care provider within 24 hours of vaccine administration. By comparison, there is no continuing education requirement for vaccination training for physicians.

All vaccinating pharmacists are currently required to report every influenza vaccination to the Louisiana Immunization Network for Kids Statewide (LINKS) registry. Therefore, to add the requirement that all vaccinations that eventually would be approved be added to LINKS would be a technical and relatively easy requirement to fulfill. The use of LINKS allows easy monitoring of both individual and overall vaccinations by pharmacists in Louisiana.

B. Copy of Rules

§521. Prescription Orders to Administer Medications (Louisiana Administrative Code, Title 46 – Professional and Occupational Standards – Part LIII, Chapter 5: Pharmacists)

A. Purpose. The rules of this section describe the minimum requirements for the administration of medications to patients by Louisiana-licensed pharmacists.

B. A licensed pharmacist may administer medication directly to a patient upon the prescription or order of a practitioner. Such a prescription or order shall be known as an "Authority to Administer."

1. An Authority to Administer is valid only for the pharmacist meeting the requirements herein and is not transferable.
2. An Authority to Administer, once granted, is valid for a period of time not to exceed six months, unless revoked sooner by the practitioner granting the order.

C. A properly executed Authority to Administer shall:

1. Identify the licensed practitioner's name, office address, and telephone number;
2. Bear the patient's name, address, gender, and date of birth;
3. Identify the medication, dose, and route of administration;
4. Identify the pharmacist authorized to administer the medication; and
5. Bear the date of the original order and the date of any authorized subsequent dose administrations.

D. Requirements. Unless otherwise specifically authorized by the board, a pharmacist shall meet the following minimum standards to qualify for an Authority to Administer:

1. Obtain and maintain a license to practice pharmacy from the board;
2. Successfully complete a board-approved course of study from a board-approved provider that:
 - a. Requires documentation by the pharmacist of current certification in the American Heart Association's Basic Cardiac Life Support for Healthcare Providers, its successor, or board-approved equivalent;
 - b. Take an evidence-based didactic course that meets current Centers for Disease Control and Prevention (CDC) training guidelines, or other guidelines as designated by the board, and provides a minimum of twenty hours of instruction and experiential training in the following content areas:
 - standards for medication administration practices;
 - basic immunology;
 - recommended medication administration schedules;
 - vaccine storage and management;
 - informed consent;
 - physiology and techniques for medication administration;
 - pre- and post-administration assessment and counseling;
 - medication administration record management; and
 - management of adverse events, including identification and appropriate response, as well as documentation and reporting; and
 - c. Provides documentation of the successful completion of the course to the participant. The pharmacist shall display the certificate of completion in the primary practice site. The pharmacist shall submit a copy of said certificate to the board office for placement in the pharmacist's permanent file.

E. The pharmacist shall maintain continuing competency to accept an Authority to Administer, as evidenced by:

1. A current certification by the American Heart Association's Basic Cardiac Life Support for Healthcare Providers, its successor, or board-approved equivalent; and
2. Successful completion of at least one hour of continuing education per year related to this area of practice.

F. Vaccines. The pharmacist shall maintain and furnish the following information to the practitioner within twenty-four hours of the administration:

1. Name and address of the patient;
2. Age of the patient, if less than fourteen years of age;
3. Name of the patient's primary care physician as provided by the patient or patient's agent;

4. Name, manufacturer, and lot number of the vaccine administered;
5. Amount administered;
6. Date of vaccine administration;
7. Site of vaccine administration;
8. Route of administration; and
9. Name, address, and telephone number of the pharmacist administering the vaccine.

G. A pharmacist certified to administer medications may train a pharmacy intern to administer medication, provided the pharmacy intern meets the same educational requirements and minimum standards identified in Subsections D.2 and E of this Section. The intern shall be under the direct and immediate supervision of the certified pharmacist at all times during such training activities.⁶

C. House Bill 872/Act No. 287

ENROLLED **ACT No. 287**

Regular Session, 2010
HOUSE BILL NO. 872
BY REPRESENTATIVE MILLS

AN ACT

To enact R.S. 37:1218, relative to the administration of influenza immunizations; to provide for allowable pharmacist services; to provide for conditions under which pharmacists may administer influenza immunizations; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 37:1218 is hereby enacted to read as follows:

§1218. Administration of influenza immunization

A pharmacist may administer an influenza immunization to any person seven years of age or older without a prescription or medical order contingent upon all of the following provisions:

(1) The pharmacist shall administer influenza immunizations in conformance with the most current annual influenza vaccination administration protocol as set forth by the United States Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practice (ACIP).

