SB 869 and SB 580 Are Unnecessary and Burdensome

The Oregon State Pharmacy Association (OSPA) and the Oregon Society of Health-System Pharmacists (OSHP) **oppose SB 869 and SB 580**. These bills are unnecessary and would make administering a vaccine more complex for providers.

In Oregon, the pharmacist must give the appropriate Vaccine Information Statement (VIS) to the patient or legal representative with each dose of vaccine covered by these forms. The pharmacist must ensure that the patient or legal representative is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the vaccine. Attached is a summary of the VIS law from the federal viewpoint.

The CDC link for all VIS is https://www.cdc.gov/vaccines/hcp/vis/current-vis.html. The VIS were specifically designed as a summary of risks and benefits for laypeople. The information about vaccine injuries is on the back side. Attached is an MMR as an example.

Also provided is a CDC link for the "Pink Book" that lists all of the chapters and the link for the excipient table within it. Pharmacists are already required to have it for reference and answer any of patient's questions. The specific chapter pharmacists refer to is attached along with a package insert for MMR II as an example. The excipient table specifically says that it is pulled from package inserts so it is completely unnecessary to provide both to a patient.

https://www.cdc.gov/vaccines/pubs/pinkbook/chapters.html

https://www.cdc.gov/vaccines/pubs/pinkbook/appendix/appdx-b.html

Also attached is a sample of a consent form (Walgreens). While neither federal or Oregon require consent, every pharmacy requires consent for legal purposes.

In summary, we already have requirements to meet the intent of these bills, to educate and inform patients prior to making a decision to vaccinate. These bills, as written, include items that are duplicative and geared towards practitioners, which complicate the education of the patient rather than improving. This information is readily available with an internet search and through CDC online. The best tool we have is the VIS and it works.

OSPA and OSHP requests your opposition to SB 869 and SB 580.

Prepared by Bill Cross & Niki Terzieff, OSPA & OSHP Government Affairs *3/28/2017*

VACCINE INFORMATION STATEMENT

MMR Vaccine

(Measles, Mumps and Rubella)

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Measles, mumps, and rubella are serious diseases. Before vaccines they were very common, especially among children.

Measles

- Measles virus causes rash, cough, runny nose, eye irritation, and fever.
- It can lead to ear infection, pneumonia, seizures (jerking and staring), brain damage, and death.

Mumps

- Mumps virus causes fever, headache, muscle pain, loss of appetite, and swollen glands.
- It can lead to deafness, meningitis (infection of the brain and spinal cord covering), painful swelling of the testicles or ovaries, and rarely sterility.

Rubella (German Measles)

- Rubella virus causes rash, arthritis (mostly in women), and mild fever.
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

These diseases spread from person to person through the air. You can easily catch them by being around someone who is already infected.

Measles, mumps, and rubella (MMR) vaccine can protect children (and adults) from all three of these diseases.

Thanks to successful vaccination programs these diseases are much less common in the U.S. than they used to be. But if we stopped vaccinating they would return.

2 Who should get MMR vaccine and when?

Children should get 2 doses of MMR vaccine:

- **First Dose**: 12–15 months of age
- **Second Dose**: 4–6 years of age (may be given earlier, if at least 28 days after the 1st dose)

Some infants younger than 12 months should get a dose of MMR if they are traveling out of the country. (This dose will not count toward their routine series.)

Some adults should also get MMR vaccine: Generally, anyone 18 years of age or older who was born after 1956 should get at least one dose of MMR vaccine, unless they can show that they have either been vaccinated or had all three diseases.

MMR vaccine may be given at the same time as other vaccines.

Children between 1 and 12 years of age can get a "combination" vaccine called MMRV, which contains both MMR and varicella (chickenpox) vaccines. There is a separate Vaccine Information Statement for MMRV.

3 Some people should not get MMR vaccine or should wait.

- Anyone who has ever had a life-threatening allergic reaction to the antibiotic neomycin, or any other component of MMR vaccine, should not get the vaccine. Tell your doctor if you have any severe allergies.
- Anyone who had a life-threatening allergic reaction to a previous dose of MMR or MMRV vaccine should not get another dose.
- Some people who are sick at the time the shot is scheduled may be advised to wait until they recover before getting MMR vaccine.
- Pregnant women should not get MMR vaccine. Pregnant women who need the vaccine should wait until after giving birth. Women should avoid getting pregnant for 4 weeks after vaccination with MMR vaccine.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

- Tell your doctor if the person getting the vaccine:
  - Has HIV/AIDS, or another disease that affects the immune system
  - Is being treated with drugs that affect the immune system, such as steroids
  - Has any kind of cancer
  - Is being treated for cancer with radiation or drugs
  - Has ever had a low platelet count (a blood disorder)
  - Has gotten another vaccine within the past 4 weeks
  - Has recently had a transfusion or received other blood products

Any of these might be a reason to not get the vaccine, or delay vaccination until later.

