2012 State Legislative Summary

The Association of State and Territorial Health Officials (ASTHO) tracks state legislation impacting state health agencies and public health across the states. We support the peer network of state health agency legislative liaisons to facilitate the sharing of information on trends and emerging issues. This document summarizes some of the issues ASTHO tracked and analyzed during the 2012 state legislative sessions.

Public Health Funding

Prevention and Wellness Trust Fund

To bring healthcare spending growth in line with the state's economy, the Massachusetts legislature enacted SB 2526. Included among the bill's provisions is the creation of a Prevention and Wellness Trust Fund, to be administered by the Department of Public Health in collaboration with the Prevention and Wellness Advisory Board, also created by the law. The fund will be financed through a one-time assessment on health plans and acute-care hospitals with more than $1 billion in net assets that derive less than 50 percent of their revenue from public payers. The expected funding is about $60 million from 2013 to 2016. Activities paid for by the fund must have at least one of the following functions: reducing the rates of common preventable health conditions; increasing healthy habits; increasing the adoption of effective health management and workplace wellness programs; addressing health disparities; and building evidence of effective prevention programming. The state public health commissioner must no less than 75 percent of the fund each year through a competitive grant process.

Public Health Organizational Structure

In North Carolina, Gov. Bev Purdue signed HB 438 into law on June 29. This was one of several bills related to the public health system considered by the legislature during the 2012 session. The new law creates options for organizing and governing county human service agencies, by allowing the board of county commissioners to assume the powers and duties of certain boards. The law also established conditions for state and federal funding for local public health agencies and transferred responsibility for essential public health services from the state public health agency to local public health agencies. The law also requires the General Assembly's Program Evaluation division to study the feasibility of transferring the functions, powers, duties, and obligations of the Division of Public Health to the University of North Carolina Healthcare System and/or the School of Public Health at the University of North Carolina. Recommendations are to be submitted no later than Feb. 1, 2013.

Florida enacted HB 1263, which revised the purpose and structure of the Department of Health by streamlining and combining some of its divisions. The bill made substantive changes to Children's Medical Services, tuberculosis control, onsite sewage, regulation of public bathing places, the nursing student loan forgiveness program, and the health professional licensure process. The original bill, as introduced in the House, would also have shifted major public health responsibilities to the counties. The proposed decentralized public health system would have funneled block grants to counties, which would have taken over duties and potentially staff from the state. Those provisions were not included in the bill as enacted.

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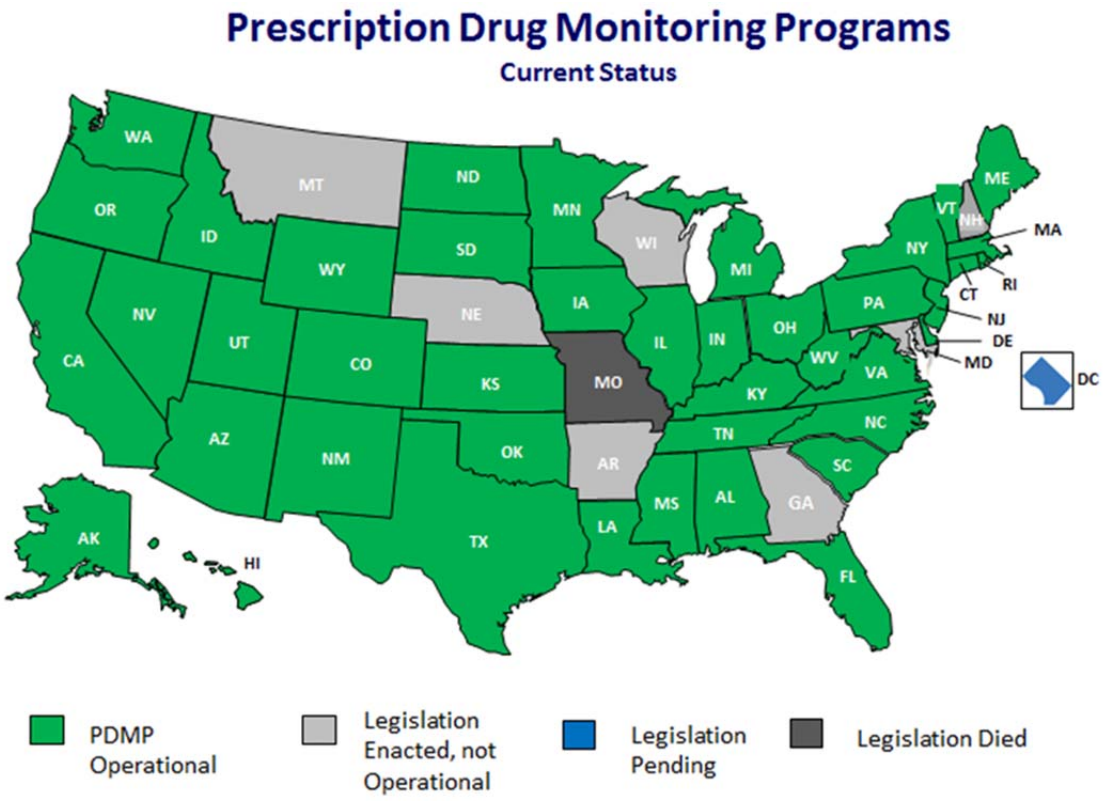
Prescription Drug Abuse, Misuse, and Overdose