⁶ AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2085 (October 2003), effective January 1, 2004, amended LR 34:1409 (July 2008).

(2) The pharmacist shall report each influenza immunization to the Louisiana Office of Public Health Immunization Registry at the time of the immunization or as soon as reasonably practicable thereafter.

(3) The pharmacist shall report all adverse events he observes or which are reported to him to the Vaccine Adverse Events Reporting System (VAERS), the cooperative program of the CDC and the United States Food and Drug Administration for vaccine safety, or its successor program; and further, the pharmacist shall refer the patient with an adverse event to the influenza immunization for appropriate medical care.

(4) The pharmacist shall maintain for at least two years a record of each influenza immunization administered.

(5) The pharmacist shall obtain the appropriate credential to administer influenza immunizations from the board, as administratively defined, prior to administering any such immunization.

SPEAKER OF THE HOUSE OF REPRESENTATIVES

PRESIDENT OF THE SENATE

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____

8. Review of Current Louisiana Pharmacist Vaccination Practices

A. Historical

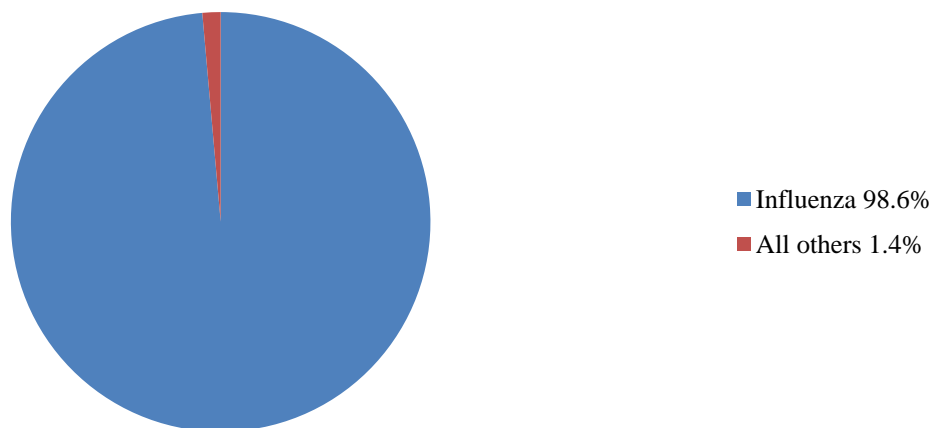
Credentialed and trained pharmacists have had the ability to provide vaccination services in Louisiana since 1988, by administering the vaccine to a patient who presents with a valid physician prescription. These specialized pharmacists are used to handling vaccines, screening patients for contraindications, administering vaccines, and handling adverse events. They record and report all vaccinations back to the primary physician or the LINKS immunization registry. Since 2009, these pharmacists have been administering influenza (both H1N1 and seasonal influenza vaccines) to anyone who requests it, by using the CDC/ACIP eligibility criteria.

B. Pharmacists Vaccinator Survey Summary

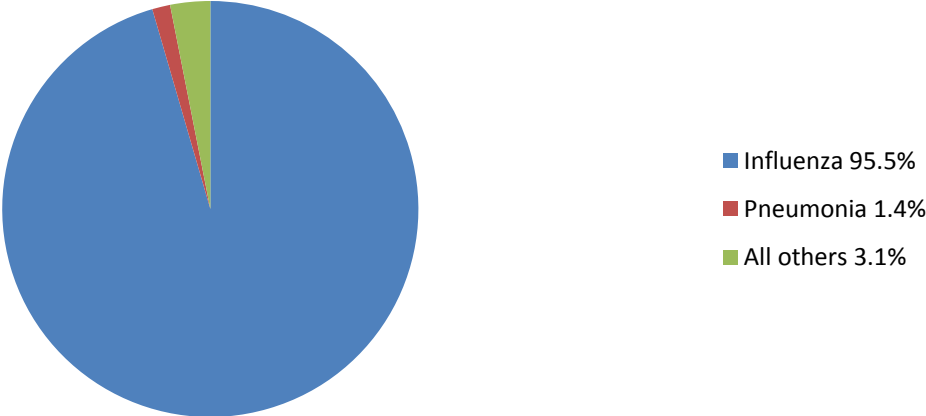
Louisiana vaccinating pharmacists were surveyed to determine their current vaccination practice. The survey tool is included as Appendix F. The survey results are as follows:

There were 228 respondents to the survey, comprised of 79% chain pharmacists, 16% independent pharmacists, and 5% in other pharmacy practice settings. For persons 0-18 years of age, 98.6% of the immunizations were for influenza. For persons 18 years of age and older, 95.5% of the immunizations were for influenza and 1.4% were for pneumonia. Each of the other vaccines administered were less than 1% of current practice.