4 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 measles, mumps or rubella.

Most people who get MMR vaccine do not have any serious 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 (about 1 person out of 75)

If these problems occur, it is usually within 6-14 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 (very rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been reported after a child gets MMR vaccine, including:
  - Deafness
  - Long-term seizures, coma, or lowered consciousness
  - Permanent brain damage

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

5 What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS is only for reporting reactions. They do not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**.

7 How can I learn more?

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)
MMR Vaccine

4/20/2012

42 U.S.C. § 300aa-26

Office Use Only

M-M-R® II
(MEASLES, MUMPS, and RUBELLA VIRUS VACCINE LIVE)

DESCRIPTION

M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine Live) is a live virus vaccine for vaccination against measles (rubeola), mumps, and rubella (German measles).

M-M-R II is a sterile lyophilized preparation of (1) ATTENUVAX® (Measles Virus Vaccine Live), a more attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and propagated in chick embryo cell culture; (2) MUMPSVAX® (Mumps Virus Vaccine Live), the Jeryl Lynn™ (B level) strain of mumps virus propagated in chick embryo cell culture; and (3) MERUVAX® II (Rubella Virus Vaccine Live), the Wistar RA 27/3 strain of live attenuated rubella virus propagated in WI-38 human diploid lung fibroblasts.{1,2}

The growth medium for measles and mumps is Medium 199 (a buffered salt solution containing vitamins and amino acids and supplemented with fetal bovine serum) containing SPGA (sucrose, phosphate, glutamate, and recombinant human albumin) as stabilizer and neomycin.

The growth medium for rubella is Minimum Essential Medium (MEM) [a buffered salt solution containing vitamins and amino acids and supplemented with fetal bovine serum] containing recombinant human albumin and neomycin. Sorbitol and hydrolyzed gelatin stabilizer are added to the individual virus harvests.

The cells, virus pools, and fetal bovine serum are all screened for the absence of adventitious agents.

The reconstituted vaccine is for subcutaneous administration. Each 0.5 mL dose contains not less than 1,000 $TCID_{50}$ (tissue culture infectious doses) of measles virus; 12,500 $TCID_{50}$ of mumps virus; and 1,000 $TCID_{50}$ of rubella virus. Each dose of the vaccine is calculated to contain sorbitol (14.5 mg), sodium phosphate, sucrose (1.9 mg), sodium chloride, hydrolyzed gelatin (14.5 mg), recombinant human albumin (≤0.3 mg), fetal bovine serum (<1 ppm), other buffer and media ingredients and approximately 25 mcg of neomycin. The product contains no preservative.

Before reconstitution, the lyophilized vaccine is a light yellow compact crystalline plug. M-M-R II, when reconstituted as directed, is clear yellow.

CLINICAL PHARMACOLOGY

Measles, mumps, and rubella are three common childhood diseases, caused by measles virus, mumps virus (paramyxoviruses), and rubella virus (togavirus), respectively, that may be associated with serious complications and/or death. For example, pneumonia and encephalitis are caused by measles. Mumps is associated with aseptic meningitis, deafness and orchitis; and rubella during pregnancy may cause congenital rubella syndrome in the infants of infected mothers.

The impact of measles, mumps, and rubella vaccination on the natural history of each disease in the United States can be quantified by comparing the maximum number of measles, mumps, and rubella cases reported in a given year prior to vaccine use to the number of cases of each disease reported in 1995. For measles, 894,134 cases reported in 1941 compared to 288 cases reported in 1995 resulted in a 99.97% decrease in reported cases; for mumps, 152,209 cases reported in 1968 compared to 840 cases reported in 1995 resulted in a 99.45% decrease in reported cases; and for rubella, 57,686 cases reported in 1969 compared to 200 cases reported in 1995 resulted in a 99.65% decrease.{3}

Clinical studies of 284 triple seronegative children, 11 months to 7 years of age, demonstrated that M-M-R II is highly immunogenic and generally well tolerated. In these studies, a single injection of the vaccine induced measles hemagglutination-inhibition (HI) antibodies in 95%, mumps neutralizing antibodies in 96%, and rubella HI antibodies in 99% of susceptible persons. However, a small percentage (1-5%) of vaccinees may fail to seroconvert after the primary dose (see also INDICATIONS AND USAGE, *Recommended Vaccination Schedule*).