Today, opiate-based prescription painkillers account for a significant amount of morbidity and mortality in the United States. According to CDC, the problem of prescription painkiller overdoses has reached epidemic proportions over the past decade. States have the authority to impose additional regulatory requirements on controlled substances provided that they do not conflict with federal laws. States have increasingly used their authority to address inappropriate prescribing. State strategies to address this complex problem have included establishing new and strengthening existing prescription drug monitoring programs (PDMP), regulating pain management facilities, and establishing education and training requirements for healthcare providers.

Prescription Drug Monitoring Programs

Going into the 2012 state legislative sessions, Missouri and New Hampshire were the only states that had not authorized the establishment of a PDMP. Both states considered bills in 2012. While New Hampshire successfully enacted SB 286 to authorize creation of a PDMP, Missouri HB 1193 was filibustered due to privacy concerns. Legislation is to create a PDMP is currently pending in the District of Columbia, B19-966.



States with Significant Activity

During a special session, Kentucky lawmakers enacted HB 1. The bill sets forth ownership and oversight requirements for pain management facilities, which are defined to include facilities where a majority of

patients are provided a controlled substance for the treatment of pain or those that advertise any form of pain management services. The health provider licensing boards will promulgate regulations addressing mandatory prescribing and dispensing standards for controlled substances; a 48-hour limit on dispensing Schedule II or III hydrocodone substances unless dispensing is part of a narcotic treatment program; procedures for emergency suspension or restriction of providers when their practice constitutes a danger to patients or the public; a process for expedited review of allegations of improper, inappropriate, or illegal prescribing or dispensing of controlled substances; and continuing education requirements in pain management, addiction disorders, or electronic monitoring. The legislature also considered moving the state's PDMP from the Cabinet for Health and Family Services to the Attorney General's Office. However, the PDMP will remain under the Cabinet.

Tennessee enacted SB 2235, the Tennessee Prescription Drug Safety Act of 2012, which increases the frequency of dispensers' reporting to the PDMP to weekly and requires most prescribers of controlled substances to register and have electronic access to the PDMP database. Prescribers are required to check the database prior to prescribing an initial course of treatment involving opioids or benzodiazepines and annually as long as the patient is being treated with the medication. Exceptions to the mandate were included for hospice, surgical procedures performed in a licensed facility, and courses of treatment that are seven days or fewer.

In New York, the Attorney General introduced a program bill in the state legislature known as the Internet System for Tracking Over-Prescribing (I-STOP) Act. The bill, A 10623, was signed into law in late August. The law enhances the tracking of prescription drugs by moving to a real time prescription monitoring registry to provide up-to-date information to practitioners. The law also requires all prescriptions to be electronically transmitted; requires prescribers to check the registry prior to prescribing Schedule II, III, and IV medications; creates a workgroup of stakeholders to guide the development of medical education courses and public awareness measures regarding pain management and prescription drugs; and requires the Department of Health to establish a safe disposal program for unused medications.