Persons 0-18 years of age



Persons 18 years of age and older



9. Senate Resolution 122 Working Group

Dr. Jimmy Guidry
State Health Officer
Department of Health and Hospitals Medical Director

Joe Fontenot
PMP Manager
Louisiana Board of Pharmacy

Dr. Robert Marier
Executive Director
Louisiana State Board of Medical Examiners

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Randall Johnson
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Ginger Adam
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Mary Staples
National Association of Chain Drug Stores

Stacy Hall
LOPH Center for Community Preparedness

Ruben A Tapia, MPH
LOPH Immunization Program

Appendix A: Child Recommended Immunization Schedule

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2011

For those who fall behind or start late, see the catch-up schedule

Vaccine ▼	Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B ¹		HepB	HepB			HepB						
Rotavirus ²			RV	RV	RV ²							
Diphtheria, Tetanus, Pertussis ³			DTaP	DTaP	DTaP	see footnote ³		DTaP				DTaP
<i>Haemophilus influenzae</i> type b ⁴			Hib	Hib	Hib ⁴		Hib					
Pneumococcal ⁵			PCV	PCV	PCV		PCV				PPSV	
Inactivated Poliovirus ⁶			IPV	IPV		IPV						IPV
Influenza ⁷						Influenza (Yearly)						
Measles, Mumps, Rubella ⁸							MMR		see footnote ⁸			MMR
Varicella ⁹							Varicella		see footnote ⁹			Varicella
Hepatitis A ¹⁰							HepA (2 doses)				HepA Series	
Meningococcal ¹¹											MCV4	

Range of recommended ages for all children

Range of recommended ages for certain high-risk groups

This schedule includes recommendations in effect as of December 21, 2010. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations: <http://www.cdc.gov/vaccines/pubs/acip-1ist.htm>. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

Appendix B: Adolescent Recommended Immunization Schedule

Recommended Immunization Schedule for Persons Aged 7 Through 18 Years—United States • 2011

For those who fall behind or start late, see the schedule below and the catch-up schedule

Vaccine ▼	Age ►	7–10 years	11–12 years	13–18 years	
Tetanus, Diphtheria, Pertussis ¹			Tdap	Tdap	Range of recommended ages for all children
Human Papillomavirus ²	see footnote ²		HPV (3 doses)(females)	HPV series	
Meningococcal ³		MCV4	MCV4	MCV4	
Influenza ⁴		Influenza (Yearly)			Range of recommended ages for catch-up immunization
Pneumococcal ⁵		Pneumococcal			
Hepatitis A ⁶		Hep A Series			Range of recommended ages for certain high-risk groups
Hepatitis B ⁷		Hep B Series			
Inactivated Poliovirus ⁸		IPV Series			
Measles, Mumps, Rubella ⁹		MMR Series			
Varicella ¹⁰		Varicella Series			

This schedule includes recommendations in effect as of December 21, 2010. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations: <http://www.cdc.gov/vaccines/pubs/acip-1ist.htm>. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

Appendix C: Adult Recommended Immunization Schedule

VACCINE ▼	AGE GROUP ►	19–26 years	27–49 years	50–59 years	60–64 years	≥65 years
Influenza ^{1,*}		1 dose annually				
Tetanus, diphtheria, pertussis (Td/Tdap) ^{2,*}		Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 years				Td booster every 10 years
Varicella ^{3,*}		2 doses				
Human papillomavirus (HPV) ^{4,*}		3 doses (females)				
Zoster ⁵					1 dose	
Measles, mumps, rubella (MMR) ^{6,*}		1 or 2 doses		1 dose		
Pneumococcal (polysaccharide) ^{7,B}		1 or 2 doses				1 dose
Meningococcal ^{9,*}		1 or more doses				
Hepatitis A ^{10,*}		2 doses				
Hepatitis B ^{11,*}		3 doses				

* Covered by the Vaccine Injury Compensation Program



For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of previous infection)



Recommended if some other risk factor is present (e.g., based on medical, occupational, lifestyle, or other indications)



No recommendation

This schedule includes recommendations in effect as of December 21, 2010. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations: <http://www.cdc.gov/vaccines/pubs/acip-1ist.htm>. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

Appendix D: U. S. Vaccine Abbreviations

March 25, 2011

Advisory Committee on Immunization Practices

Abbreviations for Vaccines Included in the Immunization Schedules for Children, Adolescents, and Adults

Following is a table of standardized vaccine abbreviations, which was developed jointly by staff of the Centers for Disease Control and Prevention, ACIP Work Groups, the editor of the *Morbidity and Mortality Weekly Report (MMWR)*, the editor of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (the “Pink Book”), ACIP members, and liaison organizations to the ACIP.