A study{4} of 6-month-old and 15-month-old infants born to vaccine-immunized mothers demonstrated that, following vaccination with ATTENUVAX, 74% of the 6-month-old infants developed detectable neutralizing antibody (NT) titers while 100% of the 15-month-old infants developed NT. This rate of seroconversion is higher than that previously reported for 6-month-old infants born to naturally immune mothers tested by HI assay. When the 6-month-old infants of immunized mothers were revaccinated at 15

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For patent information: www.merck.com/product/patent/home.html

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Vaccine Excipient & Media Summary

Excipients Included in U.S. Vaccines, by Vaccine

In addition to weakened or killed disease antigens (viruses or bacteria), vaccines contain very small amounts of other ingredients – excipients or media.

Some excipients are added to a vaccine for a specific purpose. These include:
Preservatives, to prevent contamination. For example, thimerosal.
Adjuvants, to help stimulate a stronger immune response. For example, aluminum salts.
Stabilizers, to keep the vaccine potent during transportation and storage. For example, sugars or gelatin.

Others are residual trace amounts of materials that were used during the manufacturing process and removed. These include:
Cell culture materials, used to grow the vaccine antigens. For example, egg protein, various culture media.
Inactivating ingredients, used to kill viruses or inactivate toxins. For example, formaldehyde.
Antibiotics, used to prevent contamination by bacteria. For example, neomycin.

The following table lists all components, other than antigens, shown in the manufacturers' package insert (PI) for each vaccine. Each of these PIs, which can be found on the FDA's website (see below) contains a description of that vaccine's manufacturing process, including the amount and purpose of each substance. In most PIs, this information is found in Section 11: "Description."

All information was extracted from manufacturers' package inserts, current as of January 6, 2017.
If in doubt about whether a PI has been updated since then, check the FDA's website at:
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

Vaccine	Contains
Adenovirus	human-diploid fibroblast cell cultures (strain WI-38), Dulbecco's Modified Eagle's Medium, fetal bovine serum, sodium bicarbonate, monosodium glutamate, sucrose, D-mannose, D-fructose, dextrose, human serum albumin, potassium phosphate, plasdone C, anhydrous lactose, microcrystalline cellulose, polacrilin potassium, magnesium stearate, microcrystalline cellulose, magnesium stearate, cellulose acetate phthalate, alcohol, acetone, castor oil, FD&C Yellow #6 aluminum lake dye
Anthrax (Biothrax)	amino acids, vitamins, inorganic salts, sugars, aluminum hydroxide, sodium chloride, benzethonium chloride, formaldehyde
BCG (Tice)	glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, iron ammonium citrate, lactose
Cholera (Vaxchora)	casamino acids, yeast extract, mineral salts, anti-foaming agent, ascorbic acid, hydrolyzed casein, sodium chloride, sucrose, dried lactose, sodium bicarbonate, sodium carbonate
DT (Sanofi)	aluminum phosphate, isotonic sodium chloride, formaldehyde, casein, cystine, maltose, uracil, inorganic salts, vitamins, dextrose
DTaP (Daptacel)	aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, 2-phenoxyethanol
DTaP (Infanrix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80)
DTaP-IPV (Kinrix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, VERO cells, a continuous line of monkey kidney cells, Calf serum, lactalbumin hydrolysate, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B
DTaP-IPV (Quadracel)	modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, formaldehyde, ammonium sulfate aluminum phosphate, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, MRC-5 cells, normal human diploid cells, CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, 2-phenoxyethanol, polysorbate 80, glutaraldehyde, neomycin, polymyxin B sulfate

