HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 33 Childhood Vaccinations
SPONSOR(S): Health Care Regulation Policy Committee, Ambler
TIED BILLS: **IDEN./SIM. BILLS:** SB 308

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	7 Y, 0 N, As CS	Akin	Calamas
2)	PreK-12 Policy Committee			
3)	Health & Family Services Policy Council			
4)	Human Services Appropriations Committee			
5)	Full Appropriations Council on General Government & Health Care			

SUMMARY ANALYSIS

House Bill 33 Amends section 1003.22, F.S., relating to school entry health examinations and childhood immunizations against communicable diseases. The bill requires health care practitioners to provide the parent or legal guardian of a minor child with a copy of the current vaccine information statement (VIS) published by the Centers for Disease Control and Prevention before administering any vaccine to the minor child that is required to be administered by section 1003.22, F.S.

The bill prohibits administration of vaccines to minors without a statement, signed by the parent or guardian, documenting that the vaccine information statement was provided. The bill provides specific language to be used for the signed statement, by which the parent or guardian represents that he or she:

- Has received a copy of the VIS;
- Has received information on the benefits and risks of the vaccine and how to report an adverse reaction;
- Has received information on the National Vaccine Injury Compensation Program; and
- How to get more information on childhood diseases and vaccines.

The signed statement must also include a notation of the batch and lot number for each vaccine administered to the child. The practitioner must include the signed statement in the minor's medical record.

The bill clarifies that the requirements apply to each VIS published by the Centers for Disease Control and Prevention, regardless of whether the statement is covered by the federal National Childhood Vaccine Injury Act of 1986. The bill permits a practitioner to provide a single statement covering multiple vaccines to the parent, if the Centers for Disease Control and Prevention has published a VIS that covers multiple vaccines.

The bill appears to have no fiscal impact on state or local government.

The bill takes effect July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

School-Age Vaccination Requirements

According to the Department of Health (DOH), the National Childhood Vaccine Injury Act (42 U.S.C. Section 300aa-26), requires all health care providers in the United States who administer, to any child or adult, vaccines for diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, Haemophilus influenzae type b, trivalent influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus, or varicella, shall provide a copy of the most recent and relevant edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC). These vaccine information materials are entitled Vaccine Information Statements (VIS). This information is provided to parents, legal guardians or patients prior to administering any of the above-mentioned vaccines. VISs do not include detailed information regarding the vaccine ingredients as listed on the package insert or vaccine efficacy but cover the potential side effects (adverse events) of the vaccine, risks associated with the disease that the vaccination is intended to prevent, contraindications to the vaccine, and options regarding the administration of the vaccination, including the timing or combination of multiple vaccinations.[1]

Florida law requires DOH to consult with the Florida Department of Education and adopt rules governing the immunization of children against preventable communicable diseases, and requires immunizations for poliomyelitis, diphtheria, rubeola, rubella, pertussis, mumps, tetanus, and other communicable diseases as determined by those rules.[2]

DOH rules require immunizations for diphtheria, pertussis (whooping cough), tetanus, poliomyelitis, rubeola (measles), rubella, mumps, Haemophilus influenza type b, hepatitis B series, varicella (chicken pox), and certain boosters, for school entry.[3] Other childhood vaccines, although not required for school, are recommended, including: hepatitis A, meningococcal conjugate, human papillomavirus, rotavirus, pneumococcal conjucate vaccine, trivalent inactivated influenza vaccine, and live attenuated influenza

[1] Department of Health Bill Analysis, Economic Statement and Fiscal Note, House Bill 33 (2009).
[2] Fla. Stat. S. 1003.22(3)
[3] 64d-3.011, F.A.C. (2008)

vaccine.[4] Florida law requires that "the manner and frequency of administration of the immunization or testing shall conform to recognized standards of medical practice."[5]

Further, each district school board and the governing authority of each private school must establish and enforce a policy that, prior to admittance to or attendance in school, each child have a "certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health…"[6] These provisions together effectively require children to receive certain vaccinations, as determined by DOH, before attending school in Florida.