These abbreviations are intended to provide a uniform approach to vaccine references used in ACIP Recommendations and Policy Notes that are published in the *MMWR*, the *Pink Book*, and the American Academy of Pediatrics *Red Book*; and in the U.S. immunization schedules for children, adolescents, and adults.

Vaccine	Abbreviation	Trade Name
Diphtheria, tetanus and pertussis-containing vaccines		
• Diphtheria and tetanus toxoids adsorbed (children)	DT	several mfrs [†]
• Diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed	DTaP	several mfrs
• Tetanus and diphtheria toxoids adsorbed (adult)	Td	several mfrs
• Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed	Tdap	Adacel, Boostrix
• Tetanus toxoid	TT	several mfrs
• Diphtheria and tetanus toxoids and acellular pertussis adsorbed and <i>Haemophilus influenzae</i> type b conjugate vaccine	DTaP/Hib	TriHIBit
• Diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix
• Diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine	DTaP-IPV	Kinrix
• Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and <i>Haemophilus influenzae</i> type b conjugate vaccine	DTaP-IPV/Hib	Pentacel
<i>Haemophilus influenzae</i> type b-containing vaccines		
• <i>Haemophilus influenzae</i> type b conjugate vaccine	Hib	PedvaxHIB ActHIB
• <i>Haemophilus influenzae</i> type b conjugate and hepatitis B vaccine	Hib-HepB	Comvax

Vaccine	Abbreviation	Trade Name
• Diphtheria and tetanus toxoids and acellular pertussis adsorbed and <i>Haemophilus influenzae</i> type b conjugate vaccine	DTaP/Hib	TriHIBit
• Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and <i>Haemophilus influenzae</i> type b conjugate vaccine	DTaP-IPV/Hib	Pentacel
Hepatitis- containing vaccines		
• Hepatitis A vaccine	HepA	Havrix Vaqta
• Hepatitis B vaccine	HepB	Engerix-B Recombivax HB
• Hepatitis A inactivated and hepatitis B vaccine	HepA-HepB	Twinrix
• Diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix
• <i>Haemophilus influenzae</i> type b conjugate and hepatitis B vaccine	Hib-HepB	Comvax
Human papillomavirus vaccines		
• Human papillomavirus vaccine (quadrivalent)	HPV4	Gardasil
• Human papillomavirus vaccine (bivalent)	HPV2	Cervarix
Influenza vaccines		
• Trivalent inactivated influenza vaccine	TIV	several mfrs
• Live attenuated influenza vaccine	LAIV	FluMist
Measles-containing vaccines		
• Measles, mumps, and rubella vaccine	MMR	M-M-R II
• Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad
Meningococcal vaccines		
• Meningococcal conjugate vaccine (quadrivalent)	MCV4	Menactra, Menveo
• Meningococcal polysaccharide vaccine (quadrivalent)	MPSV4	Menomune
Pneumococcal vaccines		
• Pneumococcal conjugate vaccine (7-valent)	PCV7	Prevnar
• Pneumococcal conjugate vaccine (13-valent)	PCV13	Prevnar 13
• Pneumococcal polysaccharide vaccine (23-valent)	PPSV23	Pneumovax 23
Poliovirus-containing vaccines		
• Poliovirus vaccine (inactivated)	IPV	Ipol
• Diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine	DTaP-IPV	Kinrix

Vaccine	Abbreviation	Trade Name
• Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and <i>Haemophilus influenzae</i> type b conjugate vaccine	DTaP-IPV/Hib	Pentacel
Rotavirus vaccines		
• Rotavirus vaccine (monovalent)	RV1	Rotarix
• Rotavirus vaccine (pentavalent)	RV5	RotaTeq
Varicella-containing vaccines		
• Varicella vaccine	VAR	Varivax
• Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad
• Herpes zoster (shingles) vaccine	ZOS	Zostavax

* dash (-) indicates: products that are supplied in their final form by the manufacturer and do not require mixing or reconstitution by user; slash (/) indicates: products that are mixed or reconstituted by user.