Vaccine	Contains
DTaP-HepB-IPV (Pediarix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, VERO cells, a continuous line of monkey kidney cells, calf serum and lactalbumin hydrolysate, aluminum hydroxide, aluminum phosphate, aluminum salts, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B, yeast protein.
DTaP-IPV/Hib (Pentacel)	aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate, modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin. glutaraldehyde, MRC-5 cells (a line of normal human diploid cells), CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, modified Mueller and Miller medium
Hib (ActHIB)	sodium chloride, modified Mueller and Miller medium (the culture medium contains milk-derived raw materials [casein derivatives]), formaldehyde, sucrose
Hib (Hiberix)	saline, synthetic medium, formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB)	complex fermentation media, amorphous aluminum hydroxyphosphate sulfate, sodium chloride
Hib/Mening. CY (MenHibrix)	saline, semi-synthetic media, formaldehyde, sucrose, tris (trometamol)-HCl
Hep A (Havrix)	MRC-5 human diploid cells, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic
Hep A (Vaqta)	MRC-5 diploid fibroblasts, amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride
Hep B (Engerix-B)	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
Hep B (Recombivax)	soy peptone, dextrose, amino acids, mineral salts, phosphate buffer, formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein
Hep A/Hep B (Twinrix)	MRC-5 human diploid cells, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein
Human Papillomavirus (HPV) (Gardasil)	vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein
Human Papillomavirus (HPV) (Gardasil 9)	vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein
Influenza (Afluria) Trivalent & Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multi-dose vials)
Influenza (Fluad)	squalene, polysorbate 80, sorbitan trioleate, sodium citrate dehydrate, citric acid monohydrate, neomycin, kanamycin, barium, egg proteins, CTAB (cetyltrimethylammonium bromide), formaldehyde
Influenza (Fluarix) Trivalent & Quadrivalent	octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Influenza (Flublok) Trivalent & Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and *Spodoptera frugiperda* cell proteins, baculovirus and cellular DNA, Triton X-100, lipids, vitamins, amino acids, mineral salts
Influenza (Flucelvax) Trivalent & Quadrivalent	Madin Darby Canine Kidney (MDCK) cell protein, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethlyammonium bromide, and β-propiolactone
Influenza (Flulaval) Trivalent & Quadrivalent	ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials)
Influenza (Fluvirin)	ovalbumin, polymyxin, neomycin, betapropiolactone, nonylphenol ethoxylate, thimerosal
Influenza (Fluzone) Quadrivalent	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials), sucrose

Vaccine	Contains
Influenza (Fluzone) High Dose	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde, sucrose
Influenza (Fluzone) Intradermal	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, sucrose
Influenza (FluMist) Quadrivalent	monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA)
Japanese Encephalitis (Ixiaro)	aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, host cell DNA, sodium metabisulphite, host cell protein
Meningococcal (MenACWY-Menactra)	Watson Scherp media containing casamino acid, modified culture medium containing hydrolyzed casein, ammonium sulfate, sodium phosphate, formaldehyde, sodium chloride
Meningococcal (MenACWY-Menveo)	formaldehyde, amino acids, yeast extract, Franz complete medium, CY medium
Meningococcal (MPSV4-Menomune)	Mueller Hinton casein agar, Watson Scherp casamino acid media, thimerosal (multi-dose vials), lactose
Meningococcal (MenB – Bexsero)	aluminum hydroxide, *E. coli*, histidine, sucrose, deoxycholate, kanamycin
Meningococcal (MenB – Trumenba)	defined fermentation growth media, polysorbate 80, histidine buffered saline.
MMR (MMR-II)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, vitamins, amino acids, fetal bovine serum, sucrose, glutamate, recombinant human albumin, neomycin, sorbitol, hydrolyzed gelatin, sodium phosphate, sodium chloride
MMRV (ProQuad) (Frozen)	chick embryo cell culture, WI-38 human diploid lung fibroblasts MRC-5 cells, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride; potassium phosphate dibasic, neomycin, bovine calf serum
MMRV (ProQuad) (Refrigerator Stable)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate potassium chloride, neomycin, bovine serum albumin
Pneumococcal (PCV13 – Prevnar 13)	soy peptone broth, casamino acids and yeast extract-based medium, CRM197 carrier protein, polysorbate 80, succinate buffer, aluminum phosphate
Pneumococcal (PPSV-23 – Pneumovax)	phenol
Polio (IPV – Ipol)	Eagle MEM modified medium, calf bovine serum, M-199 without calf bovine serum, vero cells (a continuous line of monkey kidney cells), phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B
Rabies (Imovax)	human albumin, neomycin sulfate, phenol red indicator, MRC-5 human diploid cells, beta-propriolactone
Rabies (RabAvert)	chicken fibroblasts, β-propiolactone, polygeline (processed bovine gelatin), human serum albumin, bovine serum, potassium glutamate, sodium EDTA, ovalbumin neomycin, chlortetracycline, amphotericin B
Rotavirus (RotaTeq)	sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum, vero cells *[DNA from porcine circoviruses (PCV) 1 and 2 has been detected in RotaTeq. PCV-1 and PCV-2 are not known to cause disease in humans.]*
Rotavirus (Rotarix)	amino acids, dextran, Dulbecco's Modified Eagle Medium (sodium chloride, potassium chloride, magnesium sulfate, ferric (III) nitrate, sodium phosphate, sodium pyruvate, D-glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids solution, L-250 glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan *[Porcine circovirus type 1 (PCV-1) is present in Rotarix. PCV-1 is not known to cause disease in humans.]*
Smallpox (Vaccinia – ACAM2000)	African Green Monkey kidney (Vero) cells, HEPES, human serum albumin, sodium chloride, neomycin, polymyxin B, Glycerin, phenol