Florida law provides several exemptions. The school-age immunization requirements do not apply if:

- A parent objects in writing that the administration of immunizing agents conflicts with his or her religious tenets or practices;
- A physician certifies in writing that the child should be permanently exempt from the required immunization for medical reasons stated in writing, based upon valid clinical reasoning or evidence;
- A physician certifies in writing that the child has received as many immunizations as are medically indicated at the time and is in the process of completing necessary immunizations;
- DOH determines that, according to recognized standards of medical practice, the required immunization is unnecessary or hazardous; or
- An authorized school official issues a temporary exemption for up to 30 days.[7]

DOH rules establish the forms and procedures for invoking an exemption.[8]

Public Health Impact of Failure to Vaccinate or Delayed Vaccination

In highly infectious diseases, greater than 90 percent of the population needs to be vaccinated to interrupt transmission and maintain elimination of the disease in populations.[9] For example, in Switzerland, a widespread outbreak of measles occurred in 2005 despite the fact that 86 percent of the population had received one dose of the vaccine and 70 percent of the population has received two doses of the vaccine.[10]

In the United States, more than 95 percent of school-aged children have received the measles vaccine during this decade.[11] In February 2008, a measles outbreak occurred in San Diego California when an unvaccinated seven year old boy contracted the disease after traveling to Switzerland.[12] The disease spread to a documented 11 additional unvaccinated children aged 10 months to nine years, and resulted in the hospitalization of one of the 11 infected children. An additional 70 children exposed to the infection were voluntarily quarantined for 21 days after their last exposure, either because their parents declined to vaccinate them or because they were too young to be vaccinated. Of the eleven infected (unvaccinated) children, nine were old enough to be vaccinated. Eight of the nine infected children old enough to be vaccinated were unvaccinated as a result of the personal belief exemption available in California.

Because not all vaccinations are 100 percent effective in preventing a person from contracting the targeted disease, even vaccinated people are at risk when fewer than 90 percent of the population is vaccinated. In April 2006, the state of Iowa reported a large outbreak of mumps (605 reported and suspected cases) that

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[4] Centers For Disease Control, "Recommended Immunization Schedules For Persons Aged 0 Through 18 Years --- United States, 2009", Mmwr Weekly, January 2, 2009, *Available At* Http://Www.Cdc.Gov/Mmwr/Preview/Mmwrhtml/Mm5751a5.Htm?S_Cid=Mm5751a5_E (Last Viewed March 21, 2009).
[5] Fla. Stat. S. 1003.22(3)
[6] Fla. Stat. S. 1003.22(4)
[7] Fla. Stat. S. 1003.22(5)
[8] 64d-3.011, F.A.C. (2008)
[9] Centers for Disease Control, *Outbreak of Measles – San Diego California*, MMWR Weekly, February 22, 2008, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a3.htm (last viewed March 24, 2009).
[10] *Id*.
[11] *Id.*
[12] Centers for Disease Control, *Outbreak of Measles – San Diego California*, MMWR Weekly, February 22, 2008, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a3.htm (last viewed March 24, 2009).

began as early as December 2005.[13] The majority of cases occurred among persons aged 18-25, many of whom were vaccinated. Data from the outbreak investigations suggests that the measles, mumps, and rubella (MMR) vaccine is about 80 percent effective in preventing infection after one dose and about 90 percent effective after two doses.[14] The source of the outbreak could not be positively identified, but the mumps strain was identified as the same strain circulating in the United Kingdom (UK). An outbreak in the UK began in 2004 and involved more than 70,000 cases, occurring mostly in unvaccinated young adults.[15]

In March 2009, an outbreak of pertussis (whooping cough) occurred in Sarasota County Florida. The outbreak involved 15 cases of pertussis in a private elementary school among students, teachers, and parents.[16] On average, Sarasota County reports 6 pertussis cases *per year,* so the one-month outbreak was more than double the annual average. The cause and origin of the outbreak are presently unclear.