† several manufacturers; for complete listing, see <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/us-vaccines.pdf> and <http://www.cdc.gov/vaccines/about/terms/USVaccines.html>

Appendix E: Possible Side-effects from Vaccines

Centers for Disease Control and Prevention – Vaccines and Immunizations Possible Side-effects from Vaccines⁷

Any vaccine can cause side effects. For the most part these are minor (for example, a sore arm or low-grade fever) and go away within a few days. Listed below are vaccines licensed in the United States and side effects that have been associated with each of them. This information is copied directly from CDC's [Vaccine Information Statements](#), which in turn are derived from the [Advisory Committee on Immunization Practices \(ACIP\) recommendations](#) for each vaccine.

Vaccines are continually monitored for safety, and like any medication, vaccines can cause side effects. However, a decision not to immunize a child also involves risk and could put the child and others who come into contact with him or her at risk of contracting a potentially deadly disease.

DTaP vaccine side-effects (Diphtheria, Tetanus, and acellular Pertussis)

What are the risks from DTaP vaccine?

Getting diphtheria, tetanus or pertussis disease is much riskier than getting DTaP vaccine.

However, a vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of DTaP vaccine causing serious harm, or death, is extremely small.

Mild Problems (Common)

- Fever (up to about 1 child in 4)
- Redness or swelling where the shot was given (up to about 1 child in 4)
- Soreness or tenderness where the shot was given (up to about 1 child in 4)

These problems occur more often after the 4th and 5th doses of the DTaP series than after earlier doses.

Sometimes the 4th or 5th dose of DTaP vaccine is followed by swelling of the entire arm or leg in which the shot was given, for 1 to 7 days (up to about 1 child in 30).

Other mild problems include:

- Fussiness (up to about 1 child in 3)
- Tiredness or poor appetite (up to about 1 child in 10)
- Vomiting (up to about 1 child in 50)

⁷ Centers for Disease Control and Prevention Vaccines and Immunizations Possible Side-effects from Vaccines <http://www.cdc.gov/vaccines/vac-gen/side-effects.htm>

These problems generally occur 1 to 3 days after the shot.

Moderate Problems (Uncommon)

- Seizure (jerking or staring) (about 1 child out of 14,000)
- Non-stop crying, for 3 hours or more (up to about 1 child out of 1,000)
- High fever, 105 degrees Fahrenheit or higher (about 1 child out of 16,000)

Severe Problems (Very Rare)

Serious allergic reaction (less than 1 out of a million doses) Several other severe problems have been reported after DTaP vaccine. These include:

- Long-term seizures, coma, or lowered consciousness
- Permanent brain damage.

These are so rare it is hard to tell if they are caused by the vaccine.

Controlling fever is especially important for children who have had seizures, for any reason. It is also important if another family member has had seizures.

You can reduce fever and pain by giving your child an *aspirin-free* pain reliever when the shot is given, and for the next 24 hours, following the package instructions.

Hepatitis A vaccine side-effects

What are the risks from hepatitis A vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of hepatitis A vaccine causing serious harm, or death, is extremely small.

Getting hepatitis A vaccine is much safer than getting the disease.

Mild Problems

- soreness where the shot was given (about 1 out of 2 adults, and up to 1 out of 6 children)
- headache (about 1 out of 6 adults and 1 out of 25 children)
- loss of appetite (about 1 out of 12 children)
- tiredness (about 1 out of 14 adults)

If these problems occur, they usually last 1 or 2 days.

Severe Problems

- serious allergic reaction, within a few minutes to a few hours of the shot (very rare)

Hepatitis B vaccine side-effects

What are the risks from hepatitis B vaccine?

Hepatitis B is a very safe vaccine. Most people do not have any problems with it.

Mild problems

- Soreness where the shot was given (up to about 1 person 4)
- Temperature of 99.9°F or higher (up to about 1 person in 15).

Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses.

A vaccine, like any medicine, could cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small. More than 100 million people have gotten hepatitis B vaccine in the United States.

Hib vaccine side-effects

What are the risks from Hib (*Haemophilus influenzae* type b) vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of Hib vaccine causing serious harm or death is extremely small.

Most people who get Hib vaccine do not have any problems with it.

Mild Problems

- Redness, warmth, or swelling where the shot was given (up to 1 out of 4 children)
- Fever over 101 degrees Fahrenheit (up to 1 out of 20 children)

If these problems happen, they usually start within a day of vaccination. They may last 2 to 3 days.

HPV--Cervarix vaccine side-effects (Human Papillomavirus Cervarix vaccine)

What are the risks from HPV--Cervarix vaccine?