Vaccine	Contains
Td (Tenivac)	aluminum phosphate, formaldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate
Td (Mass Biologics)	aluminum phosphate, formaldehyde, thimerosal, modified Mueller's media which contains bovine extracts, ammonium sulfate
Tdap (Adacel)	aluminum phosphate, formaldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, glutaraldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate, modified Mueller's growth medium
Tdap (Boostrix)	modified Latham medium derived from bovine casein, Fenton medium containing a bovine extract, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80
Typhoid (inactivated – Typhim Vi)	hexadecyltrimethylammonium bromide, formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, semi-synthetic medium
Typhoid (Vivotif Ty21a)	yeast extract, casein, dextrose, galactose, sucrose, ascorbic acid, amino acids, lactose, magnesium stearate. gelatin
Varicella (Varivax) *Frozen*	human embryonic lung cell cultures, guinea pig cell cultures, human diploid cell cultures (WI-38), human diploid cell cultures (MRC-5), sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, EDTA (Ethylenediaminetetraacetic acid), neomycin, fetal bovine serum
Varicella (Varivax) *Refrigerator Stable*	human embryonic lung cell cultures, guinea pig cell cultures, human diploid cell cultures (WI-38), human diploid cell cultures (MRC-5), sucrose, hydrolyzed gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
Yellow Fever (YF-Vax)	sorbitol, gelatin, sodium chloride, egg protein
Zoster (Shingles – Zostavax) *Frozen*	sucrose, hydrolyzed porcine gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride; MRC-5 cells, neomycin, bovine calf serum
Zoster (Shingles – Zostavax) *Refrigerator Stable*	sucrose, hydrolyzed porcine gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, MRC-5 cells, neomycin, bovine calf serum

A table listing vaccine excipients and media *by excipient* can be found in:

Grabenstein JD. *ImmunoFacts: Vaccines and Immunologic Drugs* – 2013 (38th revision). St Louis, MO: Wolters Kluwer Health, 2012.

Vaccine Administration Record (VAR)– Informed Consent for Vaccination*

Walgreens

Store number: _____ Rx number: _____
Store address: _____

SECTION A *(Please print clearly.)*

First name: _____ Last name: _____

Date of birth: _____ Age: _____ Gender: ☐ Female ☐ Male Phone: _____

Home address: _____ City: _____

State: _____ ZIP code: _____ Email address: _____

Walgreens will send immunization information from this visit to your doctor/primary care provider using the contact information provided below.

Doctor/primary care provider name: _____ Phone number: _____

Address: _____ City: _____ State: _____

I want to receive the following immunization: _____

SECTION B *The following questions will help us determine your eligibility to be vaccinated today.*

All vaccines			
1. Do you feel sick today?	☐ Yes	☐ No	☐ Don't know
2. Do you have any health conditions such as: heart disease, diabetes or asthma? If yes, please list: _____	☐ Yes	☐ No	☐ Don't know
3. Do you have allergies to latex, medications, food or vaccines? (Examples: eggs, bovine protein, gelatin, gentamicin, polymyxin, neomycin, phenol, yeast or thimerosal)? If yes, please list: _____	☐ Yes	☐ No	☐ Don't know
4. Have you ever had a reaction after receiving an immunization, including fainting or feeling dizzy?	☐ Yes	☐ No	☐ Don't know
5. Have you ever had a seizure disorder for which you are on seizure medication(s), a brain disorder, Guillain-Barré Syndrome (a condition that causes paralysis) or other nervous system problem?	☐ Yes	☐ No	☐ Don't know
6. **For women:** Are you pregnant or considering becoming pregnant in the next month?	☐ Yes	☐ No	☐ Don't know
Live vaccines (chickenpox, flu nasal spray, MMR® II, oral typhoid, shingles, yellow fever) Only answer these questions if you are receiving any immunizations listed above.			
7. Have you received any vaccinations or skin tests in the past four weeks? If yes, please list: _____	☐ Yes	☐ No	☐ Don't know
8. Do you have a condition that may weaken your immune system (e.g., cancer, leukemia, lymphoma, HIV/AIDS, transplant)?	☐ Yes	☐ No	☐ Don't know
9. Are you currently on home infusions, weekly injections such as Humira® (adalimumab), Remicade® (infliximab) and Enbrel® (etanercept), high-dose methotrexate, azathioprine or 6-mercaptopurine, antivirals, anticancer drugs or radiation treatments?	☐ Yes	☐ No	☐ Don't know
10. Are you currently taking high-dose steroid therapy (prednisone > 20mg/day or equivalent) for longer than 2 weeks?	☐ Yes	☐ No	☐ Don't know
11. Have you received a transfusion of blood, blood products or been given a medication called immune (gamma) globulin in the past year?	☐ Yes	☐ No	☐ Don't know
12. Do you have a history of thymus disease (including myasthenia gravis, DiGeorge syndrome or thymoma), or had your thymus removed? (yellow fever only)	☐ Yes	☐ No	☐ Don't know
13 Are you currently taking any antibiotics or antimalarial medications? (Oral typhoid only)	☐ Yes	☐ No	☐ Don't know
14. Do you have a history of thrombocytopenia or thrombocytopenia purpura? (MMR® II only)	☐ Yes	☐ No	☐ Don't know
Flu nasal spray (FluMist® Quadrivalent)			
15. Are you receiving aspirin therapy or aspirin-containing therapy? (18 years of age and younger only)	☐ Yes	☐ No	☐ Don't know
16. Do you have a nasal condition serious enough to make breathing difficult, such as a very stuffy nose? (For FluMist® only)	☐ Yes	☐ No	☐ Don't know