The public response to outbreaks typically involves identification of cases, isolation of patients and vaccination, administration of immune globulin, and voluntary quarantine of contacts who have no evidence of immunity.[17] The cost associated with control of these outbreaks can be substantial. In Iowa, the public health response to one measles case cost approximately $150,000.[18]

Express and Informed Consent

Florida law requires that "each patient be given express or informed consent before receiving treatment."[19] If the patient is a minor, express and informed consent for admission or treatment is also required from the patient's guardian. "Express and informed consent for admission or treatment of a patient under 18 years of age shall be required from the patient's guardian, unless the minor is seeking outpatient crisis intervention services."[20] Express and informed consent requires that the following information "be provided and explained in plain language to the patient…or to the patient's guardian:

- the reason for admission or treatment;
- the proposed treatment;
- the purpose of the treatment to be provided;
- *the common risks, benefits, and side effects thereof*;
- the specific dosage range for the medication, when applicable;
- *alternative treatment modalities*;
- the approximate length of care;
- *the potential effects of stopping treatment*;
- how treatment will be monitored; and
- that any consent given for treatment may be revoked orally or in writing before or during the treatment period by the patient or by a person who is legally authorized to make health care decisions on behalf of the patient."[21]

Vaccines and Autism Spectrum Disorder

Autism Spectrum Disorder (ASD)[22] is the name commonly used for pervasive developmental disorders, which include autistic disorder, Asperger's Syndrome, Rett's Syndrome[23], and childhood disintegrative

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[13] Centers for Disease Control, *Corrected: Multi State Mumps Outbreak*, April 14, 2006, *available at* http://health.state.ga.us/programs/emerprep/healthalerts/alerts/20060415.html (last viewed March 24, 2009).
[14] *Id*.
[15] *Id*.
[16] Sarasota County Government, *Local Public Health Officials Investigate Whooping Cough (Pertussis) Cases*, March 18, 2009, *available at* http://www.co.sarasota.fl.us/NewsStories/news2.asp (last viewed March 24, 2009).
[17] Centers for Disease Control, *Outbreak of Measles – San Diego California*, MMWR Weekly, February 22, 2008, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a3.htm (last viewed March 24, 2009).
[18] Dayan GH, Ortega-Sanchez IR, LeBaron CW, Quinlisk MP; Iowa Measles Response Team. The cost of containing one case of measles: the economic impact on the public health infrastructure---Iowa, 2004. Pediatrics 2005;116:e1--4.
[19] Fla. Stat. S. 394.459
[20] Fla. Stat. S. 394.459
[21] Fla. Stat. S. 394.459(3)(A)(2) (Emphasis Added)

disorder.[24] A child that exhibits symptoms of Asperger's Syndrome or autistic disorder, but does not meet the criteria for either, will be diagnosed as having a pervasive developmental disorder not otherwise specified (PDD-NOS). Autism spectrum disorders are generally detected by the age of three and affect from two to six per 1,000 children. The earlier a child is diagnosed with an autism spectrum disorder, the more opportunity a child will have to learn new skills and be integrated into the community. Common characteristics shared by children with autism spectrum disorders are varying degrees of deficits in social interaction, verbal and nonverbal communication, and repetitive behaviors or interest. Many children with autism spectrum disorders have some degree of mental impairment.