In March, West Virginia enacted SB 437, which is aimed at curbing prescription drug diversion. The bill contains five primary areas of focus: requiring the licensing and regulation of pain management clinics, implementing additional regulation for methadone clinics, establishing review capabilities of the PDMP under the Board of Pharmacy to flag patients with abnormal or unusual controlled substance usage patterns or usual prescribing patterns by licensed practitioners, establishing continuing education requirements for prescribers and dispensers of controlled substances, and requiring pharmacies to use a multi-state, real-time tracking system to track sales of pseudoephedrine.

Food Safety

Cottage Foods

Cottage food laws exempt certain non-potentially-hazardous foods that are produced in home kitchens for direct sale to customers from the licensing and inspection provisions of the state's food law. These laws have been gaining traction in state legislatures, in part because they are viewed as a way of promoting small businesses and local products. In 2012, at least 13 states considered enacting or amending their existing cottage food law. (Note that the map on the following page reflects both 2011

and 2012 activity, and therefore shows activity in more than 13 states). California (AB 1616), Colorado (SB 48), Maryland (HB 399/SB 550), Michigan (HB 5150), New Hampshire (HB 1402), South Carolina (SB 1038), and Tennessee (SB 3547) adopted cottage food legislation.

States with Significant Activity

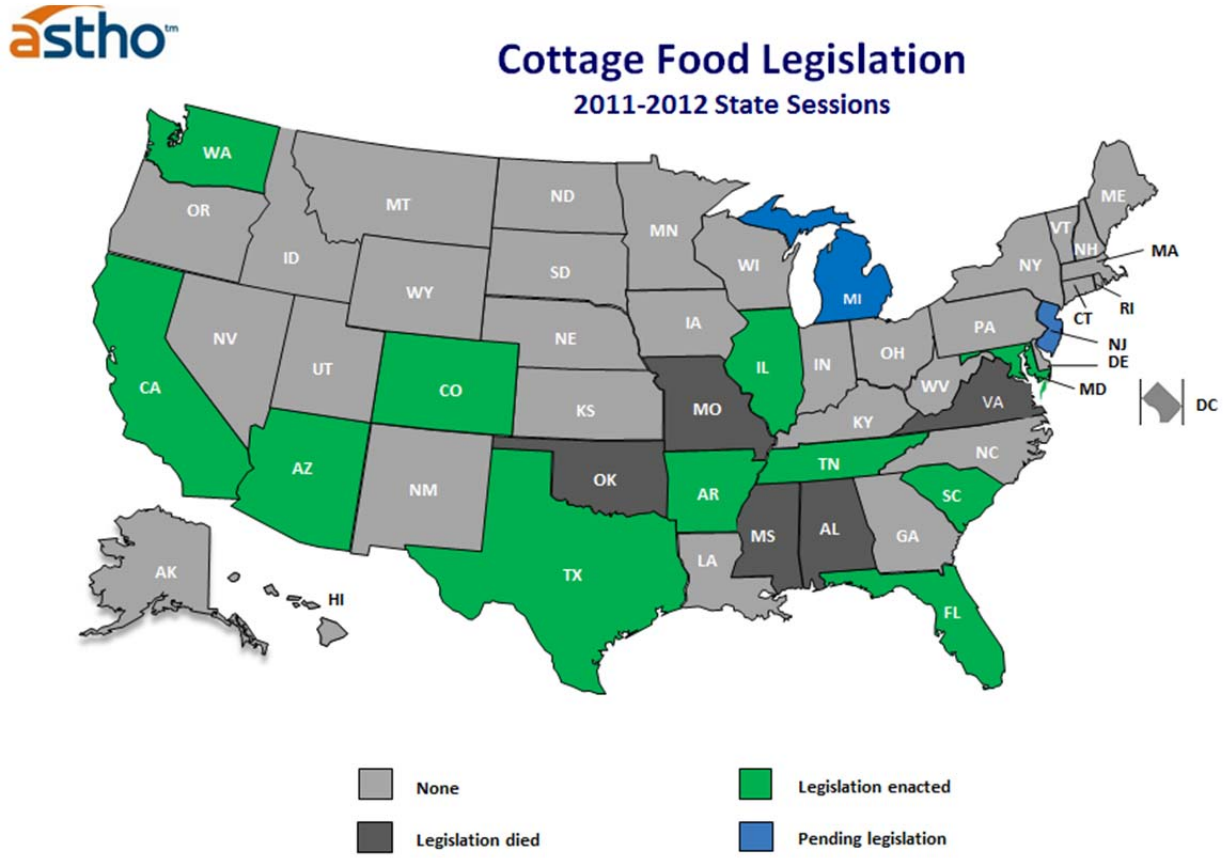
California enacted AB 1616, known as the California Home Made Food Act. Under the law, retail food operations are permitted to prepare food in a private home, as long as they have met minimum standards for training, sanitation, zoning/facility permitting, preparation, and labeling. Cottage food products served in food facilities must be identified as homemade. Cottage food operations are classified as "class A" or "class B," meaning that they can engage in direct sale of products or both direct and indirect sales of products, respectively. Cottage foods are defined to include nonperishable items and items that do not require temperature control. These products include baked goods, candy, chocolate-covered nonperishable foods, dried fruit, dried pasta, dry baking mixes, jams, jellies, preserves, fruit butter, nut mixes and nut butters, popcorn, vinegar and mustard, roasted coffee, and dried tea. To be considered a cottage food facility, gross annual sales must be limited to $35,000 in 2013. The amount rises to $45,000 in 2014 and $50,000 in 2015.