SECTION C

I certify that I am: (a) the patient and at least 18 years of age; (b) the parent or legal guardian of the minor patient; or (c) the legal guardian of the patient. Further, I hereby give my consent to the healthcare provider of Walgreens, Duane Reade, Take Care Health Services, or DR Walk-in Medical Care, as applicable (each an "applicable Provider"), to administer the vaccine(s) I have requested above. I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccine(s). I understand the risks and benefits associated with the above vaccine(s) and have received, read and/or had explained to me the Vaccine Information Statements on the vaccine(s) I have elected to receive. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. Further, I acknowledge that I have been advised to remain near the vaccination location for approximately 15 minutes after administration for observation by the administering healthcare provider. On behalf of myself, my heirs and personal representatives, I hereby release and hold harmless the applicable Provider, its staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the vaccine(s) listed above. I acknowledge that: (a) I understand the purposes/benefits of my state's immunization registry ("State Registry") and my state's health information exchange ("State HIE"); and (b) the applicable Provider may disclose my immunization information to the State Registry, to the State HIE, or through the State HIE, to the State Registry, for purposes of public health reporting or to my health care providers enrolled in the State Registry and/or State HIE for purposes of care coordination. I acknowledge that, depending upon my state's law, I may prevent, by using a state-approved opt-out form or, as permitted by my state law, an opt-out form ("Opt-Out Form") furnished by the applicable Provider. (a) the disclosure of my immunization information by the applicable Provider to the State HIE and/or State Registry; or (b) the State HIE and/or State Registry from sharing my immunization information with any of my other healthcare providers enrolled in the State Registry and/or State HIE. The applicable Provider will, if my state permits, provide me with an Opt-Out Form. I understand that, depending on my state's law, I may need to specifically consent, and to the extent required by my state's law, by signing below, I hereby do consent to the applicable Provider reporting my immunization information to the State HIE, or through the State HIE and/or State Registry to the entities and for the purposes described in this Informed Consent form. Unless I provide the applicable Provider with a signed Opt-Out Form, I understand that my consent will remain in effect until I withdraw my permission and that I may withdraw my consent by providing a completed Opt-Out Form to the applicable Provider and/or my State HIE, as applicable. I understand that even if I do not consent or if I withdraw my consent, my state's laws may permit certain disclosures of my immunization information to or through the State HIE as required or permitted by law. I also authorize the applicable Provider to disclose my, or my child's (or unemancipated minor for whom I am authorized to act as guardian or in loco parentis) proof of immunization to the school where I am, or my child (or unemancipated minor for whom I am authorized to act as guardian or in loco parentis) is, a student or prospective student. I further authorize the applicable Provider to (a) release my medical or other information, including my communicable disease (including HIV), mental health and drug/alcohol abuse information, to, or through, the State HIE to my healthcare professionals, Medicare, Medicaid, or other third-party payer as necessary to effectuate care or payment, (b) submit a claim to my insurer for the above requested items and services, and (c) request payment of authorized benefits be made on my behalf to the applicable Provider with respect to the above requested items and services. I further agree to be fully financially responsible for any cost sharing amounts, including copays, coinsurance, and deductibles, for the requested items and services as well as for any requested items and services not covered by my insurance benefits. I understand that any payment for which I am financially responsible is due at the time of service or, the applicable Provider invoices me after the time of service, upon receipt of such invoice.

Patient signature: _____ **Date:** _____
(Parent or guardian, if minor)

*Healthcare providers can be an immunization-certified pharmacist or a registered nurse, licensed practical nurse, licensed vocational nurse, nurse practitioner, physician or physicians assistant.