The HPV Cervarix vaccine has been in use around the world for several years and has been very safe.

However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Several **mild to moderate problems** are known to occur with this HPV vaccine. These do not last long and resolve.

- Reactions where the shot was given
 - Pain (about 9 people in 10)
 - Redness or swelling (about 1 person in 2)
- Other mild reactions
 - Fever of 99.5 or higher degrees Fahrenheit (about 1 person in 8)
 - Headache or fatigue (about 1 person in 2)
 - Nausea, vomiting, diarrhea, or abdominal pain (about 1 person in 4)
 - Muscle or joint pain (up to 1 person in 2)
- Fainting

Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls. Tell your doctor if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.

HPV--Gardasil vaccine side-effects (Human Papillomavirus Gardasil vaccine)

What are the risks from HPV--Gardasil vaccine?

The HPV-Gardasil vaccine has been used in the U.S. and around the world for several years and has been very safe.

However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Several **mild to moderate problems** are known to occur with this HPV vaccine. These do not last long and go away on their own.

- Reactions in the arm where the shot was given
 - Pain (about 8 people in 10)
 - Redness or swelling (about 1 person in 4)
- Fever
 - Mild (100° F) (about 1 person in 10)
 - Moderate (102° F) (about 1 person in 65)
- Other problems
 - Headache (about 1 person in 3)
 - Fainting. Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. **Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting**

and injuries caused by falls. Tell your doctor if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.

Influenza (inactivated) vaccine side-effects

What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Serious problems from inactivated influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild Problems

- soreness, redness, or swelling where the shot was given
- hoarseness; sore, red or itchy eyes; cough
- fever
- aches

If these problems occur, they usually begin soon after the shot and last 1-2 days.

Severe Problems

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, a certain type of inactivated influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

One brand of inactivated flu vaccine, called Afluria, should **not** be given to children 8 years of age or younger, except in special circumstances. A related vaccine was associated with fevers and fever-related seizures in young children in Australia. Ask your healthcare provider for more information.

The safety of vaccines is always being monitored. For more information, visit: **Vaccine Safety Monitoring and Vaccine Safety Activities.**

Influenza (live) vaccine side-effects

What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses very rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine can cause mild symptoms in people who get it (see below).

Mild Problems

Some children and adolescents 2-17 years of age have reported:

- runny nose, nasal congestion or cough
- headache and muscle aches
- fever
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

Severe Problems

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.
- If rare reactions occur with any product, they may not be identified until thousands, or millions, of people have used it. Millions of doses of LAIV have been distributed since it was licensed, and the vaccine has not been associated with any serious problems.

MMR vaccine side-effects (Measles, Mumps, and Rubella)

What are the risks from MMR vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of MMR vaccine causing serious harm, or death, is extremely small.

Getting MMR vaccine is much safer than getting any of these three diseases.

Most people who get MMR vaccine do not have any problems with it.

Mild Problems

- Fever (up to 1 person out of 6)
- Mild rash (about 1 person out of 20)

- Swelling of glands in the cheeks or neck (rare)
If these problems occur, it is usually within 7-12 days after the shot. They occur less often after the second dose.

Moderate Problems

- Seizure (jerking or staring) caused by fever (about 1 out of 3,000 doses)
- Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4)
- Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)

Severe Problems

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been known to occur after a child gets MMR vaccine. But this happens so rarely, experts cannot be sure whether they are caused by the vaccine or not. These include:
 - Deafness
 - Long-term seizures, coma, or lowered consciousness
 - Permanent brain damage

Note: The first dose of MMRV vaccine has been associated with rash and higher rates of fever than MMR and varicella vaccines given separately. Rash has been reported in about 1 person in 20 and fever in about 1 person in 5. Seizures caused by a fever are also reported more often after MMRV. These usually occur 5-12 days after the first dose.

MMRV vaccine side-effects (Measles, Mumps, Rubella, and Varicella)

What are the risks from MMRV vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of MMRV vaccine causing serious harm, or death, is extremely small.

Getting MMRV vaccine is much safer than getting measles, mumps, rubella, or chickenpox.

Most children who get MMRV vaccine do not have any problems with it.

Mild Problems

- Fever (about 1 child out of 5).
- Mild rash (about 1 child out of 20).
- Swelling of glands in the cheeks or neck (rare).

If these problems happen, it is usually within 5-12 days after the first dose. They happen less often after the second dose.