Colorado enacted SB 48, the Colorado Cottage Food Act, which establishes regulations for the cottage food industry. Under the law, cottage food producers are permitted to use a home, commercial, private, or public kitchen to prepare items for direct sale to consumers provided that they are certified in safe food handling. The law sets forth labeling requirements and establishes that a producer's total revenue cannot exceed $5,000 per calendar year. Food producers are encouraged to maintain adequate liability insurance. Nonprofit organizations are not liable for any injury caused by donated food produced pursuant to the Act, unless the organization acted unreasonably. The law also provides exemptions from civil and criminal liability to school and nonprofit kitchens used to produce cottage food unless the facility acted unreasonably. The Department of Health or a county, district, or regional health agency may create a voluntary electronic registry of cottage food producers. The law also sets forth requirements for cottage operations selling eggs at farmer's markets or community supported agricultural organizations.

Maryland enacted HB 399/SB 550 to regulate cottage food businesses. The law sets annual revenue levels for cottage food businesses at $25,000 and requires cottage food products to be labeled with the name and address of the business, the name and ingredients of the product, the weight of the product, allergen information, and the statement: "Made by a cottage food business that is not subject to Maryland's Food Safety Regulations." The Department of Health and Mental Hygiene is authorized to investigate and address any claim or issue regarding the product and cottage food business.

Tennessee enacted SB 3547, which clarified the state's cottage food law by defining a home-based kitchen as a cooking facility in a person's primary residence and identifying the non-potentially-hazardous food items that may be sold. The law also defines potentially hazardous food as "any food that consists in whole or in part of milk or milk products, eggs, meat, poultry, fish, shellfish, edible crustaceans, or other ingredients which are in a form capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms, home-canned foods other than jams and jellies, or any food that requires temperature control for safety." Cottage foods are permitted to be sold at a person's residence, community event, or farmer's market. A sign is required at the place of sale stating: "These

food products were made in a private home not licensed or inspected." The cottage food product itself requires a label with the name and address of the producer, the name of the product, the date it was packaged, the net quantity of the product, and the statement: "This product was made in a private home not licensed or inspected." The Tennessee Department of Health is authorized to inspect and investigate cottage food businesses, and their operators are encouraged to take a food safety course.