Patient care services at Walgreens Healthcare Clinic provided by Take Care Health Services, an independently owned professional corporation whose licensed healthcare professionals are not employed by or agents of Walgreen Co. or its subsidiaries, including Take Care Health Systems, LLC.

Patient name: _____

SECTION D — HEALTHCARE PROVIDER ONLY

Complete BEFORE vaccine administration

1. I have reviewed the **Patient Information** and **Screening Questions.** Initial here: _____
2. This is the **Vaccine Requested** by the patient. Initial here: _____
3. This vaccine is appropriate for this patient based on the **Age Guidelines** provided by federal, state regulations and company policies. Initial here: _____

   3a. Does this patient have a high-risk medical condition? ☐ Yes ☐ No
   If yes, please list medical condition(s): _____
4. The **Vaccine NDC Matches** the NDC on the bottom of this VAR form and the NDC on the patient leaflet. (Perform **3-way NDC match**). Initial here: _____
5. I have verified the **Expiration Date** is greater than today's date and have entered the **Lot # and Expiration Date** in the field below. Initial here: _____

Lot #: _____ Expiration Date: _____

Note: For Zostavax®, MMR® II, Varivax®, YF-Vax®, Menveo®, Imovax® and Rabavert®, ensure the vaccine is reconstituted following the package insert's instructions.

SECTION E

Complete DURING the Patient Interaction

1. I have asked the patient to confirm their Name, **DOB and Requested Vaccine** and verified it matches the information on the VAR form. Initial here: _____
2. I have reviewed the **Screening Questions** with the patient. Initial here: _____
3. I have reviewed the **VIS** with the patient. Initial here: _____

SECTION F

Complete AFTER vaccine administration

Vaccine	NDC	Manufacturer	Dosage	Site of administration	VIS published date

Immunizer name (print): _____ **Immunizer signature:** _____ **Title:** _____

If applicable, intern name (print): _____ **Administration date:** _____ **Date VIS given to patient:** _____

Notes

Reminder:

1. Update the patient's record with any new allergy, health condition or primary care provider information.
2. Enter vaccine lot #, expiration date and site of administration, then scan the VAR form into the patient's record.

It's Federal Law! You must give your patients current Vaccine Information Statements (VISs)

What are Vaccine Information Statements (VISs)?

Vaccine Information Statements (VISs) are documents produced by the Centers for Disease Control and Prevention (CDC), in consultation with panels of experts and parents, to properly inform vaccinees (or their parents/legal representatives) about the risks and benefits of each vaccine. VISs are not meant to replace interactions with health care providers, who should address any questions or concerns that the vaccinee (or parent/legal representative) may have.

Using VISs is legally required!

Federal law (under the National Childhood Vaccine Injury Act) requires a health care provider to give a copy of the current VIS to an adult patient or to a child's parent/legal representative before vaccinating an adult or child with a dose of the following vaccines: diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox).

Where to get VISs

All available VISs can be downloaded from the websites of the Immunization Action Coalition at www.immunize.org/vis or CDC at www.cdc.gov/vaccines/hcp/vis/index.html. Ready-to-copy versions may also be available from your state or local health department.

Translations: You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis.

To obtain translations of VIS in languages other than English, go to www.immunize.org/vis.

According to CDC, the appropriate VIS must be given:

- Prior to the vaccination (and prior to each dose of a multi-dose series);
- Regardless of the age of the vaccinee;
- Regardless of whether the vaccine is given in a public or private health care setting.

Top 10 Facts About VISs

FACT 1 — It's federal law! You must give current* VISs to all your patients before vaccinating them.

Federal law requires that VISs must be used for patients of **ALL ages** when administering these vaccines:

- DTaP (includes DT)
- Td and Tdap
- Hib
- hepatitis A
- hepatitis B
- HPV
- influenza (inactivated and live, intranasal)
- MMR and MMRV
- meningococcal
- pneumococcal conjugate
- polio
- rotavirus
- varicella (chickenpox)

For the vaccines not covered under the National Childhood Vaccine Injury Act (i.e., adenovirus, anthrax, Japanese encephalitis, pneumococcal polysaccharide, rabies, shingles, typhoid, and yellow fever), providers are not required by federal law to use VISs unless they have been purchased under CDC contract. However, CDC recommends that VISs be used whenever these vaccines are given.

*Federal law allows up to 6 months for a new VIS to be used.

FACT 2 — VISs can be given to patients in a variety of ways.

In most medical settings, VISs are provided to patients (or their parents/legal representatives) in paper form. However, VISs also may be provided using electronic media. Regardless of the format used, the goal is to provide a current VIS just prior to vaccination.