Moderate Problems

- Seizure caused by fever (about 1 child in 1,250 who get MMRV), usually 5-12 days after the first dose. *They happen less often when MMR and varicella vaccines are given at the same visit as separate shots (about 1 child in 2,500 who get these two vaccines), and rarely after a 2nd dose of MMRV.*
- Temporary low platelet count, which can cause a bleeding disorder (about 1 child out of 40,000).

Severe Problems

Several severe problems have been reported following MMR vaccine, and might also happen after MMRV. These include severe allergic reactions (fewer than 4 per million), and problems such as:

- Deafness.
- Long-term seizures, coma, lowered consciousness.
- Permanent brain damage.

These problems occur so rarely, it cannot be determined whether or not they are caused by the vaccine.

Meningococcal vaccine side-effects

What are the risks from meningococcal vaccines?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of the meningococcal vaccine causing serious harm, or death, is extremely small.

Mild Problems

As many as half the people who get meningococcal vaccines have mild side effects, such as redness or pain where the shot was given.

If these problems occur, they usually last for 1 or 2 days. They are more common after MCV4 than after MPSV4.

A small percentage of people who receive the vaccine develop a fever.

Severe Problems

- Serious allergic reactions, within a few minutes to a few hours of the shot, are very rare.
- A serious nervous system disorder called Guillain-Barré Syndrome (or GBS) has been reported among some people who received MCV4. This happens so rarely that it is currently not possible to tell if the vaccine might be a factor. Even if it is, the risk is very small.

PCV13 vaccine side-effects (pneumonia) (Pneumococcal Conjugate Vaccine)

What are the risks from PCV13?

Any medicine, including a vaccine, could possibly cause a serious problem, such as severe allergic reaction. However, the risk of any vaccine causing serious harm, or death, is extremely small.

In studies, most reactions after PCV13 were mild. They were similar to reactions reported after PCV7, which has been in use since 2000. Reported reactions varied by dose and age, but on average:

- About half of children were drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a higher fever (over 102.2°F).
- Up to about 8 out of 10 became fussy or irritable.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

PPSV23 vaccine side-effects (Pneumonia) (Pneumococcal Polysaccharide)

What are the risks from PPSV?

About half of people who get PPSV have mild side effects, such as redness or pain where the shot is given.

Less than 1 percent develops a fever, muscle aches, or more severe local reactions.

A vaccine, like any medicine, could cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small.

Polio vaccine side-effects

What are the risks from IPV?

Some people who get Inactivated Polio Vaccine (IPV) get a sore spot where the shot was given. The vaccine used today has never been known to cause any serious problems, and most people don't have any problems at all with it.

However, a vaccine, like any medicine, could cause serious problems, such as a severe allergic reaction. The risk of a polio shot causing serious harm, or death, is extremely small.

Rotavirus vaccine side-effects

What are the risks from rotavirus vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of any vaccine causing serious harm, or death, is extremely small.

A virus (or parts of a virus) called porcine circovirus is present in both rotavirus vaccines. There is no evidence that this virus is a safety risk or causes illness in humans. For more information, see the **rotavirus vaccination page**.

Most babies who get rotavirus vaccine do not have any problems with it.

Mild Problems

Babies might become irritable, or have mild, temporary diarrhea or vomiting after getting a dose of rotavirus vaccine.

Serious Problems

Some studies have shown a small increase in cases of intussusception within a week after the first dose of rotavirus vaccine. Intussusception is a type of bowel blockage that is treated in a hospital. In some cases surgery might be required. The estimated risk is 1 intussusception case per 100,000 infants.

Shingles (Herpes Zoster) vaccine side-effects

What are the risks from shingles vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. However, the risk of a vaccine causing serious harm, or death, is extremely small.

No serious problems have been identified with shingles vaccine.

Mild Problems

- Redness, soreness, swelling, or itching at the site of the injection (about 1 person in 3).
- Headache (about 1 person in 70).

Like all vaccines, shingles vaccine is being closely monitored for unusual or severe problems.

Td vaccine (Adult Tetanus and Diphtheria) AND Tdap vaccine (Combined Tetanus, Diphtheria and Pertussis)

What are the risks from Tdap and Td vaccines?

With a vaccine (as with any medicine) there is always a small risk of a life-threatening allergic reaction or other serious problem.

Getting tetanus, diphtheria or pertussis would be much more likely to lead to severe problems than getting either vaccine. Problems reported after Td and Tdap vaccines are listed below.