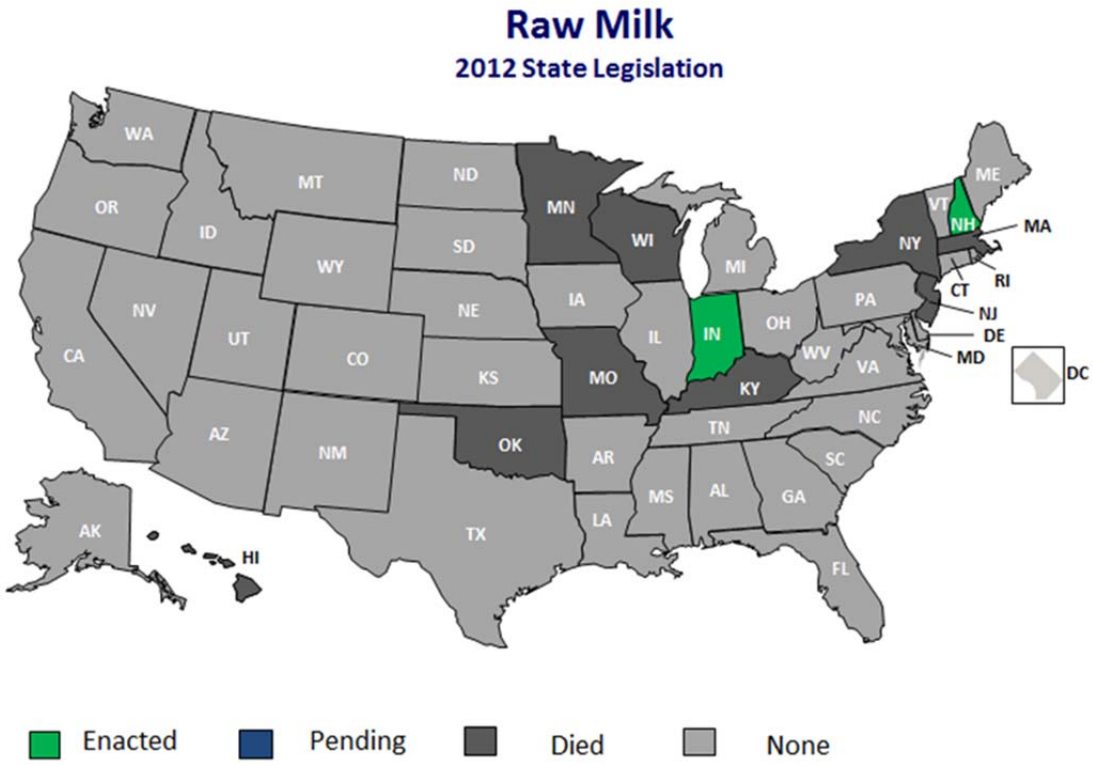


Raw Milk

Public health agencies are seeing an increased number of outbreaks related to the consumption of raw, unpasteurized milk. Raw milk may contain pathogens, which can lead to serious illness. However, a growing number of consumers are interested in drinking raw milk, for reasons ranging from a desire to buy locally produced food to a belief in its purported health benefits. Raw milk and its sale were addressed in 15 states this session. The issues considered included personal consumption, direct farm-to-consumer sales and delivery, and retail sales. Of the states considering legislation, bills were only adopted in two states, Indiana and New Hampshire. This trend is thought to be related to the outbreaks associated with raw milk this year.

Indiana adopted HB 1129, which is largely a technical bill dealing with the powers of the state chemist. Included in the bill is a requirement that the Indiana State Board of Animal Health study whether

farmers should sell unpasteurized milk to consumers. The report is expected to be published on Dec. 1. New Hampshire adopted HB 1402, which exempts small-scale producers generating less than 20 gallons of milk per day from licensure requirements. The law sets forth labeling requirements for raw milk products, which include the name, address, and telephone number of the producer-distributor farm, the name of the product, and the statement: "This product is made with raw milk and is exempt from New Hampshire licensing and inspection."



Food Freedom

Idaho, Michigan, Mississippi, and New Hampshire considered food freedom legislation in response to the Food Safety and Modernization Act. Food freedom laws declare that Congress' authority to regulate commerce does not apply to food grown and produced in the state, when sold within the state. As such, the laws are designed to allow food produced locally to be sold to consumers within the state through farmers' markets, roadside stands, and home-based kitchens. Under New Hampshire HB 1650, a product labeled "made in New Hampshire" that is sold only within the state would be exempt from federal regulations. Some proposed state laws go a step further and would utilize the state criminal code against state employees and federal officials to stop enforcement of food safety laws. For example, the New Hampshire bill stated that "any official, agent, or employee of the government of the United States, or employee of a corporation providing services to the government of the United States that enforces or attempts to enforce a federal act, order, statute, rule, or regulation of the government of the United States upon a foodstuff labeled 'Made in New Hampshire' shall be guilty of a class A misdemeanor." No state enacted food freedom legislation this session.