Recent estimates from the Center for Disease Control and Prevention (CDC) Autism and Developmental Disabilities Monitoring network found that about one in 150 children have an ASD; this estimate is higher than estimates from the early 1990s.[25] Some believe increased exposure to preservatives in vaccines (from the addition of new vaccines recommended for children) explains the higher prevalence in recent years. Specifically, a link between the preservative mercury, contained in vaccines administered to children, and the onset of ASD has been suggested.[26] Preservatives are used in vaccines to prevent microbial growth (and infection) in the event that the vaccine is accidentally contaminated, as can occur with repeated puncture of multi-dose vials. Thimerosal, which is approximately 50 percent mercury by weight, has been one of the most widely used preservatives in vaccines since the 1930s.[27]

Several studies have been performed on the potential link between mercury and ASD, all concluding that no link exists between the thimerosal/mercury in vaccines and ASD.[28] Specifically, some have theorized that the administration of multiple vaccines containing mercury together or in a short time period, has the potential to overload the immune system of a young child, and may lead to the onset of ASD. However, evidence from several studies examining trends in vaccine use and changes in autism frequency does not support such an association.[29] Furthermore, a scientific review by the Institute of Medicine (IOM) concluded that "the evidence favors rejection of a causal relationship between thimerosal/mercury-containing vaccines and autism."[30] CDC supports the IOM conclusion.[31] In July 1999, the Public Health Service agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal/mercury should be reduced or eliminated in vaccines as a precautionary measure. Since 2001, with the exception of some influenza (flu) vaccines, thimerosal/mercury is not used as a preservative in routinely recommended

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[22] Information For This Section Was Obtained From The National Institute Of Mental Health, "Autism Spectrum Disorders, Pervasive Developmental Disorders", U.S. Department Of Health And Human Services, With Addendum January 2007 (Citations Omitted); *Available At* : Http://Www.Nimh.Nih.Gov/Health/Publications/Autism/Nimhautismspectrum.Pdf (Last Viewed March 21, 2009).

[23] Rett Syndrome Is Linked Almost Exclusively To Females, Affecting One Out Of 10,000 To 15,000 Females. It Is Typically Diagnosed At Some Time Between A 6 And 18 Months When Autism-Like Symptoms Begin To Develop.

[24] Childhood Degenerative Disorder Is A Very Rare Autism Spectrum Disorder With A Strong Male Preponderance. Symptoms Typically Onset Between The Ages Of Three And Four Years, And May Result In The Loss Of Motor, Language And Social Skills, As Well As Bladder And Bowel Control.

[25] *Id*.

[26] A Series Of Articles In The Lancet First Posed This Theory. However, The Suggestion Of A Link Between Certain Vaccines And Autism Was Retracted By Ten Of The Thirteen Authors Of That Study In 2004. See, Wakefield Aj, Murch Sh, Anthony A, Linnell J, Casson Dm, Malik M, Berelowitz M, Dhillon Ap, Thomson Ma, Harvey P, Valentine A, Davies Se, And Walker-Smith Ja. (1998). Ileal-Lymphoid-Modular Hyperplasia, Non-Specific Colitis, And Pervasive Developmental Disorder In Children. Lancet, 351(9103), 637-641; Murch Sh, Anthony A, Cassen Dh, Et Al. (2004) Retraction Of An Interpretation. *Lancet*, 363: 750, *Available At* Http://Www.Thelancet.Com/Journals/Lancet/Article/Piis0140-6736(04)15715-2/Fulltext (Last Viewed March 21, 2009).

[27] The Information Contained In This Section Was Gathered From The United States Food And Drug Administration's Report On Thimerosal In Vaccines Found At Http://Www.Fda.Gov/Cber/Vaccine/Thimerosal.Htm And The Center For Disease Control Report *Available At* Http://Www.Cdc.Gov/Vaccinesafety/Concerns/Thimerosal.Htm.

[28] *See* Institute Of Medicine, *Immunization Safety Review: Vaccines And Autism*, Washington, Dc: National Academies Press 2004, *Available At* Http://Www.Nap.Edu/Catalog.Php?Record_Id=10997 (Last Viewed March 21, 2009), Reported In, Anne Ziegler, *Mercury In Vaccines Doesn't Hurt Kids*, January 27, 2009, *Available At* Http://Www.Fiercehealthcare.Com/Story/Study-Mercury-Vaccines-Doesnt-Hurt-Kids/2009-01-27?Utm_Medium=Rss&Utm_Source=Rss&Cmp-Id=Otc-Rss-Fh0#Comments.