CONTINUED ON NEXT PAGE ▶

Most current versions of VISs (table)

As of December 2, 2016, the most recent versions of the VISs are as follows:

Adenovirus	6/11/14
Anthrax	3/10/10
Chickenpox	3/13/08
DTaP	5/17/07
Hib	4/2/15
Hepatitis A	7/20/16
Hepatitis B	7/20/16
HPV	12/2/16
Influenza	8/7/15
Japanese enceph	1/24/14
MCV4/MPSV4	3/31/16
MenB	8/9/16
MMR	4/20/12
MMRV	5/21/10
Multi-vaccine	11/5/15
PCV13	11/5/15
PPSV	4/24/15
Polio	7/20/16
Rabies	10/6/09
Rotavirus	4/15/15
Shingles	10/6/09
Td	2/24/15
Tdap	2/24/15
Typhoid	5/29/12
Yellow fever	3/30/11

A handy list of current VIS dates is also available at www.immunize.org/catg.d/p2029.pdf.

immunization action coalition
IAC
immunize.org

Technical content reviewed by the Centers for Disease Control and Prevention

Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

www.immunize.org/catg.d/p2027.pdf • Item #P2027 (12/16)

(For information on special circumstances involving vaccination of a child when a parent/legal representative is not available at the time of vaccination, see CDC's *Frequently Asked Questions* at www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html.)

Prior to vaccination, VIS may be:

- Provided as a paper copy
- Offered on a permanent, laminated office copy
- Downloaded by the vaccinee (parent/legal representative) to a smartphone or other electronic device (VISs have been specially formatted for this purpose)
- Made available to be read before the office visit, e.g., by giving the patient or parent a copy to take home during a prior visit, or telling them how to download or view a copy from the Internet. These patients must still be offered a copy in one of the formats described previously to read during the immunization visit, as a reminder.

Regardless of the way the patient is given the VIS to read, providers must still offer a copy (which can be an electronic copy) of each appropriate VIS to take home following the vaccination. However, the vaccinee may decline.

FACT 3 VISs are required in both public and private sector health care settings.

Federal law requires the use of VISs in both public and private sector settings, regardless of the source of payment for the vaccine.

FACT 4 You must provide a current VIS *before* a vaccine is administered to the patient.

A VIS provides information about the disease and the vaccine and must be given to the patient **before** a vaccine is administered. It is also acceptable to hand out the VIS well before administering vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide a current VIS right before administering vaccines.

FACT 5 You must provide a current VIS for *each* dose of vaccine you administer.

The most current VIS must be provided before **each dose** of vaccine is given, including vaccines given as a series of doses. For example, if 5 doses of a single vaccine are required (e.g., DTaP), the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.

FACT 6 You must provide VISs whenever you administer combination vaccines.

If you administer a combination vaccine that does not have a stand-alone VIS (e.g., Kinrix, Quadracel, Pediarix, Pentacel, Twinrix) you should provide the patient with individual VISs for the component vaccines, or use the Multi-Vaccine VIS (see below).

The Multi-Vaccine VIS may be used in place of the individual VISs for DTaP, Hib, hepatitis B, polio, and pneumococcal when two or more of these vaccines are administered during the same visit. It may be used for infants as well as children through 6 years of age. The Multi-Vaccine VIS should not be used for adolescents or adults.

FACT 7 VISs should be given in a language/format that the recipient can understand, whenever possible.

For patients who don't read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive a VIS, regardless of their ability to read English. To obtain VISs in more than 30 languages, visit the Immunization Action Coalition website at www.immunize.org/vis. Providers can supplement VISs with visual presentations or oral explanations as needed.

FACT 8 Federal law does not require signed consent in order for a person to be vaccinated.

Signed consent is not required by federal law for vaccination (although some states may require it).

FACT 9 To verify that a VIS was given, providers must record in the patient's medical record (or permanent office log or file) the following information:

- The edition date of the VIS (found on the back at the right bottom corner)
- The date the VIS is provided (i.e., the date of the visit when the vaccine is administered)

In addition, providers must record:

- The office address and name and title of the person who administers the vaccine
- The date the vaccine is administered
- The vaccine manufacturer and lot number

FACT 10 VISs should not be altered before giving them to patients, but you can add some information.

Providers should not change a VIS or write their own VISs. However, it is permissible to add a practice's name, address, and contact information to an existing VIS.

Additional resources on VISs and their use are available from the following organizations:

Immunization Action Coalition

- *VIS general information and translations in more than 30 languages:* www.immunize.org/vis
- *Current Dates of Vaccine Information Statements:* www.immunize.org/catg.d/p2029.pdf

Centers for Disease Control and Prevention

- *VIS website:* www.cdc.gov/vaccines/hcp/vis
- *VIS Facts:* www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html
- *VIS FAQs:* www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html