Hydraulic Fracturing

During the 2012 legislative session, approximately 140 bills were introduced in 19 states addressing hydraulic fracturing (fracking). Trends in legislation on this issue include chemical disclosure requirements; casing integrity, well spacing, setback, water withdrawal, flowback, waste regulations, or other measures to protect water; and new or amendments to existing severance taxes. Vermont enacted HB 464, a moratorium prohibiting fracking. Maryland Gov. Martin O'Malley issued an executive order imposing a ban on fracking through 2014. In New York, regulations are on hold until a health impact review of shale gas drilling is complete.

Pennsylvania enacted HB 1950, which provides for a broad overhaul of the state's gas drilling regulations, including restrictions on local zoning rules, fees on drilling companies, and chemical disclosure requirements. There has been some controversy in Pennsylvania over the state's chemical disclosure law, as it protects certain information as a trade secret. Under the law, physicians are entitled to trade secret information to diagnose and treat a patient, but the information is subject to a confidentiality agreement. A physician in the state has filed a lawsuit against the state Department of Environmental Protection claiming the law violates health care providers' rights to open and free exchange of information and advice to their patients, colleagues, medical researchers, and the public, as guaranteed under the First and Fourteenth Amendments of the United States Constitution.

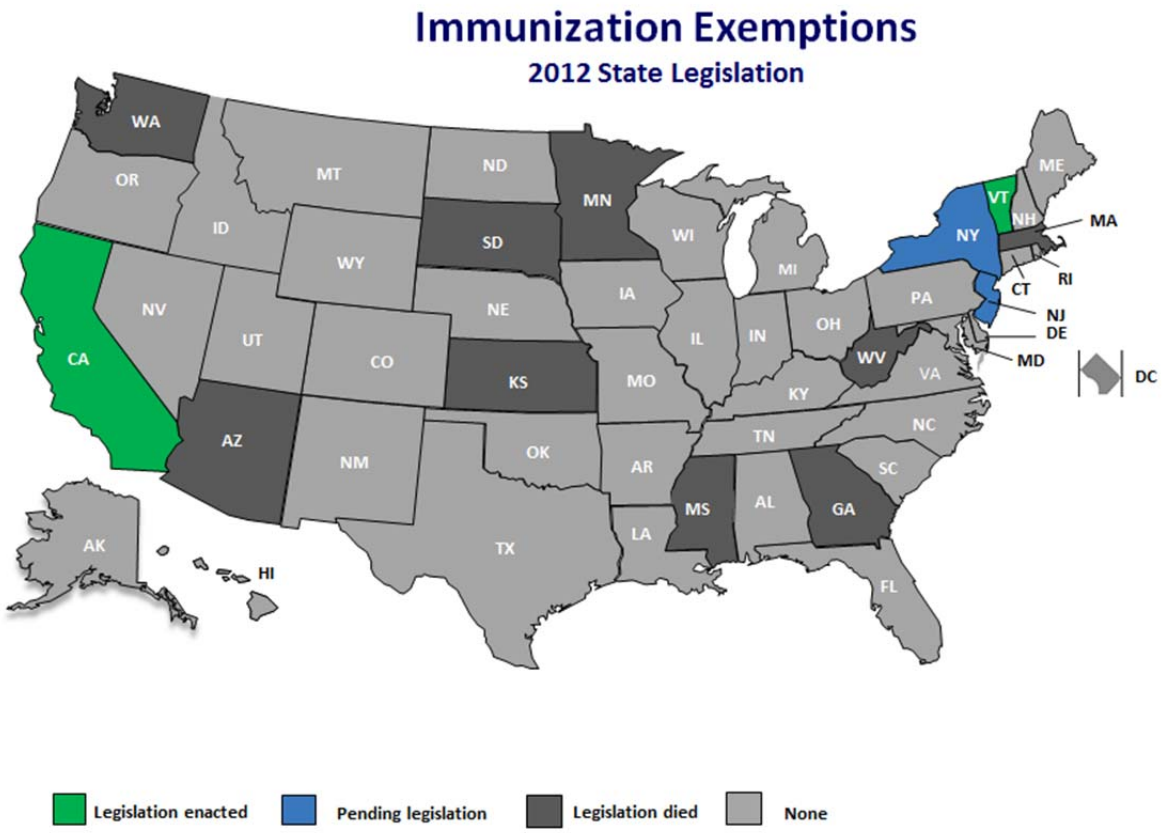
Immunizations

Exemptions
Thirteen states considered legislation pertaining to immunization exemptions in the 2012 session. The majority of those states considered bills that would add additional exemptions or weaken requirements, thereby making exemptions easier to obtain. None of these bills were enacted in 2012. Four states attempted to eliminate existing exemptions or strengthen the requirements to obtain an exemption.