[29] *See* Anne Ziegler, *Mercury In Vaccines Doesn't Hurt Kids*, January 27, 2009, *Available At* Http://Www.Fiercehealthcare.Com/Story/Study-Mercury-Vaccines-Doesnt-Hurt-Kids/2009-01-27?Utm_Medium=Rss&Utm_Source=Rss&Cmp-Id=Otc-Rss-Fh0#Comments And Institute Of Medicine, *Immunization Safety Review: Vaccines And Autism*, Washington, Dc: National Academies Press 2004.

[30] Id. At Supra, Note 16.

[31] Centers For Disease Control And Prevention, Mercury And Vaccines (Thimerosal), *Available At* Http://Www.Cdc.Gov/Vaccinesafety/Concerns/Thimerosal.Htm (Last Viewed March 21, 2009).

childhood vaccines.[32] Autism awareness groups maintain that there is a causal link between the mercury levels present in childhood vaccines and ASD.

The amount of litigation surrounding the debate over mercury in vaccines, and its alleged link to autism and other neurological defects in children has increased in recent years. Parents of autistic children across the United States have begun filing lawsuits alleging that vaccine manufacturers should have been more thorough in testing the preservative thimerosal, and should have warned parents of potential risks. In other cases, plaintiffs have alleged that the manufacturers knew of the potential harmful effects of thimerosal/mercury in vaccines and took no action to warn the public or mitigate the harm. Some courts have dismissed these claims on summary judgment in favor of the manufacturers, while other courts have allowed the claims to go forward with mixed results. [33]

Most recently, three families sought compensation from the National Vaccine Injury Compensation Program[34], alleging that vaccinations led to their children's neuro-developmental conditions. The United States Court of Federal Claims denied the claims, concluding there was no causal link between the vaccines and the injuries.[35] The Court found that "the numerous medical studies concerning these issues, performed by medical scientists worldwide, have come down strongly against the [parent's] contentions."[36] A total of 5,564 autism-related petitions have been filed with the Program since 1989; none led to compensation.[37]

In March 2008, Governor Charlie Crist created the Task Force on Autism Spectrum Disorders (Task Force).[38] The Task Force, which is administratively housed at DOH, is charged with exploring options for health coverage of autism treatments and assessing the economic impact of autism on families and the state. In addition, the 21-member Task Force is to work to coordinate and review the efforts of state agencies and organizations, encourage public-private partnerships, develop a comprehensive Florida autism website, and develop a strategy for early diagnosis and intervention. The Task Force will present a report to the Governor on March 20, 2009.

B. EFFECT OF PROPOSED CHANGES:

House Bill 33 Amends section 1003.22, F.S., relating to school entry health examinations and childhood immunizations against communicable diseases. The bill requires health care practitioners to provide the parent or legal guardian of a minor child with a copy of the current vaccine information statement (VIS) published by the Centers for Disease Control and Prevention before administering any vaccine to the minor child that is required to be administered by section 1003.22, F.S.

The bill prohibits administration of vaccines to minors without a statement, signed by the parent or guardian, documenting that the vaccine information statement was provided. The bill provides specific language to be used for the signed statement, by which the parent or guardian represents that he or she:

- Has received a copy of the VIS;