Mild Problems (noticeable, but did not interfere with activities)

Tdap

- Pain (about 3 in 4 adolescents and 2 in 3 adults)
- Redness or swelling (about 1 in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents and 1 in 100 adults)
- Headache (about 4 in 10 adolescents and 3 in 10 adults)
- Tiredness (about 1 in 3 adolescents and 1 in 4 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents and 1 in 10 adults)
- Chills, body aches, sore joints, rash, swollen glands (uncommon)

Td

- Pain (up to about 8 in 10)
- Redness or swelling (up to about 1 in 3)
- Mild fever (up to about 1 in 15)
- Headache or tiredness (uncommon)

Moderate Problems (interfered with activities, but did not require medical attention)

Tdap

- Pain at the injection site (about 1 in 20 adolescents and 1 in 100 adults)
- Redness or swelling (up to about 1 in 16 adolescents and 1 in 25 adults)
- Fever over 102°F (about 1 in 100 adolescents and 1 in 250 adults)
- Headache (1 in 300)
- Nausea, vomiting, diarrhea, stomach ache (up to 3 in 100 adolescents and 1 in 100 adults)

Td

- Fever over 102°F (rare)

Tdap or Td

- Extensive swelling of the arm where the shot was given (up to about 3 in 100).

Severe Problems (unable to perform usual activities; required medical attention)

Tdap

- Two adults had nervous system problems after getting the vaccine during clinical trials. These may or may not have been caused by the vaccine. These problems resolved and did not cause any permanent harm.

Tdap or Td

- Swelling, severe pain, and redness in the arm where the shot was given (rare).

A severe allergic reaction could occur after any vaccine. They are estimated to occur less than once in a million doses.

Varicella (Chickenpox) vaccine side-effects

What are the risks from chickenpox vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of chickenpox vaccine causing serious harm, or death, is extremely small.

Getting chickenpox vaccine is much safer than getting chickenpox disease. Most people who get chickenpox vaccine do not have any problems with it. Reactions are usually more likely after the first dose than after the second.

Mild Problems

- Soreness or swelling where the shot was given (about 1 out of 5 children and up to 1 out of 3 adolescents and adults)
- Fever (1 person out of 10, or less)
- Mild rash, up to a month after vaccination (1 person out of 25). It is possible for these people to infect other members of their household, but this is extremely rare.

Note: The first dose of MMRV vaccine has been associated with rash and higher rates of fever than MMR and varicella vaccines given separately. Rash has been reported in about 1 person in 20 and fever in about 1 person in 5. Seizures caused by a fever are also reported more often after MMRV. These usually occur 5-12 days after the first dose.

Moderate Problems

- Seizure (jerking or staring) caused by fever (very rare).

Severe Problems

- Pneumonia (very rare)

Other serious problems, including severe brain reactions and low blood count, have been reported after chickenpox vaccination. These happen so rarely experts cannot tell whether they are caused by the vaccine or not. If they are, it is extremely rare.

Content Source: National Center for Immunization and Respiratory Diseases

Full Page Located on the Web at <http://www.cdc.gov/vaccines/vac-gen/side-effects.htm>

Appendix F: Survey of Immunizing Pharmacists in Louisiana

Louisiana is collecting information for a better understanding of current immunization practices by pharmacists within the State. Your information will be useful in making informed decisions. We appreciate your assistance in completing this brief survey.

1. Relative to Louisiana law, is your business considered an independent pharmacy (14 or fewer locations in the state) or a chain pharmacy (15 or more locations in the state)? (Checkbox one or the other)

Independent

Chain

2. Other than Influenza, do your pharmacists report vaccinations to the State Immunization registry (LINKS)? (check yes or no)

Yes

No

3. What vaccines, including Influenza did you administered over the calendar year (January 1, 2010 to January 1, 2011)? Please put the number you administered by each vaccine for both children and adults. A zero indicates that you did not administer that vaccine. (zero as default, number by each for both Children and Adults)

Children aged 0-18

Influenza

Measles/Mumps/Rubella

Tetanus/Diphtheria

Tetanus/Diphtheria/Pertussis

Meningococcal

Pneumococcal

Varicella

Shingles

HPV

Hepatitis B

Other

Adults Over age 18

Influenza

Measles/Mumps/Rubella

Tetanus/Diphtheria

Tetanus/Diphtheria/Pertussis

Meningococcal

Pneumococcal

Varicella

Shingles

HPV

Hepatitis B

Other

4. Approximately what percentage of the vaccines you administered over the calendar year January 1, 2010 to January 1, 2011 was for Influenza? (Percentage 0 to 100)

Percentage

5. Besides Influenza, when vaccinating patients do you require an individual prescription for each vaccine, or do you use a protocol underwritten by a physician? (check protocol, prescription, or both)

Protocol

Individual prescription

Both