Vermont considered SB 199. As introduced, the legislation would have eliminated the state's philosophical exemption. The Senate passed the bill as introduced. However, a large coalition, the Vermont Coalition for Vaccine Choice, grew and spoke in opposition to the bill. The House took hours of testimony and ultimately passed a bill that required additional reporting and increased education about immunizations but did not eliminate the philosophical exemption. The conference committee tasked with bridging the gap between the two versions of the bill had agreed to keep the exemption and put a trigger in to eliminate it if rates for certain vaccinations (MMR, DTaP, and Tdap) dropped below 90 percent. However, that agreement fell apart, and the bill as enacted kept the philosophical exemption in place without the trigger.

California enacted AB 2109, which strengthened the state's exemption by requiring parents to speak with a healthcare provider to discuss the benefits and risks of vaccines and the health risks of specified communicable diseases. The provider has to sign an attestation indicating that the parent or guardian has been counseled, and the parent or guardian has to sign a corresponding written statement indicating that he or she received the information. This is similar to legislation that was enacted in Washington state during the 2011 session. In signing the bill, Gov. Jerry Brown directed the California Department of Health to oversee this policy so that parents are not overly burdened by its

implementation. In addition, he directed the department to allow for a separate religious exemption on the form so people whose religious beliefs preclude vaccinations would not be required to seek a healthcare practitioner's signature.



Tobacco

Clean Indoor Air Laws

During the 2012 legislative session, Indiana adopted HB 1149, a partial clean indoor air law. Several exemptions were added to the law allowing smoking in bars, taverns, casinos, cigar and hookah bars, retail tobacco stores, nonprofit private clubs, and fraternal organizations. Nursing homes, mental health facilities, and charity events will be smoke-free under the law. Mississippi considered, but did not enact a clean indoor air law this session. In November, North Dakota passed ballot Measure 4, which prohibits smoking in public places and worksites. The prohibition also includes the use of electronic smoking devices.