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[32] *Id.* At *Supra*, Note 16.
[33] *See American Home Products Corp. V. Ferrari,* 668 S.E.2d 236 (Ga. 2008), *Aventis Pasteur, Inc. V. Skevofilax*, 914 A.2d 113 (Md. 2007), *In Re Vaccine Cases* 134 Cal. App. 4th 438, 36 Cal.Rptr.3d 80.
[34] The National Vaccine Injury Compensation Program Was Created By The National Childhood Vaccine Injury Act Of 1986 (Public Law 99-660) As A No-Fault Alternative To Traditional Tort Litigation Related To Vaccine Injuries. It Is Administered By U.S. Department Of Health And Human Services, Health Resources And Services Administration (Hrsa), And Cases Are Decided By The U.S. Court Of Federal Claims. Additional Information Is Available At The Hrsa Website: Http://Www.Hrsa.Gov/Vaccinecompensation/.
[35] *See Cedillo V. Sec'y Of U.S. Dept. Of Health And Human Svcs*., No. 98-916v, 2009 Wl 331968 (Fed. Cl.) (Feb. 12, 2009); *Hazlehurst V. Sec'y Of U.S. Dept. Of Health And Human Svcs.*, No. 03-654v, 2009 Wl 332258 (Fed. Cl.) (Feb. 12, 2009); *Snyder V. Sec'y Of U.S. Dept. Of Health And Human Svcs*., No. 01-162v, 2009 Wl 332044 (Fed. Cl.) (Feb. 12, 2009); Avery Johnson, *U.S. Court Rejects Vaccine Connection To Autism*, February 12, 2009, *Available At* Http://Online.Wsj.Com/Article/Sb123445313976177691.Html.
[36] *Cedillo* At 1.
[37] National Vaccine Injury Compensation Program, Statistics Report, March 6, 2009, *Available At* Http://Www.Hrsa.Gov/Vaccinecompensation/Statistics_Report.Htm (Last Viewed March 21, 2009).
[38] See Executive Order 08-36.

- Has received information on the benefits and risks of the vaccine and how to report an adverse reaction;
- Has received information on the National Vaccine Injury Compensation Program; and
- How to get more information on childhood diseases and vaccines.

The signed statement must also include a notation of the batch and lot number for each vaccine administered to the child. The practitioner must include the signed statement in the minor's medical record.

The bill clarifies that the requirements apply to each VIS published by the Centers for Disease Control and Prevention, regardless of whether the statement is covered by the federal National Childhood Vaccine Injury Act of 1986. The bill permits a practitioner to provide a single statement covering multiple vaccines to the parent, if the Centers for Disease Control and Prevention has published a VIS that covers multiple vaccines.

The effect of this bill may be increased awareness of the potential benefits and risks of administering vaccines to children. Health care practitioners may incur additional workloads. According to DOH, the bill may create potential public health concerns as some parents may delay vaccinating children, which increase both vaccinated and un-vaccinated children's chances of contracting a vaccine-preventable disease.

C. SECTION DIRECTORY:

Section 1: Amends section 1003.22, F.S., relating to school-entry health examinations and immunizations.

Section 2: Amends section 381.003(1)(e) F.S., relating to communicable disease and AIDS prevention and control.

Section 3: Amends section 1002.42(6)(a), F.S., relating to private schools.

Section 4: Provides an effective date of July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None identified.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is required to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 25, 2009, the Health Regulation Policy Committee adopted a strike all amendment and reported the bill favorably as a committee substitute. The amendment:

- Requires practitioners to give the parent or legal guardian of a minor child a copy of the current vaccine information statement (VIS) published by the Centers for Disease Control and Prevention before administering any school-required vaccine to the minor child;
- Prohibits administration of school-required vaccines to minors without a statement, signed by the parent or guardian, documenting that the vaccine information statement was provided;
- Provides specific language to be used for the signed statement;
- Requires the practitioner to include on the signed statement a notation of the batch and lot number for each vaccine administered to the child;
- Requires the practitioner to include the signed statement in the minor's medical record;
- Provides that the requirements apply to each VIS published by the Centers for Disease Control and Prevention, regardless of whether the statement is covered by the federal National Childhood Vaccine Injury Act of 1986;
- Permits a practitioner to provide a single statement covering multiple vaccines to the parent, under certain circumstances.

The analysis is drafted to the committee substitute.