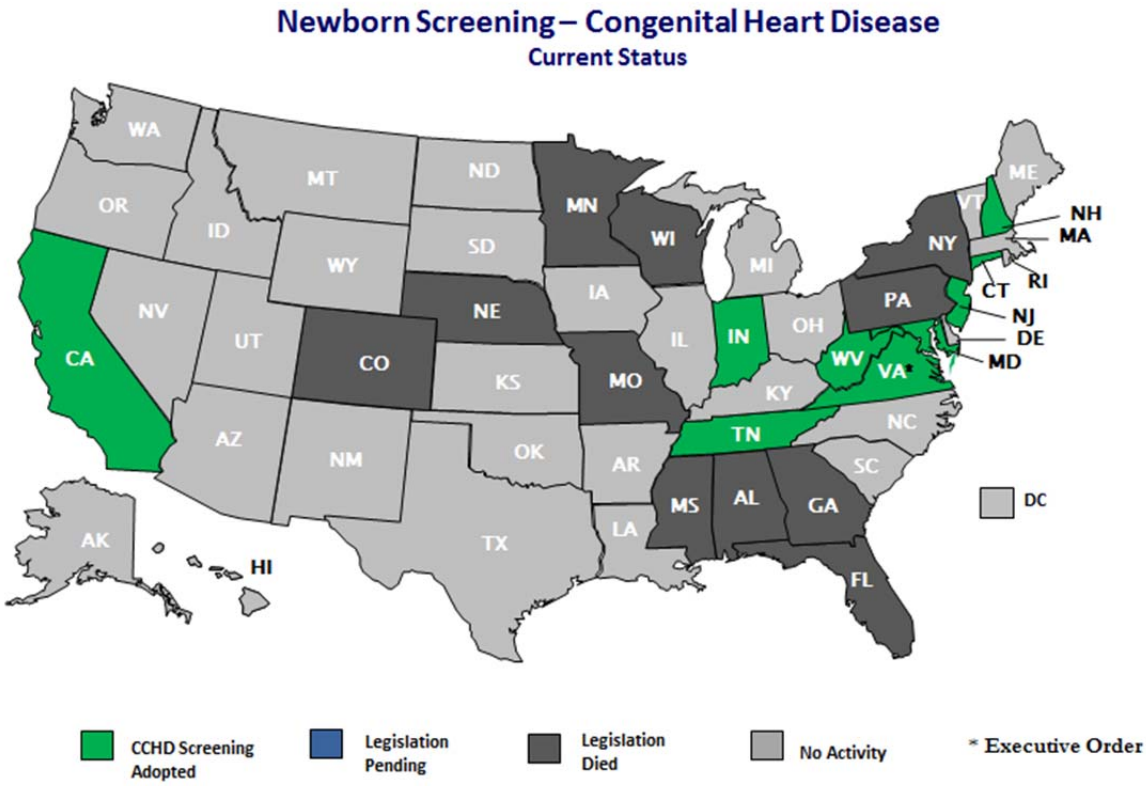
Electronic Cigarettes

During the 2012 state sessions trends included adding electronic cigarettes to the definition of tobacco products for the purpose of clean indoor air and taxation laws. States also acted to prohibit the sale of electronic cigarettes to minors. States successful in enacting such prohibitions include: Arizona (SB 1280), Idaho (HB 405), Kansas (HB 2324), Maryland (HB 1272), and New York (A.9044/S.2926).

Newborn Screening

Critical Congenital Heart Disease

In 2012, 17 states considered legislation to add screening for critical congenital heart disease (CCHD) to their newborn screening program. Five states successfully enacted legislation requiring pulse oximetry screening for CCHD: California (AB 1781), Connecticut (SB 56), New Hampshire (SB 348), Tennessee (SB 65), and West Virginia (HB 4327). The Virginia legislature passed HB 399, which would have directed the Department of Health to convene a work group to develop a plan to implement screening for CCHD. However, the bill was vetoed by Gov. Bob McDonnell. Two months after vetoing the bill, Governor McDonnell signed Executive Directive No. 4, which, similar to the proposed legislation, creates a work group to implement screening for CCHD.



Funding

This session, Kansas adopted SB 14, which established a newborn screening fund to be administered by the Secretary of Health and Environment. Kansas is one of three states that do not charge parents a fee for newborn screening. The new law provides that screening will be financed through fee-for-service by the existing health maintenance organization privilege fee starting in fiscal year 2013.

Genetic Privacy and Informed Consent

In November 2011, the Minnesota Supreme Court held in *Bearder et al. v. Minnesota* that the Department of Health could retain bloodspots only as long as necessary for "testing the samples for

heritable and congenital disorders." The court concluded that the 2006 Genetic Information Act mandated that any other use, storage, or dissemination of the blood samples required written, informed consent from parents or legal guardians. In 2012, the Minnesota legislature adopted HF 2967, which relates to informed consent for newborn screening services. The new law requires that bloodspots be destroyed after 71 days and bloodspot test results be destroyed after 24 months. Within the 71 day window, the Minnesota Department of Health is permitted to use the bloodspots for calibration and quality control activities. The new law also allows parents to provide consent for long-term (up to 18 years) storage of bloodspots and test results as well as use of those spots for new test development. The states of Alabama, California, Massachusetts, and New York considered, but did not enact, legislative proposals establishing informed consent requirements for the storage and analysis of genetic information, including newborn screening samples. Additional activity is expected on the issue of bloodspot retention during the 2013 legislative session.

For more information on ASTHO's state health policy initiatives, please contact Andrea Garcia, director of state health policy, at agarcia@astho.org.